LABOR RELATIONS

UNITED STATES POSTAL SERVICE

October 25, 2021

Mr. Ivan Butts
President
National Association of Postal Supervisors
1727 King Street, Suite 400
Alexandria, VA 22314-2753

Dear Mr. Butts:

As a matter of general interest, the Postal Service is updating the "Field Information Kit" for the Prevent All Cigarette Trafficking (PACT) Act of 2009, to include Electronic Nicotine Delivery Systems (ENDS) products.

The revised "Field Information Kit" is based on a final rule in the Federal Register to incorporate new federal statutory restrictions on mailing ENDS, including their liquids, parts, components, and accessories. Effective October 21, 2021, such items will be subject to the same prohibitions as cigarettes and smokeless tobacco due to the December 27, 2020 enactment of the Preventing Online Sales of E-Cigarettes to Children Act (POSECCA). This Act adds ENDS to the definition of "cigarettes" under the Jenkins Act (15 U.S.C. §375-378, which governs the collection of taxes on, and trafficking in, cigarettes and smokeless tobacco administered by the ATF) and prohibits mailing ENDS unless they qualify for an exception.

Please find enclosed copies of the "Field Information Kit." Included in the kit are the following documents:

- Field Information Kit cover page which summarizes the PACT Act and presents the meaning of ENDS.
- Acceptance Service Talk
- Acceptance Procedures
- Delivery Service Talk
- Delivery Procedures
- PACT Act Frequently Asked Questions (FAQ's)
- PACT Act Job Aid Chart

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In addition, please find enclosed a July 2021 Stand-Up Talk entitled "Prevent All Cigarette Trafficking (PACT) Act and a copy of the final rule published in the October 21, 2021 *Federal Register*.

Please contact Bruce Nicholson at extension 7773 if you have questions concerning this matter.

Sincerely,

David E. Mills
Director
Labor Relations Policies and Programs

Enclosures

POSTAL SERVICE

39 CFR Parts 111 and 211

Treatment of E-Cigarettes in the Mail

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service revises its regulations in Publication 52, *Hazardous, Restricted, and Perishable Mail,* to incorporate new statutory restrictions on the mailing of electronic nicotine delivery systems. Like cigarettes and smokeless tobacco, such items are generally nonmailable, subject to certain exceptions.

DATES: This rule is effective October 21, 2021.

FOR FURTHER INFORMATION CONTACT: Dale E. Kennedy, Director, Product Classification, at 202–268–6592.

SUPPLEMENTARY INFORMATION:

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I. Background

The Postal Service hereby amends Publication 52, *Hazardous, Restricted, and Perishable Mail,* with the provisions set forth herein. While not codified in Title 39, Code of Federal Regulations ("CFR"), Publication 52 is a regulation of the Postal Service, and changes to it may be published in the **Federal Register**. 39 CFR 211.2(a)(2). Moreover, Publication 52 is incorporated by reference into *Mailing Standards of the United States Postal Service,* Domestic Mail Manual ("DMM") section 601.8.1, which is incorporated by reference, in turn, into the Code of Federal Regulations. 39 CFR 111.1, 111.3. Publication 52 is publicly available, in a read-only format, via the Postal Explorer® website at *https://pe.usps.com.* In addition, links to Postal Explorer are provided on the landing page of *USPS.com,* the Postal Service's primary customer-facing website; and *Postal Pro,* an online informational source available to postal customers.

On February 19, 2021, the Postal Service published a notice of proposed rulemaking (86 FR 10218) to implement the Preventing Online Sales of E-Cigarettes to Children Act ("POSECCA"), Public Law 116–160, div. FF, title VI (2020). Section 602 of the POSECCA adds "electronic nicotine delivery systems" ("ENDS") to the definition of "cigarettes" subject to regulation under the Jenkins Act, codified at 15 U.S.C. 375 *et seq.* As a result, ENDS are now subject not only to rules and restrictions governing remote sales under the Jenkins Act, but also to separate restrictions and exceptions for postal shipments, which rely on the same definition. 18 U.S.C. 1716E(a)(1). Section 603 of the POSECCA requires the Postal Service to promulgate implementing regulations and provides that the prohibition on mailing ENDS will apply immediately "on and after" the date of this final rule.

The statutory framework into which ENDS must now fit was established by the Prevent All Cigarette Trafficking Act of 2009 ("PACT Act"), Public Law 111–154, sec. 3, 124 Stat. 1087, 1103–1109 (2010), codified at 18 U.S.C. 1716E. Briefly, the PACT Act allows cigarettes and smokeless tobacco to be mailed only in the following circumstances:

Intra-Alaska and Intra-Hawaii Mailings: Intrastate shipments within Alaska or Hawaii;

Business/Regulatory Purposes: Shipments between verified and authorized tobacco-industry businesses for business purposes, or between such businesses and federal or state agencies for regulatory purposes;

Certain Individuals: Lightweight, noncommercial shipments by adult individuals, limited to 10 shipments per 30-day period;

Consumer Testing: Limited shipments of cigarettes sent by verified and authorized manufacturers to adult smokers for consumer testing purposes; and

Public Health: Limited shipments of cigarettes by federal agencies for public health purposes under similar rules applied to manufacturers conducting consumer testing.

18 U.S.C. 1716E(b)(2)–(6). Outside of these exceptions, the Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable smokeless tobacco or cigarettes. *Id.* at (a)(1).

Nonmailable cigarettes and smokeless tobacco deposited in the mail are subject to seizure and forfeiture. 18 U.S.C. 1716E(c). Senders of nonmailable cigarettes or smokeless tobacco are subject to criminal fines, imprisonment, and civil penalties, in addition to enforcement under other Federal, State, local, and Tribal laws. *Id.* at (d), (e), (h).

In inviting public comment, the notice of proposed rulemaking highlighted certain topics on which comments would be especially helpful: The definition of ENDS, appropriate "catch-all" terminology, standards for determining mailability, and the potential applicability of the PACT Act's exceptions, particularly the Consumer Testing and Public Health exceptions. 86 FR 10219–10220. We received more than 15,700 comments on these and other topics, most of which appear to be electronically generated form letters and general expressions of ENDS users' dissatisfaction with the POSECCA.

In considering the comments, and in view of Congress's abrogation of the standard 30-day notice period for a final rule under the Administrative Procedure Act ("APA"), see *id.* at 10220, the Postal Service determined that additional guidance might assist the industry in preparing for the final rule. On April 19, 2021, the Postal Service published a guidance document ("April 2021 Guidance") (86 FR 20287) on two topics. First, the Postal Service informed ENDS industry participants that it

would not accept exception applications until the final rule had been issued, but that industry participants might instead use the intervening period to compile various types of documentation for submission with exception applications following the final rule (should such exceptions be made available). Second, the Postal Service reminded ENDS industry participants that, regardless of the impending applicability of PACT Act restrictions or exceptions, certain ENDS products are currently, and will remain, subject to other mailability prohibitions and restrictions (*e.g.*, cannabis and other controlled substances, drug paraphernalia, lithium batteries, liquids, certain chemicals found in ENDS liquids, and certain advertisements and promotional materials). Readers of this final rule are encouraged to review the April 2021 Guidance and Publication 52 overall for additional information on these prohibitions and restrictions, which can render even a PACT-Act-exempt item nonmailable.

II. Summary of Final Rule

ENDS products are generally nonmailable, except as authorized by an exception, and then only if all PACT-Act-related and non-PACT-Act-related conditions of mailability are met. Congress did not grant the Postal Service authority to make policy decisions to waive or defer the operation of the POSECCA, to create new PACT Act exceptions, or to expand, restrict, or modify the scope of existing exceptions, beyond the reasonable application of the conditions enumerated in the PACT Act.

ENDS products comprise (1) any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device; and (2) any component, liquid, part, or accessory of an ENDS, regardless of whether sold separately from the device. This statutory definition resides in the Jenkins Act, which is administered by the Bureau of Alcohol, Tobacco, Firearms, and Explosives ("ATF"), and inquiries about whether specific products are covered should be directed to ATF. Provisionally, however, certain aspects of the definition are apparent from the plain statutory language, such as that a user must inhale from the device and that a covered ENDS product must be, or be capable of use with, a liquid solution. At the same time, Congress expressly provided that covered ENDS products extend beyond nicotine-related use, as relevant products may deliver "nicotine, flavor, or any other substance."

The POSECCA excludes from the mailing ban any ENDS product that is approved by the U.S. Food and Drug Administration ("FDA") for sale as tobacco cessation products or for other therapeutic purposes and marketed and sold solely for such purposes. At this time, the FDA has not approved any such devices or drugs.

The statutory parameters for the Intra-Alaska/Intra-Hawaii, Business/Regulatory Purposes, and Certain Individuals exceptions are compatible with and administrable for ENDS products, and so they will be made available for such products.

The preexisting centralized application process for the Business/Regulatory Purposes exception will be extended to ENDS products, albeit with certain modifications to improve administration. Other, statutorily-derived requirements relating to acceptance and delivery will apply to ENDS products in like manner to cigarettes and smokeless tobacco. For example, approved shippers of Business/Regulatory Purposes mailings must use specified product combinations that allow for age and identity verification at delivery (*e.g.*, Priority Mail with Adult Signature service) and must tender items in a face-to-face transaction either at a Postal Service retail office or at a Postal Service business mail acceptance location. For clarity, product combinations that include Adult Signature service can receive normal carrier delivery, subject to identity and age verification.

The Certain Individuals exception will apply to ENDS products, subject to all of the same frequency, weight, age-verification, and other conditions that apply to other shipments covered by the PACT Act. By statute, this exception applies to qualifying shipments by individual adult mailers without regard to the nature of the recipient entity, expressly including the return of damaged or unacceptable products to manufacturers. Among other conditions, however, the statute limits the exception to shipments for noncommercial purposes. Thus, the compatibility of ENDS manufacturers' recycling programs with this exception may depend on whether such programs are structured so as not to involve any exchange of commercial value. The final rule also clarifies the standard for noncommercial purposes in the context of returns of damaged or unacceptable products, to the effect that any value provided in exchange for the returned item cannot exceed that which would restore the sender to the status quo ante.

As for the Consumer Testing and Public Health exceptions, it is apparent that Congress intended those exceptions to apply only to combustible cigarettes, and not to ENDS products or smokeless tobacco. First, the Consumer Testing exception is statutorily restricted to cigarette manufacturers with a permit under section 5713 of the Internal Revenue Code ("IRC"), which does not apply to ENDS manufacturers. Second, shipments under the Consumer Testing exception (and, by extension, the Public Health exception) are expressly limited to specified quantities of "packs of cigarettes" containing 20 cigarettes each. This standardized quantification is meaningful in the context of combustible cigarettes, but not in the context of ENDS products or smokeless tobacco. Upon consideration of the public comments, there does not appear to be a workable standard by which to apply this material condition for the Consumer Testing and Public Health exceptions to ENDS products, notwithstanding their treatment as "cigarettes" for broader purposes of the PACT Act. Given this context-based plain reading of the statute and the narrow construction typically due exceptions, the Postal Service concludes that current law does not support applying these exceptions to ENDS products.

Upon original implementation of the PACT Act, the Postal Service determined that the PACT Act exceptions cannot feasibly be applied to inbound or outbound international mail or to mail to or from the Freely Associated States. The Postal Service cannot fulfill the PACT Act's verification requirements in locations where it does not interact directly with shippers and addressees. Nothing has changed in that regard. As such, all cigarettes and smokeless tobacco in such mail will continue to be nonmailable, without exception, and the same will be true of ENDS products.

Moreover, consultation with partner agencies regarding the PACT Act's requirements and the availability of relevant postal services has indicated that the statutory prerequisites for the PACT Act's exceptions cannot reliably be fulfilled at overseas U.S. military postal addresses. Thus, while shipments from such installations to the United States were already ineligible for any PACT Act exceptions, shipments from the United States to such installations must likewise be ineligible for the exceptions at this time.

III. Response to Comments

The Postal Service received more than 15,700 responses to the notice of

proposed rulemaking, several of which included comments on multiple topics. Commenters included businesses that ship ENDS products; individual consumers of ENDS products; organizations representing ENDS shippers and/or consumers; organizations representing taxpayer and/or business interests generally; a group of state and local attorneys general; public-health researchers, research institutions, and advocacy organizations; and a number of individual law students. In addition, the Postal Service consulted informally with ENDS researchers, industry participants, State and local attorneys general, and Federal agencies involved in regulating tobacco and ENDS products. Comments and Postal Service responses are summarized as follows.

A. Lack of Policy Discretion

1. Extra-Statutory Expansion of Mailability

A large number of ENDS consumers, ENDS shippers, and some law students (collectively, "pro-ENDS commenters") urged the Postal Service not to subject ENDS products to the PACT Act. As rationales, these commenters invoked the purported public benefits associated with ENDS products; the impact of a mailing ban on businesses and the Postal Service; the possibility of unanticipated and even perverse economic, distributive, and public-health effects of a mailing ban; doubts about the role that the mails may play in youth access to ENDS products (perceived to be the policy motivation for the mailing ban); skepticism about enforceability; [1] perceived hypocrisy in the roster of mailable and nonmailable items; [2] and concerns about restriction of individual liberty.

A number of ENDS consumers and shippers also proposed that the Postal Service implement some alternative method of regulating the mailability of ENDS products, in lieu of the PACT Act's ban and exceptions. Proposals included the following:

- Permit the mailing of ENDS products with age verification of recipients.
- Permit the mailing of ENDS products with warning labels.
- Permit the mailing of ENDS products under the same conditions provided for non-postal delivery channels under the Jenkins Act (as amended by section 2 of the PACT Act).
- Allow the ENDS industry to regulate itself, subject to a requirement to conduct age verification of consumers.
- Limit mailability to ENDS products containing less than a specified threshold of nicotine.
- Limit mailability to non-nicotine-containing ENDS products.
- Limit mailability to single-use ENDS products.
- Scale mailability restrictions according to a policy-based hazard assessment of the product, shipper, and recipient.

In addition, some public-health-oriented commenters and law students, as well as some Federal agency partners with which the Postal Service consulted, proposed that the Postal Service ensure that ENDS products can be shipped in circumstances not covered by any statutory exception, such as between public-health researchers and individual test subjects; between governmental actors for enforcement, investigative, or testing purposes; and from the government to non-governmental public-health entities. These commenters invoked the interests of promoting public-health research into and effective regulation of ENDS products. Many of these stakeholders also urged the Postal Service to allow use of the Public Health exception for ENDS products on policy grounds and to allow ENDS-industry businesses to ship ENDS products to governmental actors for any regulatory purpose, without regard to the statutory parameters of the existing PACT Act exceptions.

Finally, a number of commenters of varying orientations—including some in the ENDS industry—acknowledged that the POSECCA charges the Postal Service merely with incorporating ENDS products into the existing PACT Act framework, rather than authorizing it to revisit and alter that framework.

The latter group of commenters is correct: In this context, the Postal Service lacks the authority to adopt a regulatory scheme different from what Congress has prescribed. In general, the Postal Service, as part of the Executive Branch, is bound to faithfully execute the laws enacted by Congress and can act only within the scope of discretion that Congress has delegated to it. U.S. Constitution article I, section 1; *id.* at article II, section 3; see, *e.g., Gundy* v. *United States*, ___U.S. ___, ___, 139 S. Ct. 2116, 2123 (2019). The PACT Act expressly provides that cigarettes and smokeless tobacco are generally nonmailable, that the Postal Service generally may not accept them for delivery or transmit them through the mails, and that those prohibitions give way only in circumstances defined by a number of statutory parameters and conditions. 18 U.S.C. 1716E(a)–(b). The POSECCA extends that treatment to ENDS products by including them within the term "cigarette." POSECCA section 602(a)(1)(C).

Neither the PACT Act nor the POSECCA includes any provision authorizing the Postal Service to waive the mailing ban for ENDS products or any other subcategory of "cigarettes," with or without other regulatory conditions devised by the Postal Service (*e.g.*, age verification, nicotine limits). In particular, the POSECCA charges the Postal Service only with "clarify[ing] the applicability" of the PACT Act's mailing ban to ENDS products. POSECCA section 603(a). Clarification means to make something clear or understandable or to dispel confusion, presupposing the pre-establishment of the proposition being clarified: A self-evidently modest task that falls far short of substantive change to that proposition. See Clarify, Merriam-Webster.com (last visited Oct. 14, 2021). As such, whatever policy judgments the Postal Service might reach as to public-health effects, commercial impact, the need to facilitate effective regulation, or other considerations, those judgments have already been made by Congress in legislating that ENDS products cannot be mailed except in statutorily prescribed circumstances.

Congress could have left ENDS products mailable, subjected them to alternative restrictions (as section 2 of the PACT Act does for non-postal delivery carriers), or delegated authority to the Postal Service to grant waivers, create new exceptions, or devise some other appropriate mailability scheme. Cf. 18 U.S.C. 1716(b)–(e) (authorizing the Postal Service to permit or limit the mailing of potentially hazardous materials); 39 U.S.C. 3018(b) (giving the Postal Service discretion to declare hazardous materials to be nonmailable or to restrict the time, place, and manner of their mailing). Yet Congress did none of those things. Instead, it chose to bar the Postal Service from carrying ENDS products, except pursuant to a limited set of specifically delineated statutory exceptions. See

[1] These last two sets of arguments, typically expressed by ENDS consumers, are in tension with one another: One holds that youth do not tend to get ENDS products through the mails, the other that youth will continue to access ENDS products through the mails regardless.

[2] Some ENDS consumers expressed outrage that ENDS products should be nonmailable while alcohol, cigarettes, firearms, gun parts, lettuce, marijuana, and other controlled substances supposedly remain mailable. In fact, each of these types of items is nonmailable in at least some—and, in some cases, most or all—circumstances. See Publication 52 subchapters 42, 43, 47, 53 & part 453.

Treatment of Cigarettes and Smokeless Tobacco as Nonmailable Matter, 75 FR 29662, 29664 (2010) (notice of final rule); see also *Gordon* v. *Holder*, 721 F.3d 638, 657 (D.C. Cir. 2013) (declining, on rational basis review, to "second-guess the wisdom of [Congress's] choice" to enact the PACT Act's mailing ban in lieu of some alternative measure).

In sum, arguments to relax the PACT Act's application to ENDS products on policy grounds are misdirected to the Postal Service. Whatever the merits of ENDS products generally or the anticipated effects of the POSECCA, the forum for that debate is Congress, which has declined to delegate, and thus has reserved to itself, policy discretion over the pertinent parameters.

2. Extra-Statutory Restriction of Mailability

Conversely, some public-health-oriented commenters, State and local attorneys general, law students, and other individual commenters (collectively, "anti-ENDS commenters") urged the Postal Service to deny or restrict the application of the PACT Act's exceptions to ENDS products, due to concerns about hazardous materials, controlled substances, public health, youth access, and the purported risk of circumventing law enforcement.

For the reasons discussed in the preceding section, neither the PACT Act nor the POSECCA authorizes the Postal Service to make policy judgments to narrow or rescind the availability of the statutory exceptions. Cf. 18 U.S.C. 1716(d)–(e). The parameters of the exceptions are expressly set forth in the statute. Notwithstanding some limited interpretive and administrative latitude in implementing the statute, the Postal Service cannot repeal, disregard, or amend the statute's explicit parameters on policy grounds. Like policy arguments to relax the PACT Act for ENDS products, policy arguments to tighten it should be directed to Congress, not the Postal Service. See *United States* v. *Rodgers*, 466 U.S. 475, 484 (1984) ("Resolution of the pros and cons of whether a statute should sweep broadly or narrowly is for Congress.").

Moreover, the public-health and worker-safety concerns raised by certain public-health-oriented commenters are already addressed by statutes and regulations independent of the PACT Act. As noted in the April 2021 Guidance, ENDS products that constitute controlled substances or drug paraphernalia are nonmailable regardless of whether the PACT Act would also preclude mailability. 21 U.S.C. 843(b)–(c), 863; Publication 52 part 453; see 86 FR at 20289.

Likewise independently of the PACT Act's application, liquids and hazardous materials are also nonmailable to the extent that the shipper has not observed applicable mailing requirements and restrictions. 18 U.S.C. 1716(a), (h); 39 U.S.C. 3018; DMM section 601.3.4; Publication 52 chapter 3 & parts 451, 711–728 & app. A, C; see 86 FR at 20289. The hazardous-materials rules already embody determinations by the Department of Transportation, the Postal Service, and other relevant authorities about how to balance worker safety against commercial interests, resulting in, for example, differing levels of restriction and mailing requirements for differing concentrations of nicotine.[3]

That said, the public-health-oriented commenters rightly point out that the broad array of covered ENDS products is more likely than cigarettes and smokeless tobacco to implicate mailability rules outside of the PACT Act. ENDS products include or may contain lithium batteries, as well as nicotine and other chemicals that are flammable or toxic. See April 2021 Guidance, 86 FR at 20289; Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions; Request for Comments, 84 FR 38032, 38033–38034 (2019). Once again, all mailers, including businesses, individuals, and governmental entities that may ship ENDS products pursuant to the PACT Act's exceptions, are strongly encouraged to review and comply with all pertinent statutes and Postal Service regulations.[4] ENDS manufacturers and distributors are further encouraged to educate ENDS consumers about the need to ensure that any further mailing of ENDS products conforms to applicable legal requirements regarding controlled substances, drug paraphernalia, and potentially hazardous materials, in addition to the PACT Act.

3. Effective Date

Some pro-ENDS commenters proposed that, if the Postal Service does implement the mailing ban, the Postal Service should defer its effective date or exercise its enforcement discretion to effectively allow the continued mailing of ENDS products for some period (*e.g.*, a period long enough to allow some segment of the ENDS industry to apply for and receive authorization to use the Business/Regulatory Purposes exception). One ENDS consumer urged the Postal Service to stay implementation until after the COVID–19 pandemic, and another suggested a delay in the general interest of facilitating industry compliance and reducing diversion to the black market. A law student suggested that the Postal Service could delay implementation in areas where brick-and-mortar stores do not meet ENDS demand.

The Postal Service lacks discretion as to the effective date. The POSECCA expressly provides that the prohibition will apply to mailings of ENDS "on and after" the publication date of the final rule. POSECCA section 603(b). If anything, it is the effective date of any applicable PACT Act exceptions, and not the PACT Act's general mailing ban, about which the POSECCA is silent. Whatever transition-related challenges that the POSECCA's effective date might pose on the industry (despite having had an extended period to prepare for the mailing ban), Congress conferred no authority on the Postal Service to derogate from the requirement that the final rule have immediate effect.

As for enforcement discretion, the scope of the Postal Service's enforcement discretion under the PACT Act is the subject of ongoing litigation. See generally *City of New York* v. *U.S. Postal Serv.*, No. 1:19–CV–05934 (E.D.N.Y. filed Oct. 22, 2019). To the extent that the Postal Service can exercise discretion as to enforcement of the PACT Act, however, the Postal Service declines to exercise it in the manner proposed by the commenters here. While law-enforcement discretion can encompass decisions not to enforce a law, such decisions are expressly and exclusively vested in the relevant Executive Branch entity, which must balance policy and resource considerations, and are not amenable to judicial review. *E.g.*, *Heckler* v. *Chaney*, 470 U.S. 821, 831–32 (1985). The Postal Service does not regard the commenters' proposal—in effect, implementing the POSECCA on paper only while broadly

[3] One public-health-oriented commenter opined that PACT Act exceptions should be disallowed for ENDS products because they may contain hazardous materials and yet be transported by air, including in intrastate shipments pursuant to 18 U.S.C. 1716E(b)(2). But many hazardous materials are not categorically barred from air transportation; rather, they can be transported by air transportation so long as they are properly prepared and labeled and/or are packaged in limited quantities. See Publication 52 parts 327, 331–337, 343, 346, 349. To the extent that these restrictions are not observed, then—as was the case prior to this final rule—an ENDS shipment is nonmailable under the hazardous-materials rules regardless of the PACT Act.

[4] As noted in the April 2021 Guidance, advertisements and promotional or sales matter regarding controlled substances and certain hazardous materials are generally also nonmailable. 18 U.S.C. 1716(h); 21 U.S.C. 843(b), (c)(1); DMM section 601.9.4.1; 86 FR at 20289.

maintaining the status quo ante in practice—to be a viable or preferable exercise of its law-enforcement discretion.

B. Constitutionality

A number of pro-ENDS commenters advanced various theories as to the supposed unconstitutionality of the POSECCA and the proposed implementing regulations: They would impair the rights of adults to receive ENDS through the mails; the law is too vague; and the POSECCA is overbroad in its impact on adult users of ENDS products, not only minors.

As an initial matter, the constitutionality of the POSECCA has no bearing on the Postal Service's obligation to execute it. As discussed in section III.A.1, the Constitution requires the Postal Service, as an entity within the Executive Branch, to faithfully execute the laws. U.S. Constitution article II, section 3. By contrast, "it is, emphatically, the power and duty of the [Judicial Branch], to say what the law is." *Marbury* v. *Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). For the Postal Service unilaterally to decide not to execute a duly enacted law on constitutional grounds would abdicate its constitutional duty and usurp the powers of the Legislative and Judicial Branches. See *Ameron, Inc.* v. *U.S. Army Corps of Engineers*, 787 F.2d 875, 889 & n.11 (3d Cir. 1986) (the President can "veto, criticize, or even refuse to defend in court, statutes which he regards as unconstitutional," but may not refuse to execute them on constitutionality grounds) (citing *Marbury* and other significant Supreme Court opinions to that effect); *see also Am. Coalition for Competitive Trade* v. *Clinton*, 128 F.3d 761, 766 n.6 (D.C. Cir. 1997) ("administrative agencies . . . cannot resolve constitutional issues"). As such, barring a contrary judicial determination, any concerns about the POSECCA's constitutionality are no bar to its Congressionally mandated implementation by the Postal Service.

That said, by all indications, the relevant statutes appear to be constitutional. Congress has plenary powers to enact laws governing the postal system, as well as to regulate interstate commerce and commerce with foreign and Tribal nations. U.S. Constitution article I, section 8, clauses 3, 7. In exercising those powers, Congress's authority to ban a class of products from the mails—even those that are legal in all States and that are not harmful to Postal Service personnel—is well-established: Indeed, Congress has historically done so with a number of other such products. *U.S. Postal Serv.* v. *Council of Greenburgh Civic Ass'ns*, 453 U.S. 114, 126 (1981) ("The validity of legislation describing what should be carried has never been questioned. The power possessed by Congress embraces the regulation of the entire Postal System of the country. The right to designate what shall be carried necessarily involves the right to determine what shall be excluded.") (quoting *Ex parte Jackson*, 96 U.S. 727, 732 (1878)) (cleaned up); *Gordon*, 721 F.3d at 656; *Musser's Inc.* v. *United States*, 1 F. Supp. 3d 308, 318 (E.D. Pa. 2014). The PACT Act's mailing ban in particular has been upheld as a rational exercise of Congress's constitutional powers. *Gordon*, 721 F.3d at 657; *Musser's*, 1 F. Supp. at 318.

Given Congress's plenary power over the very existence of the postal system, it cannot be said that there is a fundamental right to mail any particular item, let alone ENDS products, and shippers or users of ENDS products do not constitute a protected class any more than shippers or users of cigarettes or smokeless tobacco. *See Gordon*, 721 F.3d at 657 (regarding the PACT Act as a "law that does not infringe on a fundamental right or involve a suspect classification"). As such, Congress's action is presumptively legitimate as long as any rational basis is conceivable. *Id.* at 656–57 (plaintiff challenging the PACT Act must meet a "high burden to negative every conceivable basis which might support" it) (quoting *FCC* v. *Beach Communs., Inc.*, 508 U.S. 307, 315 (1993)).

It does not require much to conceive of a legislative rationale in this case. Although the task is "by no means restricted to the stated reasons for passing a law," the statute here expressly offers multiple rational bases for a mailing ban on ENDS products. See *id.* at 657.

By modifying the PACT Act's definition of "cigarettes" to extend to ENDS products, the 116th Congress effectively incorporated ENDS products into the statement of findings and purposes underlying the PACT Act. Public Law 111–154, sec. 1(b)–(c), 124 Stat. 1087–1088. For example, the 116th Congress presumably believed that "the sale of illegal cigarettes [now including ENDS products] and smokeless tobacco over the internet, and through mail, fax, or phone orders, makes it cheaper and easier for children to obtain tobacco products" and that a mailing ban would "prevent and reduce youth access to inexpensive cigarettes [including ENDS products] and smokeless tobacco through illegal internet or contraband sales": Indeed, the title of the POSECCA and the relevant House committee report indicate as much. *See id.* at section 1(b)(4)–(5), (c)(6); H. Rept. 116–260 at 3–4 (2019).

Contrary to the commenters' overbreadth argument, the PACT Act's purposes are not limited to youth access. Other stated purposes of the PACT Act—combating illegal trafficking, circumvention of state and local laws, and unfair competition with law-abiding retailers—implicate adult as well as youth consumers and can apply as easily to ENDS products as to cigarettes and smokeless tobacco. See *id.* at section 1(b)(1)–(3), (b)(6)–(7), (c)(1)–(5); *Gordon*, 721 F.3d at 657.

So, too, can Congress's judgment that an outright ban on the mailing of ENDS products, notwithstanding the applicability of other, more targeted requirements and enforcement opportunities, is necessary to address these harms. *Gordon*, 721 F.3d at 657.

As discussed in section III.D.1.iii, many pro-ENDS commenters questioned the evidence of legislative intent to ban the mailing of ENDS products that do not contain nicotine. For purposes of the constitutionality discussion here, it is noted that plain language of the statute makes that intent clear, and the legislative history does, in fact, attest to the framers' public-health concerns in relation to non-nicotine-related ENDS products. Even without such expressions of intent, however, there would certainly be a rational basis for Congress to have specified the POSECCA's breadth as it did. Given operational and legal constraints, it is not simple—indeed, it is generally impossible—for Postal Service personnel prohibited from accepting or transmitting ENDS products to distinguish liquids that contain nicotine from those that do not, and it is equally difficult for acceptance personnel to distinguish devices intended to be used with nicotine-containing versus non-nicotine-containing liquids. Even barring any more specific motive for banning non-nicotine-related ENDS products from the mails, it would be conceivable that Congress intended to ensure effective enforcement against nicotine-related ENDS products, rather than letting a safe harbor for non-nicotine-related ENDS products get in the way of advancing Congress's nicotine-related policy concerns.

Again, however, such speculation is unnecessary, because the youth-access and public-health concerns underlying the POSECCA were not restricted to nicotine. The relevant House committee report cites information from the Centers for Disease Control and Prevention (CDC) about lung injuries associated with the use of ENDS

products, which were ultimately—after the committee report but prior to floor debate on and passage of the POSECCA—attributed to non-nicotine constituents of ENDS liquids. H. Rept. 116–260 at 3 & nn.22–23 (citing CDC, Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products, *https://go.usa.gov/xHd78* (last updated Feb. 25, 2020)). There is no indication in the legislative record that the POSECCA framers' concern about ENDS-related lung injuries was conditional upon or limited to any eventual nexus specific to nicotine-related ENDS products.

Turning to the vagueness contention, it is difficult to see what is "vague" about the POSECCA or the PACT Act. The POSECCA makes nonmailable (with exceptions) "any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device," as well as "any component, liquid, part, or accessory" of such a device. 15 U.S.C. 375(7)(A), (7)(B)(vii). While certain terms may benefit from interpretation pursuant to well-established principles of administrative law, it cannot be said that the statute fails to give the public or law-enforcement agencies reasonable notice about what is prohibited. If anything, the POSECCA definition is more prescriptive than some other longstanding mailability statutes. Cf. 18 U.S.C. 1716(a) ("hazardous materials, inflammable materials, infernal machines, and mechanical, chemical, or other devices or compositions which may ignite or explode, . . . and all other natural or artificial articles, compositions, or material which may kill or injure another, or injure the mails or other property"); *id.* at (j) ("spirituous, vinous, malted, fermented, or other intoxicating liquors of any kind"). While the POSECCA definition may be broad in a manner that some persons find objectionable, that is not the same as being vague.

For all of these reasons, the Postal Service maintains that it is not constitutionally barred from executing the POSECCA.

C. Relation to Other Laws

1. FDA Regulation of Certain ENDS as "Tobacco Products"

Multiple pro-ENDS commenters noted the FDA's definition of ENDS as noncombustible tobacco products, asserted that the FDA has confined the scope of its regulations to devices intended to be used with nicotine-containing ENDS liquids, and urged us to harmonize the POSECCA's ENDS definition with this purported FDA policy. At least one commenter pointed to the POSECCA's rule of construction, which provides that the POSECCA definition shall not "be construed to affect or otherwise alter any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), including its implementing regulations." POSECCA section 602(c). Additionally, some pro-ENDS commenters asserted that the FDA excludes "accessories" from regulation as "tobacco products" and urged the Postal Service to follow suit. See 21 CFR 1100.1–.2.

As an initial matter, the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and the PACT Act (as modified by the POSECCA) govern different subjects. Under the FD&C Act, the FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect the public health. FDA regulation of tobacco products is not necessarily tied to a given distribution method. By contrast, the relevant portion of the PACT Act governs whether such products—following or pending authorization for interstate commerce—may be sent through the federally administered postal system, or whether they may be transported only through non-postal channels. Indeed, section 2 of the PACT Act provides that covered items may be carried through non-postal delivery channels, so long as carriers and sellers comply with various requirements. Although nonmailability may influence the practicalities of interstate commerce (*e.g.*, products' costs and accessibility), it does not constitute an outright legal bar to interstate commerce.[5]

The FDA's regulation of ENDS emanates from a statutory framework regarding tobacco products that is unrelated to and distinct from the POSECCA. More specifically, the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Public Law 111–31, granted the FDA the authority to regulate tobacco products by, among other things, adding Chapter IX (Tobacco Products) to the FD&C Act, 21 U.S.C. 387a. Section 901 of the FD&C Act provides that this chapter applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, as well as to any other tobacco products that the Secretary of Health and Human Services by regulation deems subject to it. It is pursuant to that delegation of "deeming" authority that the FDA decided to subject certain ENDS products—specifically, those that meet the FD&C Act definition of a "tobacco product"—to tobacco regulation under the FD&C Act. 81 FR 28973, 28982 (2016). The FDA's broad discretion under the FD&C Act encompasses the ability to define the scope of ENDS products that the FDA considers amenable to regulation, subject to the FD&C Act's parameters. For example, FDA-regulated tobacco products (including ENDS products) must be either made or derived from tobacco and intended for human consumption, or else a part, component, or accessory of such a product. 21 U.S.C. 321(rr)(1), 387a(c)(1). Pursuant to its discretion, the FDA decided to regulate "components or parts" of ENDS products but not "accessories." *Id.* at 28,975.

The context here is different, because the statute itself explicitly defines the scope of nonmailable ENDS in a manner that departs from the FD&C Act and FDA definitions. Specifically, the POSECCA makes nonmailable "any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device." The POSECCA refers to "nicotine" without distinguishing on the basis of origin (tobacco or otherwise). Furthermore, the POSECCA definition of ENDS sweeps beyond nicotine to include, as standalone triggers, "flavor[ ] or any other substance." Clearly, Congress could have phrased the POSECCA to tie to or mirror the FD&C Act terminology, or it could have used other terminology that aligned with the scope of FDA regulation. Yet Congress did not do so; instead, it chose to specify a broader universe of nonmailable items than those that are subject to FDA regulation.

It is apparent that the POSECCA neither alters nor conflicts with the FD&C Act, and that it impinges in no way on the FDA's implementing regulations. Rather, the two laws apply concurrently, albeit with only a partial overlap in scope. This is nothing new. For example, the universe of products subject to FDA regulation as "tobacco products" is itself broader than the scope of "tobacco products" subject to Treasury Department regulation under IRC chapter 52, which expressly does not include ENDS products. See 26 U.S.C. 5702. Among other laws, manufacturers of combustible cigarettes must contend with IRC chapter 52 and FDA tobacco regulation as well as the PACT Act; manufacturers of ENDS

[5] Of course, it is possible for multiple Federal authorities to apply concurrently. FDA authorization of a cigarette for introduction or delivery into interstate commerce does not absolve an actor from other Federal requirements that govern the manufacture and distribution of cigarettes and other covered products: Rather, all overlapping requirements must be complied with in order to offer the product in interstate commerce.

products within the FD&C Act definition of "tobacco product" must contend with FDA tobacco regulation and now the PACT Act, but not IRC chapter 52; and manufacturers of other ENDS products must now contend with the PACT Act, but neither IRC chapter 52 nor FDA tobacco regulation. There is no conflict of laws here; Congress simply chose to subject different products to different layers of regulation.

It also bears mention that certain commenters mischaracterized the FDA's policy on ENDS liquids, suggesting that the FDA has deemed only liquid nicotine and nicotine-containing liquid to fall within its regulatory purview. This is not necessarily true. Rather, the FDA observed that non-nicotine-containing liquids may be FDA-regulated as components or parts of ENDS liquids, to the extent that they are "intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not meet the definition of accessory." 81 FR at 29041. It therefore may be that the POSECCA's coverage of ENDS products that deliver "flavor[ ] or any other substance" beyond nicotine, as well as non-tobacco-derived nicotine, represents less of a step beyond FDA regulation than these commenters asserted.

As for "accessories" of ENDS products, it is true that the FDA's "deeming" rule exempted them from regulation under the FD&C Act. Yet Congress chose to render them nonmailable under the POSECCA. We note that the POSECCA does not define "accessories," and so Congress has not spoken to whether the term should be interpreted in a manner consistent with the scope of items that the FDA has defined as outside of its regulatory framework. As discussed in section III.D, the POSECCA definition resides in a statute administered by ATF, and so the Postal Service will look to ATF for interpretive guidance about the scope of "accessories" for PACT Act purposes.

2. Laws Regarding Marijuana, Hemp, and Hemp Derivatives

Numerous pro-ENDS commenters urged that the POSECCA be construed, or the Postal Service's implementing regulations be written, to exempt ENDS items consisting of, containing, or used with marijuana and marijuana- or hemp-derived products. Many of these commenters asserted that rendering such items nonmailable would conflict with State and local laws decriminalizing or legalizing cannabis for medical or recreational purposes. Some claimed that the inclusion of such products would conflict with provisions in recent appropriations Acts (including that which includes the POSECCA) that bar the Department of Justice from using appropriated funds to prevent certain States and Territories "from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana." *E.g.*, Public Law 116–260, div. B, sec. 531. Finally, some argued that inclusion of such products would conflict with the removal of hemp and hemp derivatives (with not more than 0.3 percent tetrahydrocannabinol ("THC") by dry weight) from the definition of marijuana in the Controlled Substances Act ("CSA"). See Agriculture Improvement Act of 2018, Public Law 115–334, sec. 10113, 12619, 132 Stat. 4490, 4908, 5018, Public Law 91–513, sec. 102(16)(B), codified at 7 U.S.C. 1639o(1); 21 U.S.C. 802(16)(B), 812(c)(17).

As discussed further in section III.D.1.i, notwithstanding Congress's use of "nicotine" in the term "electronic nicotine delivery systems," the plain language of the POSECCA definition makes clear that nonmailable ENDS products include those containing or used with not only nicotine, but also "flavor[ ] or any other substance." It goes without saying that marijuana, hemp, and their derivatives are substances. Hence, to the extent that they may be delivered to an inhaling user through an aerosolized solution, they and the related delivery systems, parts, components, liquids, and accessories clearly fall within the POSECCA's scope.

That said, THC is generally nonmailable for reasons independent of the POSECCA and the PACT Act. THC-containing substances remain generally prohibited under the CSA, regardless of whether they are intended for purportedly medical or recreational purposes or whether the shipper or recipient resides in a State or locality that has decriminalized either or both such uses. 21 U.S.C. 812(c)(17), 843(b); Publication 52 section 453. Devices, parts, components, and accessories used with such substances can qualify as drug paraphernalia, which is likewise nonmailable. 21 U.S.C. 863; Publication 52 part 453. The only exceptions to this mailing ban are for hemp and hemp derivatives that contain no more than 0.3 percent THC by dry weight. See Publication 52 section 453.37.

Thus, ENDS products containing or used with THC (*e.g.*, THC-containing liquids, cannabis waxes, dry cannabis herbal matter) are already nonmailable under the CSA. Congress's decision to keep such items out of the Federal postal network does not bear on whether their use or exchange violates State or local law. Nor does it alter whether the Department of Justice—a Federal entity independent of the Postal Service—may use its appropriated funds to interfere with the operation of State or local laws.

For clarity, even if a shipper could avail itself of a PACT Act exemption with respect to ENDS products generally, the shipper is still prohibited from mailing ENDS products that contain THC (other than hemp derivatives with no more than 0.3 percent THC by dry weight). Nor does the lack of civil or criminal sanction under State or local law entitle any person to ship THC through the Federal postal network or absolve them of penalties under Federal law, so long as the Federal CSA remains applicable.

Conversely, THC-containing substances that are excluded from the CSA—that is, hemp and hemp derivatives with no more than 0.3 percent THC by dry weight—are not subject to CSA-based mailability restrictions, and items used with such substances (and not with controlled substances) may fall outside the definition of drug paraphernalia. Publication 52 section 453.37. As such, those substances continue to be mailable generally, to the extent that they are not incorporated into an ENDS product or function as a component of one. To the extent that they do comprise or relate to an ENDS product, however, then that product is now nonmailable under the PACT Act and POSECCA, except pursuant to a PACT Act exception.

The POSECCA and the Agriculture Improvement Act overlap, but they do not conflict. The Agriculture Improvement Act merely excludes certain products from the CSA. It does not affirmatively declare hemp and hemp derivatives to be mailable in any and all circumstances, superseding all other relevant laws (such as the POSECCA). For its part, the POSECCA restricts the mailability of only certain hemp-based and related products; hemp-based non-ENDS products are unaffected, as are ENDS products falling within one of the PACT Act's exceptions. That Congress has rendered some subset of a class of goods to be nonmailable while leaving the remainder mailable is not some sort of legal conflict, but, rather, how mailability regulation typically works.

3. Other Issues

Certain ENDS industry commenters argued that the PACT Act should not apply to non-nicotine-related ENDS

products to avoid conflicts with State and local law. Specifically, commenters asserted that the PACT Act requires manufacturers to register and certify tax compliance to State and local authorities, yet some States and localities do not specially tax non-nicotine-related ENDS products. One cannabis industry coalition also opined that requirements to report consumer sales could violate State privacy laws. Another complained that statutory labeling requirements regarding "nicotine" and "tobacco" are inapt for non-nicotine-related ENDS products.

Whatever their merit, these comments are misdirected. It is true that section 2 of the PACT Act amended the Jenkins Act to impose various registration, labeling, and tax-compliance requirements on remote sales of cigarettes and smokeless tobacco, and that the POSECCA's amendment of the "cigarette" definition now subjects ENDS products to those requirements. See generally 15 U.S.C. 375 *et seq.* But that portion of the PACT Act is not germane here. Section 3 of the PACT Act—the portion at issue here—more broadly prohibits consumer sales from being effected through the mails (except for intrastate shipments within Alaska and Hawaii). Thus, the Jenkins Act requirements bear almost entirely on sales through non-postal delivery channels. Whatever their application to sales of ENDS products shipped through non-postal channels or to intrastate sales within Alaska and Hawaii effected through the mails, it should be noted that the Jenkins Act is administered by ATF, not by the Postal Service. As such, inquiries about the application of the Jenkins Act's requirements to non-nicotine ENDS products should be directed to ATF.

Finally, a Federal agency partner inquired whether the final rule would include an analysis pursuant to the Regulatory Flexibility Act (RFA). The Postal Service is generally exempt from Federal statutes that govern administrative matters. 39 U.S.C. 410(a); see *Kuzma* v. *U.S. Postal Serv.*, 798 F.2d 29, 31–32 (2d Cir. 1986) (exemption from Paperwork Reduction Act is consistent with legislative intent to expand business discretion and modernize day-to-day managerial operations of the postal system);[6] accord *Shane* v. *Buck*, 658 F. Supp. 908, 913–15 (D. Utah 1985), aff'd, 817 F.2d 87 (10th Cir. 1987).[7] The RFA is not among those statutes that Congress has enumerated as specifically applicable, 39 U.S.C. 410(b), nor does the RFA itself expressly include the Postal Service as a covered "agency," such as might arguably supersede the Postal Service's general exemption. See 5 U.S.C. 601(1). Indeed, the RFA's definition of covered "agencies" points back to the APA, *id.* (cross-referencing 5 U.S.C. 551(1)), from the ambit of which Congress removed the Postal Service. 39 U.S.C. 410(a). Although Congress, as a narrow exception, has provided that proceedings concerning mailability, such as this one, must be "conducted in accordance with chapters 5 and 7 of title 5" (that is, the APA), 5 U.S.C. chapter 6 (the RFA) is conspicuously absent from this prescription. 39 U.S.C. 3001(m). Congress's decision to reference two sets of provisions but not a third is logically dispositive, *e.g.*, *Longview Fibre Co.* v. *Rasmussen*, 980 F.2d 1307, 1312–13 (9th Cir. 1992); accord *Friends of the Earth* v. *EPA*, 333 F.3d 184, 189–90 (D.C. Cir. 2003), and the contrast is particularly conspicuous here, where the non-referenced chapter resides between the two referenced chapters. For all of these reasons, the RFA does not apply.

Even if the RFA did apply, however, the substance of this final rule would address all of the elements of a regulatory flexibility analysis. Sections I–II state the need for and objectives of the final rule: Namely, fulfillment of a specific statutory directive. See 5 U.S.C. 604(a)(1). This section III states the significant issues raised by public comments, the Postal Service's assessment of those issues, and any changes to the proposed rule made as a result of the comments. See *id.* at (a)(2). No response is made to comments by the Chief Counsel for Advocacy of the Small Business Administration because no such comments were filed; nonetheless, the Postal Service consulted informally with staff of that office, and issues raised by such staff are addressed throughout this section. See *id.* at (a)(3). Because of the breadth and heterogeneity of persons and entities who might send or receive ENDS products, there is no available estimate of the number of small entities to which the rule will apply. See *id.* at (a)(4). The final rule does not impose reporting or recordkeeping requirements; to the extent that the final rule—or, rather, the governing statute—imposes various types of compliance requirements, the classes of entities subject to those requirements should be evident from this final rule. See *id.* at (a)(5). Finally, as explained in section III.A and elsewhere, this rulemaking fulfills statutory directives as to which the Postal Service was not delegated substantial policy discretion. As such, the Postal Service has few, if any, means to minimize the economic impact on small entities. See *id.* at (a)(6). To the extent that the Postal Service, in this final rule, does exercise some limited administrative authority, such as with respect to the precise method for verifying eligibility for the Business/Regulatory Purposes exception, the relevant portion of section III will explain the legal, policy, and/or factual rationale for the chosen measures and why they are superior to alternatives. Thus, despite their inapplicability, the substantive requirements of the RFA are fulfilled in this instance.

D. Scope of Covered ENDS Products

1. Non-Nicotine-Related ENDS Products Generally

The POSECCA defines ENDS products in relation to their delivery of "nicotine, flavor, or any other substance." 15 U.S.C. 375(7)(A). Through use of this list and the disjunctive "or," this language is clear on its face: Covered ENDS products may be used to deliver nicotine, *or* they may be used to deliver flavor, *or* they may be used to deliver any other substance (with or without nicotine or flavor). For this reason, the Postal Service observed in the notice of proposed rulemaking that, "[d]espite the name, an item can qualify as an ENDS product without regard to whether it contains or is intended to be used to deliver nicotine; liquids that do not actually contain nicotine can still qualify as ENDS, as can devices, parts, components, and accessories capable of or intended for

[6] The *Kuzma* court noted that the Paperwork Reduction Act was passed ten years after the enactment of 39 U.S.C. 410(a); that the Paperwork Reduction Act does not mention the Postal Service or otherwise expressly indicate Congressional intent that it apply to the Postal Service; and that repeals by implication are disfavored. *Kuzma*, 798 F.2d at 32. The same can be said of the RFA, which was likewise passed ten years after 39 U.S.C. 410(a), see Public Law 96–354 (1980), and does not expressly indicate intent to apply to the Postal Service.

[7] The *Shane* court noted that the Postal Service's businesslike economic operations and financial self-sufficiency framework, in contradistinction to typical Federal bureaucracies, give it inherent incentives to minimize paperwork for customers. *Shane*, 658 F. Supp. at 915. The same is true with respect to the policy motives for the RFA. Unlike most Federal agencies, the Postal Service is supported almost entirely by revenues, not appropriations. See generally 39 U.S.C. 2401. As such, the Postal Service has inherent business incentives to minimize burdens for small-business customers and to encourage their patronage, to the extent permitted by law. The Postal Service is highly mindful of the particular needs of small businesses and has designed various services and outreach tools especially with such customers in mind. See, *e.g.*, U.S. Postal Service, Small Business Solutions, *https://www.usps.com/smallbusiness* (last visited Oct. 14, 2021).

use with non-nicotine-containing liquids." 86 FR at 10219.

Before addressing comments on non-nicotine substances, it must be emphasized that ATF is charged with administering the statute in which the relevant definitions reside. While the Postal Service consulted with ATF in developing the discussion that follows, questions of whether a particular product falls within these definitions therefore should be directed to ATF.

i. Relation to Nicotine and Flavor

Two ENDS industry commenters presented multiple legal arguments for an alternative construction. First, they invoked the canon of statutory construction known as ejusdem generis, which "instructs that, where general words follow specific words in an enumeration describing a statute's legal subject, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words." Norman & Shambie Singer, 2A Sutherland Statutes & Statutory Construction section 47:17 (7th ed. 2020). One of the commenters argued that, applied here, "any other substance" must be interpreted as "any other substance that mimics nicotine or flavor." The other argued that "any other substance" should be "limited to substances related to nicotine and flavor, such as liquid nicotine and liquid nicotine combined with colorings, flavorings, or other ingredients," and posited that Congress may have intended this to encompass non-nicotine liquids used with e-cigarettes but not with other ENDS devices.

This argument is unpersuasive. "Nicotine" and "flavor" do not admit of any common characteristic, such as might define a class of substances beyond nicotine and flavor. See *id.* section 47:18 (application of the canon requires the enumerated things to constitute a class that is not exhausted by the enumeration); see, *e.g., Yates* v. *United States,* 574 U.S. 528, 543–46 (2015) ("tangible object" means "object used to record or preserve information" when used in connection with "record [or] document"). The commenters do not propose any characteristic common to nicotine and flavor. Nor do they offer any examples of what things might share characteristics with nicotine and flavor besides substances that themselves contain nicotine and flavor. The impression left by these comments is that their proposals' chief import would be to render the catch-all "any other substance" a nullity, running headlong into the canon against superfluities. See Singer & Singer, 2A Sutherland Statutes section 46:6; *Ali* v. *Fed. Bureau of Prisons,* 552 U.S. 214, 227 (2008).

Moreover, the ejusdem generis canon readily gives way "when the whole context dictates a different conclusion." *Norfolk & Western Ry. Co.* v. *Am. Train Dispatchers Ass'n,* 499 U.S. 117, 129 (1991); see also *Ali,* 552 U.S. at 227 ("we do not woodenly apply limiting principles every time Congress includes a specific example along with a general phrase"). Here, Congress's enumeration demonstrates its intent to include non-nicotine-containing substances within the scope of nonmailable ENDS: The definition includes solutions containing "nicotine" as well as—separately and thus independent of any nicotine content—those containing "flavor." Thus, despite the focus on nicotine in the shorthand term "electronic nicotine delivery system," the explicit listing of "flavor" shows that Congress intended the scope of covered ENDS products to cover some substances that do not contain nicotine. This enumeration strengthens, rather than weakens, the ordinary inference that "any other substance" extends to non-nicotine substances. Cf. *Norfolk & Western Ry.,* 499 U.S. at 129 ("all other law" in exemption means that "[a] carrier is exempt from *all law,*" with enumeration of antitrust law serving merely to overcome presumptions against its inclusion).

As in *Norfolk & Western,* the enumeration here, with its lack of any reasonably salient shared characteristic among "nicotine" and "flavor," implies that Congress intended covered ENDS products to be those used to deliver any substance, with nicotine and flavor indicated expressly as examples. The framers may have believed that "nicotine" was necessary to justify the use of the shorthand term "electronic nicotine delivery systems," and/or that listing "nicotine" and "flavor" would most clearly evince the aim of combating youth access to nicotine products. As discussed in section III.D.1.iii, youth access was certainly a major focus of the framers' concern, albeit far from their exclusive focus: Hence their expressed intent not to limit the statute to "nicotine or flavor."

The statute here is clear on its face: "any other substance" means "any other substance," limited not by some dubiously inferred principle but explicitly by the surrounding text, which confines the scope to substances delivered from an electronic device to an inhaling user via an aerosolized solution. Given that the enumerated list already includes one non-nicotine substance ("flavor," as an alternative to nicotine), it cannot be said that other non-nicotine substances are "as dissimilar [from the enumerated items] as documents and fish." See *Yates,* 574 U.S. at 546; *id.* at 550 (Alito, J., concurring). In effect, the commenters' invocation of the ejusdem generis principle is an effort to create ambiguity where none exists, and so there is no occasion to resort to it here. See *Ali,* 552 U.S. at 227; *United States* v. *Turkette,* 452 U.S. 576, 581 (1981).

Finally, the second commenter's alternative hypothesis that Congress may have intended "any other substance" to encompass non-nicotine and non-flavor substances, but only in connection with e-cigarette devices, finds no support in the statute. The phrase "delivers nicotine, flavor, or any other substance" appears in the definition's opening paragraph, which establishes the qualifying parameters for all covered ENDS products, without differentiation as to any particular species of ENDS device. 15 U.S.C. 375(7)(A). The next paragraph offers an illustrative list of various devices that are included within the definition, such as an e-cigarette, e-hookah, e-cigar, or vape pen. *Id.* at (B). Nothing in either paragraph ties the phrase "any other substance" exclusively to e-cigarette devices. Absent such an indication, a plain reading of the statute indicates that any of the listed devices, along with any part, component, liquid, or accessory of the device, qualifies as an ENDS if it is used to deliver any substance through an aerosolized solution, whether or not the substance is or contains nicotine or flavor.

ii. Relation to Listed Devices

One ENDS industry commenter attempted to enlist a second canon of construction: Noscitur a sociis, whereby "doubtful words in an ambiguous statute [are] given more precise content by the neighboring words with which [they are] associated." Singer & Singer, 2A Sutherland Statutes section 47:16. The commenter proposed that "any other substance" be construed in light of the list of included devices in 15 U.S.C. 375(7)(B), which, the commenter claimed, "can only be used with nicotine-based products." The commenter further asserted that a nicotine-focused construction would be consistent with the FDA and CDC's construction of the term "ENDS."

This argument, too, founders for multiple reasons. First, the canon overlaps heavily with ejusdem generis and "does not apply absent ambiguity, or to thwart legislative intent, or to make general words meaningless." *Id.;* see, *e.g., Yates* v. *United States,* 574 U.S.

528, 564 (2015) (Kagan, J., dissenting) (citing *Ali*, 552 U.S. at 227). As described in the preceding section, a construction of "any other substance" to mean only substances that contain nicotine, which is separately enumerated, would indeed make general words meaningless and thwart legislative intent. And there is no ambiguity in the phrase "any other substance": It means what it says, and there is no apparent reason to infer a (redundant) nicotine-only construction. See, *e.g., Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 559 U.S. 280, 286–90 (2010) (rejecting noscitur a sociis as a basis to construe "administrative" to refer exclusively to Federal activities, as opposed to those by State and local governments).

Even if there were reason to resort to noscitur a sociis here, it would not produce the limiting construction proposed by the commenter. Several, and possibly even all, of the statutorily enumerated terms (not to mention parts, components, and accessories) are used to refer to devices marketed for use with cannabis, for example, without concomitant reference to nicotine.[8] Absent further technical specificity in the statute, there is no apparent technological or economic reason why such devices would be capable of use only with nicotine-containing substances.

Finally, as explained in section III.C.1, the FDA operates under statutory authority that explicitly requires a nexus to tobacco. The POSECCA does not; instead, it refers to "any other substance" in the alternative to "nicotine" and "flavor." As such, the scope of ENDS products made nonmailable by the POSECCA is self-evidently and materially broader than the scope of ENDS products regulated as "tobacco products" by the FDA.

iii. Legislative History of the POSECCA

Some ENDS industry commenters purported that certain floor statements by the POSECCA's sponsors evince an exclusive focus on nicotine-containing or -delivering ENDS products. From these supposed floor statements, the commenters concluded that non-nicotine-related ENDS products are beyond the scope of what Congress intended.

Legislative history ordinarily is useful only for resolving ambiguity in a statute, not for superseding or ambiguating already-plain statutory text. See Singer & Singer, 2A Sutherland Statutes & Statutory Construction section 48:1. Here, the statutory text is clear in its coverage of ENDS used with "nicotine, flavor, or any other substance [*i.e.*, any substance other than nicotine or flavor]." Even if the legislative history contained only examples of concern relating to nicotine substances, that would not be a basis to read out of the statute the catch-all that Congress expressly included. In that hypothetical instance, absence of evidence of intent as to non-nicotine-related ENDS products would not equate to evidence of the absence of such intent.

Moreover, the commenters are incorrect: The legislative history of the POSECCA actually attests to concerns about non-nicotine-related and nicotine-related ENDS products alike. Bill sponsors frequently decried an epidemic of youth vaping without specifying the chemical composition of the vapors thus inhaled. One Senate sponsor spoke of teens "regularly vaping both nicotine and THC products" and singled out "closed systems that deliver only nicotine" as but one subset of a larger universe of devices, all of which his sponsored bill impliedly targeted. 165 Cong. Rec. S6,898 (daily ed. Dec. 9, 2019) (statement of Senator Cornyn).

Most tellingly, perhaps, the POSECCA was introduced in the 116th Congress during a widely reported health crisis related to vaping practices, which led to at least 68 deaths and 2,807 hospitalizations across the country from lung damage related to ENDS use. Hassan Z. Sheikh, Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Select Policy Issues in the 117th Congress 9 (Cong. Research Serv. Sept. 30, 2021). As discussed in section III.B, the House committee report on the POSECCA expressly adverted to this crisis as a motivating factor, as did floor statements regarding the POSECCA. See H. Rept. 116–260 at 3; 166 Cong. Rec. S7,028 (daily ed., Nov. 17, 2020) (statement of Senator Cornyn); 166 Cong. Rec. S4,174 (daily ed., July 2, 2020) (statement of Senator Feinstein); 165 Cong. Rec. H8,491 (daily ed., Dec. 9, 2019) (statement of Representative Mucarsel-Powell); 165 Cong. Rec. S6,586 (daily ed., Nov. 14, 2019) (statement of Senator Cornyn); 165 Cong. Rec. S5,431 (daily ed., Sept. 11, 2019) (statement of Senator Durbin). The CDC ultimately determined—several months prior to Congress's passage of the POSECCA, and some of the relevant floor statements—that this crisis was related to a chemical found in non-nicotine-related (specifically, THC-related) ENDS products. CDC, Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products, *https://go.usa.gov/xHd78* (last updated Feb. 25, 2020); see also Sheikh, Regulation of Electronic Nicotine Delivery Systems at 9 ("Among a subset of hospitalized [e-cigarette or vaping use–associated lung injury] patients, 82% reported using THC-containing products.").

It is evident, then, that, while youth nicotine consumption was a prominent concern animating this bill, it by no means constituted the sole motivating concern. The framers' expressed concerns about the dangers of both nicotine-related and non-nicotine-related ENDS use underscore the plain import of the POSECCA's inclusion of all such ENDS products.

2. Products That Aerosolize Non-Solution Solids

Some ENDS industry commenters urged the Postal Service to exclude personal vaporizers intended for use with waxes or dry herbs, as such substances do not take the form of an "aerosolized solution." However, one public-health-oriented commenter recommended including solid substances and devices that aerosolize them, noting that, according to at least one definition, "solution" includes solid as well as liquid mixtures.

Once again, ATF is charged with administering the statute in which the relevant definitions reside. Questions of whether a particular product falls within these definitions therefore should be directed to ATF.

As a further initial matter, we note that many such products are already nonmailable regardless of the POSECCA. To the extent that personal vaporizers are intended for use with waxes or dry herbs containing THC (other than the limited class of hemp and hemp-based products under Publication 52 section 453.37), those substances are controlled substances and the vaporizers are drug paraphernalia under the CSA. Indeed, online marketing, reviews, and blog posts frequently tout the suitability of such products for use with controlled substances. See Publication 52 section 453.131 (listing such circumstances as

[8] E.g., Jen Bernstein, "The Best Vape Pens: High Times' Vape Pen Buyers' Guide," *High Times*, *https://hightimes.com/products/high-times-2015-vape-pen-buyers-guide* (last visited Oct. 14, 2021); "Marijuana Vaporizers & Vapes," *Leafly*, *https://www.leafly.com/products/vaping* (last visited Oct. 14, 2021) (vape pens, portable vaporizers, batteries, power supplies, and accessories); "Sherlock Vape Pipe," *WeedGadgets.com*, *https://www.weedgadgets.com/sherlock-vape-pipe* (last visited Oct. 14, 2021) (e-pipe); see also "Cannabis E-Cigarettes: Risks vs. Advantages," *Way of Leaf* (last updated Mar. 17, 2021) ("An e-cigarette, also known as a vaporizer or a vape pen, is an electronic device that heats up your marijuana and enables you to consume it in vapor form.").

evidence that an item is drug paraphernalia). For further discussion of the nonmailability of such products, see section III.C.2.

The Postal Service recognizes that some personal vaporizers may also be used as aromatherapy devices with herbs that do not contain controlled substances (*e.g.*, mint or chamomile). Of course, at least some of the same products may also be used with controlled substances, and some are capable of use with liquid solutions as well as solid matter. The remainder of this section will therefore consider aerosolizing devices (and their related parts, components, and accessories) intended for use with *solids other than controlled substances* (*e.g.*, aromatherapy herbs) and *incapable* of use with a liquid solution.

Such devices appear to fall outside of the POSECCA definition of a generally nonmailable ENDS product (and also would not be nonmailable as drug paraphernalia). As discussed in the preceding section, the POSECCA defines ENDS by reference to "an aerosolized solution" containing "nicotine, flavor, or any other substance." Regardless of the constituent substance or substances, they must form part of a "solution." A solution is a mixture of chemical substances that is both homogenous (*i.e.*, uniformly mixed) and stable (*i.e.*, not prone to separating upon standing or filtration).[9]

Raw or minimally processed organic matter, such as aromatic herb leaves, does not qualify as a "solution." As such, if a device heats such matter to produce vapors for the user to inhale, that device does not operate "through an aerosolized solution" and thus falls outside the scope of the POSECCA definition. By the same token, its parts, components, and accessories (as well as the herbal matter used in the device) likewise fall outside of the POSECCA's scope.[10]

It is emphasized that this analysis covers only devices used *exclusively* with non-solution matter. If a device can be used to aerosolize a solution as well as non-solution matter for delivery to a user inhaling from the device, then the POSECCA definition applies notwithstanding the device's capability of alternative use with non-solution matter. Finally, it is emphasized again that a device intended for use with controlled substances (*e.g.*, cannabis herbal matter or wax) is nonmailable regardless of the POSECCA, irrespective of any dual capability of alternative licit use.

3. Heat-Not-Burn Cigarettes

One public-health-oriented commenter and two Federal agency partners inquired whether so-called "heat-not-burn cigarettes" are nonmailable under the PACT Act, either as ENDS products or as other forms of "cigarettes."

Once again, ATF is charged with administering the statutes in which the relevant definitions reside. Questions of whether a particular product falls within these definitions therefore should be directed to ATF.

To the extent that "heat-not-burn cigarette" refers to a product that functions by heating tobacco leaf matter just shy of the point of combustion, such products vaporize a solid mass of processed tobacco leaf, not an aerosolized solution. As discussed in the preceding section, it seems likely that such products fall outside the POSECCA's definition of ENDS products.

Nevertheless, many, and perhaps all, such products contain or comprise a roll of tobacco wrapped in paper or another substance not containing tobacco. As such, these products may already be nonmailable under the preexisting definition of "cigarette" used for PACT Act purposes. 18 U.S.C. 2341(1)(A), referenced in 15 U.S.C. 375(2)(A)(i), referenced in 18 U.S.C. 1716E(a)(1). Such products may also be nonmailable as "smokeless tobacco," insofar as they contain tobacco and are intended to be consumed without being combusted. 15 U.S.C. 375(13). Parties interested in a definitive opinion are advised to contact ATF, as instructed in the new rules.

4. Products That Release Aerosols Into Ambient Air, Not for Direct Inhalation

One ENDS industry commenter expressed concern that the POSECCA definition of ENDS would prove so expansive as to encompass air fresheners, essential oil misters, portable aromatherapy diffusers, electric incense burners, household humidifiers, and other products that aerosolize matter for release into ambient air, rather than for direct inhalation. The commenter proposed that the Postal Service preclude this purportedly untoward construction by appending, to the statutory definition of ENDS ("any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device") an implied limitation: "into the lungs."

We note again that ATF, not the Postal Service, is charged with administering the definitional statute. Nevertheless, we note that the commenter's concern may be misplaced. The POSECCA definition restricts the scope of covered ENDS products based on delivery of a substance "to the user inhaling *from the device*." 15 U.S.C. 375(7)(A) (emphasis added). This language could suggest physical contact or proximity between the user's nose or mouth and the vapor-emitting ENDS device. By contrast, the products described in the comment release aerosolized matter into the ambient air, which in turn is breathed by persons in the room without directly placing their nose or mouth on the product. While these products may aerosolize solution to be inhaled by a user, the user arguably does not inhale directly "from the device." As such, these products (and their components, liquids, parts, and accessories) might not fall within the scope of the POSECCA's definition of ENDS.[11] Again, however, these observations are necessarily tentative; for a definitive interpretation, parties are advised to contact ATF as directed in the new rules.

5. Natural vs. Synthetic Nicotine

One ENDS manufacturer, two public-health-oriented commenters, and a Federal agency partner asked the Postal Service to clarify that ENDS products include those containing or used with all forms of nicotine, whether natural or synthetic in origin.

The POSECCA defines ENDS products by reference to the delivery of "nicotine," among other things. There is no statutory basis to read this term as referring only to natural-origin nicotine, as opposed to synthetic nicotine. As discussed in section III.C.1, this scope of regulation is different from that under the FD&C Act, for which purposes the FDA regulates nicotine-related ENDS products to the extent that the nicotine is made or derived from tobacco. Beyond this observation about the POSECCA's plain language, interested

[9] See, *e.g.*, Solution, in Int'l Union of Pure & Applied Chemistry, Compendium of Chemical Terminology (2d ed. 1997), *https://goldbook.iupac.org/terms/view/S05746* (last edited Feb. 24, 2014); Solution (chemistry), Brittanica, *https://www.britannica.com/science/solution-chemistry* (last edited Dec. 19, 2019); Solution (chemistry), Wikipedia, *https://en.wikipedia.org/wiki/Solution_(chemistry)* (last edited Aug. 26, 2021).

[10] As the public-health-oriented commenter noted, solutions may be typically liquid, but they are not exclusively so. Because the matter at issue here is not a solution in any event, it is unnecessary to discuss here whether the reference to "liquid" in the POSECCA's inclusion of "any component, liquid, part, or accessory of [an ENDS] device" excludes the possibility that covered devices may be used with solid solutions.

[11] We further note that the commenter's proposed addition of "into the lungs" would not have any material effect. By definition, all inhalation, whether of ambient air or of vapor directly from the emitting device, is "into the lungs."

parties are encouraged to contact ATF for further interpretive guidance.

6. Scope of Components and Parts

In addition to fully assembled vaping devices, the POSECCA includes in its definition of ENDS "any component, liquid, part, or accessory of [an ENDS], without regard to whether the component, liquid, part, or accessory is sold separately from the device." 15 U.S.C. 375(7)(B)(vii). Some pro-ENDS commenters found this definition to create a line-drawing conundrum, noting that certain materials used in ENDS devices and liquids are used in a wide array of non-ENDS consumer products. A partner agency also suggested that the terms could be interpreted in a manner similar to the definitions of "accessory" and "component or part" for purposes of the FDA's regulation of certain ENDS products. See 21 CFR 1100.3.

The Postal Service recognizes the point and notes that it resonates with other contexts in which parts, components, or accessories of a given type of item may be regulated. *E.g.*, 18 U.S.C. 921(4)(C), (24), (29)(B); 22 U.S.C. 2778(b)(1)(B); 26 U.S.C. 5845(b), (f)(3); 15 CFR pt. 774, supp. no. 1; 22 CFR 121.1. It is necessarily a fact-specific question whether an item has a sufficient nexus to the regulated end product to itself warrant control; as such, such questions may require case-by-case determination.

Here, too, interpretative questions about whether the POSECCA definition codified in the Jenkins Act applies to specific precursor parts, components, or accessories should be directed to ATF.

E. Exclusion of Tobacco Cessation and Therapeutic Products

The POSECCA excludes from the definition of ENDS products any such products that are approved by the FDA for sale as a tobacco cessation product or for any therapeutic purpose, and that are marketed and sold solely for such purposes. 15 U.S.C. 375(7)(C).

Multiple public-health-oriented commenters and law students recommended that the Postal Service disallow the exclusion at this juncture, or at least establish a presumption that mailed ENDS products are not covered by the exclusion. These commenters pointed out that no such products have been approved by the FDA. Hence, given the prevalence of non-validated tobacco-cessation and other health claims by the industry in association with ENDS products, allowing mailers to purport to use the exclusion would arguably invite deceptive practices and complicate enforcement.

Two public-health-oriented commenters and one law student went farther and offered specific proposals for how the Postal Service could administer the exclusion if and when the FDA issues a pertinent approval. As envisioned by one public-health-oriented commenter, the FDA would formally inform the Postal Service of its approval, whereupon the Postal Service would collaborate with the FDA and manufacturers to establish a list of eligible shippers (*e.g.*, medical-product distributors, health departments, or healthcare facilities) who might apply for permission to mail under the exclusion. The second such commenter proposed that mailers should have to provide an FDA approval letter at the time of mailing, not merely mark the package as an excluded tobacco-cessation or therapeutic product. The law student recommended that mailers be required to clearly mark the manufacturer and brand on the exterior of mailpieces, to ease verification against a Postal Service list of approved products, and that age verification be required at delivery.

One ENDS industry commenter opined that the exclusion pertains to drug protocols and would paradoxically exclude the ENDS industry. The commenter went on to quote from a court opinion to the effect that the FDA is authorized to regulate "customarily marketed tobacco products—including e-cigarettes—under the Tobacco Control Act" and "therapeutically marketed tobacco products under the [FD&C Act's] drug/device provisions." *Sottera, Inc.* v. *FDA*, 627 F.3d 891, 898–99 (D.C. Cir. 2010).

A manufacturer of herbal vaporizers proposed that mailers be allowed to self-certify the eligibility of a product for the exclusion via distinctive labeling on the package, backed by recordkeeping requirements similar to those for hemp-based cannabidiol ("CBD") products. See Publication 52 section 453.37.b. The commenter considered the analogy to be apt because of the difficulty in distinguishing CBD products that do and do not qualify for the CSA exception, similar to the likely difficulty in distinguishing ENDS products that do and do not qualify for the POSECCA exclusion. The commenter opined that this approach would provide a credible means of verifying eligibility, while minimizing burdens on the Postal Service's operational and enforcement personnel.

Finally, a large number of individual ENDS consumers commented about the perceived tobacco-cessation benefits of ENDS products, both in their own experience and in relation to U.K. studies and purported official European health recommendations.[12] Other individual ENDS consumers wrote of the perceived therapeutic benefits of cannabis or, in rare instances, aromatherapy delivered using ENDS products.

The first set of commenters is correct: The FDA has not approved any ENDS product for smoking-cessation or other therapeutic use.[13] Unless and until the FDA approves any ENDS product for smoking-cessation or another therapeutic use, then, the statutory exclusion lies dormant and has no real-world import.

While the distinction between excluded and nonmailable ENDS products may be difficult to get right in practice, it is essential to get it right, given the PACT Act's directive that the Postal Service not "accept for delivery or transmit through the mails" any package as to which "reasonable cause" exists to believe that it contains nonmailable ENDS products. See 18 U.S.C. 1716E(a)(1). Whatever merit the ideas raised by commenters on this topic may have, the Postal Service finds it inadvisable to attempt (in consultation with ATF) to set forth appropriate standards in the abstract. Rather, if and when any product is approved by the FDA, concrete circumstances will guide the development of a practical approach.

Therefore, the final rule contains language clarifying that the exclusion does not apply at this time, but inviting

[12] See Máirtín S. McDermott et al., "The Effectiveness of Using E-Cigarettes for Quitting Smoking Compared to Other Cessation Methods Among Adults in the United Kingdom," *Addiction* (2021), *https://onlinelibrary.wiley.com/doi/10.1111/add.15474;* Peter Hajek et al., "A Randomized Trial of E-Cigarettes Versus Nicotine-Replacement Therapy," 380 *New Eng. J. Med.* 629 (2019), *https://www.nejm.org/doi/full/10.1056/NEJMoa1808779;* Jamie Brown et al., "Real-World Effectiveness of E-Cigarettes When Used to Aid Smoking Cessation: A Cross-Sectional Population Study," 109 *Addiction* 1531 (2014), *https://onlinelibrary.wiley.com/doi/full/10.1111/add.12623.* It should be noted that the Hajek article website includes a number of letters by other researchers pointing out limitations in the study design and questioning the reliability of its findings.

[13] FDA, Drugs@FDA: FDA-Approved Drugs, *https://go.usa.gov/xHHxa* (search for "nicotine" conducted Oct. 14, 2021 yielded no ENDS-related results); Hassan Z. Sheikh, Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Select Policy Issues in the 117th Congress 5 (Cong. Research Serv. Sept. 30, 2021); Richard J. Wang et al., "E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis," 111 *Am. J. Pub. Health* 230 (2020), *https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2020.305999* ("E-cigarettes have been promoted for smoking cessation even though, as of November 2020, no e-cigarette has been approved as a smoking cessation medication by the FDA Center for Drug Evaluation and Research (CDER)." (citations omitted)).

any ENDS manufacturer of an FDA-approved product to notify ATF and the Postal Service in the event of such approval. At that time, ATF and the Postal Service may develop appropriate rules governing the exclusion.

The FDA likewise has not approved any ENDS product for therapeutic delivery of any non-nicotine substance, including, in particular, CBD or other substances derived from marijuana.[14] Once again, except for hemp-derived CBD containing no more than 0.3 percent THC by dry weight, cannabis and cannabis derivatives remain nonmailable under the Controlled Substances Act regardless of the POSECCA and notwithstanding any State or local laws on "medical" marijuana. See *supra* section III.C.2; 84 FR at 12970. Far from taking marketing claims of therapeutic benefit at face value, the FDA has undertaken enforcement action against companies making such claims about CBD and other cannabis-related products absent new drug approvals from the FDA. See 84 FR at 12970.

The concern that the statutory exclusion pertaining to FDA drug or device protocols would paradoxically exclude the ENDS industry appears to be off-base. The very court opinion quoted by the commenter notes that the FDA's regulatory authority extends to "therapeutically marketed tobacco products under the [FD&C Act's] drug/device provisions." *Sottera,* 627 F.3d at 898–99. Moreover, with respect to ENDS comprising, containing, or used with CBD, the FDA's authority to approve drugs and medical devices extends to cannabis and cannabis-derived products that could form part of an ENDS. See 84 FR at 12972–12974.

Finally, a Federal agency partner suggested that the Postal Service clarify the scope of "other therapeutic purposes," perhaps in line with the *Sottera* court's borrowing of "diagnosis, cure, mitigation, treatment, or prevention of disease" phraseology from the FD&C Act's "drug" and "device" definitions. *Sottera,* 627 F.3d at 894 (quoting 21 U.S.C. 321(g)(1)(B)); accord 21 U.S.C. 321(h)(1)(B). Such an interpretation may be reasonable, and even tautological, given that the POSECCA exclusion requires FDA approval of an ENDS product, which itself would require an FDA determination that the product meets the purposive criteria for a "drug" or "device." However, it may also be that "therapeutic purposes" means something narrower in this context, given the term's juxtaposition with "tobacco cessation." The Postal Service declines to announce any particular interpretation of "therapeutic purposes" at this time, both out of deference to ATF's authority to interpret the relevant statute and because no ENDS products have been FDA-approved for any arguably relevant purpose at any rate. In the event that any such product garners FDA approval for a use other than tobacco cessation, then ATF may find it appropriate to opine on whether that product fulfills a "therapeutic purpose" for purposes of the POSECCA exclusion.

F. Intra-Alaska/Intra-Hawaii Shipments

One public-health-oriented commenter proposed that the Postal Service clarify that, while the PACT Act's exception for intrastate shipments within Alaska and Hawaii may apply to ENDS products, it does not apply to interstate ENDS shipments into or out of either state.

The Postal Service does not believe that such clarification is necessary. The PACT Act is already abundantly clear that the exception applies only to "mailings *within* the State of Alaska or *within* the State of Hawaii." 18 U.S.C. 1716E(b)(2) (emphasis added). Longstanding Postal Service rules, which will now encompass ENDS products, make this even more explicit, by requiring such a mailing to be tendered to a Postal Service employee in a face-to-face transaction within the relevant State, to destinate in the same state as the state of origin, and to bear a valid, complete return address within the state of origin. Publication 52 section 472.21.a–.c.[15] These requirements allow Postal Service personnel at the point of acceptance to verify that the shipment will destinate in the noncontiguous state of origin. Treatment of Cigarettes and Smokeless Tobacco as Nonmailable Matter, 75 FR 24534, 24535 (2010) (notice of proposed rulemaking). It is difficult to imagine how the geographic limitation on this exception could be made any clearer.

G. Business/Regulatory Purposes Exception

The Business/Regulatory Purposes exception was a major area of commenter discussion, and so it is discussed extensively here. In short, the exception permits shipments between legally operating businesses in certain industry sectors and between such businesses and Federal or State government agencies, subject to multiple conditions. 18 U.S.C. 1716E(b)(3)(A). Those conditions include Postal Service verification of the sender and recipient's respective eligibility, as well as the recipient's age and employee status; restriction of available products to those that allow tracking and confirmation of delivery; capture and retention of package-specific identifying information by the Postal Service; and certain package markings. *Id.* at (b)(3)(B).

In implementing these requirements, the Postal Service adopted a process whereby potential senders must first submit an advance application to the Postal Service's Pricing and Classification Service Center (PCSC) for an eligibility verification as to the applicant and any anticipated recipients of that applicant's shipments. Publication 52 section 472.221. Upon a PCSC determination of eligibility, the authorized sender must show the resulting authorization letter when tendering any covered mailing via a face-to-face transaction with a Postal Service employee at an approved acceptance location. *Id.* section 472.222. The mailer may use only certain combinations of postal services that allow for age verification, tracking, and confirmation of delivery, as well as a return receipt returnable to the PCSC for recordkeeping purposes. *Id.* section 472.222.a–.b. Finally, the Postal Service conducts the requisite verification of age, identity, and employment status upon face-to-face delivery. *Id.* section 472.223.

In the notice of proposed rulemaking, the Postal Service proposed a simple amendment to the terminology used in the Business/Regulatory Exception rules, such that the same rules would automatically apply to ENDS products as to other PACT Act–covered products. 86 FR at 10220.

1. Availability in General

As an initial matter, a few comments dealt with existential aspects of the exception. Two ENDS industry commenters sought confirmation that the exception would extend to ENDS products, in order to sustain industry supply chains, regulatory activities, and the channeling of ENDS to retail outlets subject to State and local law (in lieu of direct-to-consumer shipments). Conversely, one law student urged the abolition of the exception for ENDS

[14] The FDA has approved a small number of drugs that contain CBD, a synthetic THC (dronabinol), and a synthetic chemical similar to THC (nabilone), but only for oral delivery in capsule or solution form, not via an ENDS. FDA, Drugs@FDA: FDA-Approved Drugs (searches conducted Oct. 14, 2021); see Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds, 84 FR 12969, 12972–12973 (2019).

[15] All citations to Publication 52 chapter 47 throughout this section III refer to the version in effect prior to this final rule.

products except as necessary for regulatory activities.

As discussed in section III.A.2, the Business/Regulatory Purposes exception is established by statute, and the Postal Service lacks the delegated authority to modify or restrict the exception's applicability on policy grounds. Unlike the Consumer Testing and Public Health exceptions discussed in section III.I, nothing in the statutory language concerning the Business/Regulatory Purposes exception indicates Congressional intent to exclude ENDS products from the exception, and there is no other basis to find such products to be incompatible with the exception's terms. As such, the exception is available in connection with ENDS products as a legal matter, regardless of whatever policy arguments might militate for or against it.

Another pro-ENDS commenter feared that the conditions for the exception could be expanded into termination of the exception altogether. This comment appears to misconstrue the exception as a freestanding entitlement, upon which the Postal Service somehow discretionarily grafted conditions as a means to subvert the intended scope of the exception. In fact, however, Congress itself specified the criteria as conditions precedent that must be met in order to qualify for the limited exception: The conditions are therefore integral to the statutory framework for the exception. The longstanding conditions in Publication 52 merely bear out that framework, either by literally transmuting the statutory requirements or by means designed to fulfill those requirements. The regulatory framework has applied to cigarettes and smokeless tobacco since 2010. The POSECCA charges the Postal Service with clarifying the applicability of the limited exception, with its eligibility conditions, to ENDS products, and the final rules here do that.

One public-health-oriented commenter viewed the Business/Regulatory Purposes exception as being cabined by 18 U.S.C. 1716, such that 18 U.S.C. 1716(a) and (e) would preclude use of the Business/Regulatory Purposes exception as a "bulk distribution method" for manufacturers and wholesalers to transport ENDS products to retailers. It is true that eligibility to use the Business/Regulatory Purposes exception to the PACT Act does not excuse a mailer from compliance with other applicable mailability statutes, including 18 U.S.C. 1716. But the Postal Service cannot join the commenter's sweeping conclusion that all "bulk distribution" shipments of ENDS products that could be sent under the Business/Regulatory Purposes exception would necessarily be prohibited or restricted under 18 U.S.C. 1716. Many ENDS products do not qualify as injurious articles subject to 18 U.S.C. 1716, and as discussed in section III.A.2, Postal Service regulations permit many hazardous materials to be mailed pursuant to specified precautions. The precautions in existing regulations have historically been deemed sufficient to fulfill 18 U.S.C. 1716 for otherwise mailable shipments of ENDS products; it has never been the case that otherwise mailable ENDS products were deemed so extraordinarily dangerous as to warrant outright prohibition in the face of lesser applicable hazardous-materials safeguards. While the scope of generally mailable ENDS products will now be limited by the PACT Act's exceptions, the Postal Service perceives no rational basis to upset the highly reticulated harm-based framework for hazardous-materials regulation.

In the course of its 18 U.S.C. 1716 argument, the same commenter raised policy concerns about use of the Business/Regulatory Purposes exception to evade state and local taxes. But 18 U.S.C. 1716 has nothing to do with tax collection or evasion. Nor has Congress specifically conditioned eligibility for the Business/Regulatory Purposes exception on any particular standard of tax compliance, as it expressly did for the Consumer Testing exception. 18 U.S.C. 1716E(b)(5)(A)(iv), (b)(5)(C)(ii)(III) (Consumer Testing exception). Of course, noncompliance with applicable tax laws may subject a business to penalties under other Federal, State, local, or Tribal laws. It may also affect the business's ability to obtain relevant licenses or permits, which is a prerequisite for eligibility to use the Business/Regulatory Purposes exception. *Id.* at (b)(3)(A)(i). Where information may indicate that an entity that may be authorized to use the Business/Regulatory Purposes exception is not, in fact, operating lawfully, all parties are encouraged to bring such information to the attention of the Postal Inspection Service.

Finally, a Federal agency partner sought clarification of whether the Business/Regulatory Purposes exception encompasses shipments from businesses to Federal regulatory agencies and vice versa for enforcement or investigational purposes. The PACT Act permits use of the exception "for regulatory purposes *between* any [covered] business . . . and an agency of the Federal Government or a State government." *Id.* at (b)(3)(A)(ii) (emphasis added). The word "between" plainly denotes movement in either direction. See, *e.g.*, *Atlas Aerospace LLC* v. *Advanced Transp., Inc.*, No. 12–1200–JWL, 2012 WL 5398027, at *1 (D. Kan. Nov. 2, 2012); Union Pacific Corp. et al., 2 S.T.B. 276, 280 (1997) ("Citation is hardly necessary on this point."). It is further apparent that "regulatory purposes" encompasses enforcement against and investigation of regulated entities, among other governmental activities. Therefore, shipments from a business to a Federal or State governmental body and vice versa are within the ambit of the Business/Regulatory Purposes exception, provided that all of the other conditions for use of the exception are met.

2. Eligible Parties

The Business/Regulatory Purposes exception permits shipments of PACT Act-covered products between "legally operating businesses that have all applicable State and Federal Government licenses or permits and are engaged in tobacco product manufacturing, distribution, wholesale, export, import, testing, investigation, or research" and between such businesses and Federal or State government agencies. 18 U.S.C. 1716E(b)(3)(A)(i)–(ii).

A number of ENDS industry commenters opined that "businesses . . . engaged in . . . distribution" should be understood to include retailers, common carriers, and contract delivery services. This interpretation accords with the Postal Service's longstanding practice in applying the statutory term, as well as with dictionary and related statutory definitions. See, *e.g.*, Distribute, Black's Law Dictionary (11th ed. 2015) ("3. To deliver."); Distribute, Merriam-Webster.com (last visited Oct. 14, 2021) ("2b: To give out or deliver especially to members of a group"); cf. 21 U.S.C. 802(8), (11) (distribution of a controlled substance or listed chemical generally means transfer between parties). Because the Postal Service considers this meaning to be plain from the statutory term, there does not appear to be a basis to deviate from or elaborate upon the statutory language. It is emphasized that the statutory Business/Regulatory Purposes exception permits shipments between a retail or other distributor and another industry business or regulator, but not a distributor's (or any other entity's) direct shipments to consumers. The measures discussed in sections III.G.3–.7 are designed to ensure that the Business/Regulatory Purposes exception is used only for eligible business-to-business or business-to-government shipments and not for shipments to or

from ineligible parties, including retail consumers.

An ENDS industry association proposed to clarify that "testing, investigation, or research" includes contracted research organizations and laboratories. It seems self-evident that such entities would be covered, to the extent that they are "engaged in . . . testing, investigation, or research" as to PACT Act-covered products; the statute provides no basis for distinction according to such entities' contractual relationships. Here, too, the Postal Service regards the statutory language as sufficiently clear in encompassing the relevant entities, without further elaboration. While the statute does not appear to preclude eligibility for such parties generally, verification of any particular research organization or laboratory's eligibility will involve a case-specific determination based on the documentation submitted with the relevant application.

The same ENDS industry association asked that marketing firms be treated as eligible. The PACT Act does not appear to permit such treatment. None of the categories of business activity enumerated in the statute encompasses marketing or related activities, such as advertising or promotion. Nor does the statute extend eligibility to agents of enumerated businesses, in contrast to the Consumer Testing exception. Cf. 18 U.S.C. 1716E(b)(5)(A). As an exception to a general policy of nonmailability, the Business/Regulatory Purposes exception merits narrow construction. See, *e.g.*, *Maracich* v. *Spears*, 570 U.S. 48, 60 (2013) (quoting *Comm'r* v. *Clark*, 489 U.S. 726, 739 (1989)). The PACT Act delegates to the Postal Service only the authority to "establish the standards and requirements that apply to all mailings" defined by the statutory criteria for the Business/Regulatory Purposes exception, 18 U.S.C. 1716(b)(3)(B)(i), and the POSECCA permits the Postal Service only to "clarify the applicability" of the PACT Act's prohibition (and, by implication, its exceptions). POSECCA section 603(a). As discussed in section III.A.1, neither statute permits the Postal Service to modify those criteria themselves. As such, the Postal Service lacks any authority or basis to add businesses engaged in marketing to the roster of eligible entities.

An ENDS manufacturer asserted that licensed independent mystery-shopper contractors should count as entities "engaged in . . . testing, investigation, or research." To the extent that such a contractor is a business entity, then it could potentially come within the scope of the exception, depending on the Postal Service's assessment of the documentation submitted with the relevant application. To the extent that the contractor is an individual tester, however, then it would appear to fall outside of the scope of the exception, which is restricted to "legally operating businesses that have all applicable State and Federal Government licenses or permits." Rather, shipments from businesses to individual testers would appear to be akin to the shipments governed by the Consumer Testing and Public Health exceptions, which Congress narrowly circumscribed and, as discussed in section III.I, did not make available for ENDS products in any event. To the extent that individual testers may wish to send ENDS products to a manufacturer, testing firm, or other entity, these shipments would fall within the scope of the Certain Individuals exception, subject to the relevant criteria and limitations.

The same manufacturer inquired whether "between legally operating businesses" would be construed to include shipments between two offices of the same eligible firm, in addition to shipments between separate firms. The Postal Service agrees that this construction makes sense, provided that all relevant intra-firm sender and recipient addresses are listed in the firm's application and approved by the Postal Service. Indeed, it is difficult to conceive of why Congress would permit shipments between duly authorized facilities of separate firms, while prohibiting them between identical facilities that happen to be within the same corporate structure. This understanding accords with the Postal Service's historical practice in administering the exception prior to the POSECCA.

Certain pro-ENDS commenters suggested that the Business/Regulatory Purposes exception could be used to facilitate the return of ENDS products from consumers to businesses. The PACT Act does not permit this use of the Business/Regulatory Purposes exception. Eligibility for the Business/Regulatory Purposes exception is restricted to shipments between eligible businesses or between such businesses and Federal or State government agencies. By contrast, 18 U.S.C. 1716E(b)(3) does not contain any indication of legislative intent to encompass shipments either to or from individual consumers. That said, business-to-business product returns and recycling- or reuse-related shipments may be permissible between eligible and approved businesses, and consumer-to-business shipments for such purposes may be permissible under the Certain Individuals exception, as discussed in section III.H.

State and local attorneys general opined that a business's status as "legally operating" implies compliance with all pertinent laws, and that a business does not qualify as "legally operating" for purposes of the Business/Regulatory Purposes exception if it markets products that are counterfeit, that are not the subject of a timely premarket application to the FDA, or that are otherwise inconsistent with applicable law. The Postal Service agrees that all mailers must comply with all applicable laws with respect to products that they mail, and that a pattern of violations may rise to a level where a business may no longer be considered "legally operating." It seems equally apparent, however, that a business may violate a law with respect to certain of its products while operating legally in other respects. Therefore, the Postal Service regards the question of whether and when violations suffice to render a business no longer "legally operating" to be a case-specific one, dependent on the totality of relevant facts and circumstances in a particular situation. The Postal Service encourages its Federal, State, local, and Tribal governmental partners, as well as any other party, to bring to the attention of the Postal Inspection Service any indication that an ENDS-industry business mailer may have committed material legal violations such that it may no longer be considered "legally operating."

The same commenters proposed that the Business/Regulatory Purposes exception be restricted to recipients using their physical address as the delivery address and that recipients using a different delivery address (such as a Post Office Box or private rental mailbox) be barred from eligibility. The Postal Service declines to adopt this recommendation. Such a restriction is not among the statutory eligibility criteria. Even if the Postal Service had the policy discretion to adopt such a categorical restriction, the basis for such a potentially overbroad rule is unclear. The Postal Service notes that Post Office Boxes and private rental mailboxes are used by a variety of business and governmental actors for a variety of reasons.[16] Most such uses are presumably lawful and legitimate, and while some such mail recipients may engage in unlawful activity, the same is

[16] Indeed, in subscribing to this set of comments, one of the commenting State attorneys general provided contact information that listed a Post Office Box address.

true of persons who use a physical mailing address. The commenters offer no empirical support for the implied notion that addressees who use certain types of mailboxes are more likely than other addressees to engage in activity disqualifying them from the Business/Regulatory Purposes exception, let alone to such an overwhelming and disparate degree as to warrant barring *all* persons using such mailboxes from otherwise permissible eligibility for the exception. That said, if any person or entity believes that a sender or recipient is using a Post Office Box or private mailbox to violate the law, such persons and entities are encouraged to notify the Postal Inspection Service and/or to nominate the entity to the List of Unregistered or Noncompliant Delivery Sellers compiled by the Attorney General under section 2A(e) of the Jenkins Act ("Noncompliant List"), if appropriate.

Two Federal agency partners inquired whether the Business/Regulatory Purposes exception, or some other exception, would accommodate shipments from one governmental actor to another, such as between a governmental field agent and an agency laboratory or between two separate agencies. Congress has made the Business/Regulatory Purposes exception available only for shipments (1) from one covered business to another and (2) from such a business and governmental actor or vice versa, 18 U.S.C. 1716E(b)(3)(A)(i)–(ii), but *not* (3) from one governmental actor to another. Nor does any other PACT Act exception encompass such shipments. While the Postal Service understands that effective regulation may require shipments of tobacco and ENDS products between governmental actors, such shipments must occur through non-postal channels unless and until Congress amends the PACT Act to permit the use of the mails for such shipments.

3. Application Process

The PACT Act charges the Postal Service with verifying that any person submitting an otherwise nonmailable tobacco product into the mails, and any person receiving such a product through the mails, as authorized under the Business/Regulatory Purposes exception, is a business or government agency within the scope of the exception. 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II); see also *id.* at (b)(3)(B)(ii)(VI) (markings must enable Postal Service employees' awareness that the mailing "may be delivered only to a permitted government agency or business"). To fulfill these eligibility verification requirements, the Postal Service created a centralized application process. 76 FR at 24535–24536; 76 FR at 29665–29666. The Postal Service reasonably determined that centralization of eligibility determinations would allow for more effective and efficient assessment of eligibility, and would be less disruptive to retail and delivery operations and the customer experience, than the alternative of having retail and delivery personnel attempt to verify documentation and other criteria for eligibility each and every time an ENDS mailing is tendered or delivered.[17] Eleven years of the existing practice have provided no fresh basis to think that a decentralized approach to eligibility verification would work better.

In general, pro-ENDS commenters expressed concern that the centralized authorization process set forth in Publication 52 section 472.221, in combination with the fact that the POSECCA's mailing prohibition would take effect immediately upon adoption of the final rule, would have an unduly disruptive effect on the ENDS industry, at least to the extent that supply-chain-related and regulatory mailing activity might ultimately be deemed permissible under the Business/Regulatory Purposes exception.

Some industry commenters recommended that the Postal Service develop a streamlined process involving an online application portal. The Postal Service agrees that this recommendation might well benefit applicants, as well as improve the effectiveness and efficiency of Postal Service review. Unfortunately, the Postal Service's existing information technology infrastructure does not allow for such a solution in the near term, and the need for prompt implementation precludes development and implementation of an online application portal prior to adoption of the final rule. The Postal Service will continue to explore the feasibility of digitizing the application process and may amend its rules appropriately at a later time.

Particularly given the lack of a digital-based application process, at least one industry commenter expressed concern that the Postal Service may not be prepared for a potential flood of applications, and two others asked the Postal Service to ensure adequate staffing to process applications. The Postal Service recognizes that the ENDS industry is less consolidated, more complex, and more reliant on the mail than the industries previously subject to the PACT Act. As such, the Postal Service shares the commenter's anticipation of a large number of applications that far exceeds the historical rate of such applications and involves numbers of parties and products far greater than past applications. See 86 FR at 20288. The Postal Service is therefore undertaking multiple steps in an effort to improve the efficiency of the application review process and to mitigate the likely increase in processing times:

- The Postal Service provided advance guidance to ENDS industry actors about application documentation that they could compile while awaiting the final rule, in the interest of filing an application as soon as possible following the final rule and minimizing the chances of delayed processing due to insufficient supporting documentation. *Id.*
- The Postal Service also provided advance guidance about other mailability restrictions that might apply to ENDS products, so that potential applicants may preemptively consider whether their products would be nonmailable in any case and, in appropriate cases, narrow the scope of their Business/Regulatory Purposes applications accordingly or forgo applying altogether. See *id.* at 20,289.
- For at least a temporary period, the Postal Service is assigning additional analyst resources to assist the PCSC with reviewing Business/Regulatory Purposes exception applications. This internal workload-management change does not affect any aspect of the rules themselves and therefore is not reflected in the text of the final rule.

Despite these measures, it must be recognized that the Postal Service has limited financial and other resources with which to fulfill its universal service mission and fulfill myriad other statutory obligations,[18] and Congress did not provide the Postal Service with any additional funding for POSECCA implementation activities. As such, there are limits to the Postal Service's ability to timely process substantial numbers of Business/Regulatory Purposes applications at any given time. The statutory requirements for Postal Service verification of mailers' and

[17] The Postal Service is statutorily obligated to pursue economy and efficiency in its operations. 39 U.S.C. 101(a), 403(a), (b)(1), 2010, 3661(a).

[18] Unlike most Federal agencies, the Postal Service is supported almost entirely by revenues, not appropriations of taxpayer dollars. See generally 39 U.S.C. 2401. The Postal Service incurred multibillion-dollar net losses in each the past fourteen years, with a cumulative deficiency of $87.0 billion as of the end of FY 2020 and liquidity levels that place the current and future fulfillment of its statutory mission at risk. U.S. Postal Serv., 2020 Report on Form 10–K, at 68, *https://about.usps.com/what/financials/10k-reports/fy2020.pdf.*

recipients' eligibility, 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II), (b)(5)(C)(ii)(I), leave the Postal Service unable to simply suspend such verification. Hence, applicants and other interested parties should expect review of their applications to require potentially substantial processing time. The duration of any review would be determined by the number and complexity of the applications that the Postal Service receives and the amount of engagement with applicants during processing. The Postal Service recommends that applicants provide complete, accurate information in their applications and limit their current and anticipated mailing activity to bona fide mailable content, so that applications can be processed as efficiently and expeditiously as possible.

A number of pro-ENDS commenters expressed concern that an immediate effective date, coupled with a time-consuming application process for the Business/Regulatory Purposes exception, would disrupt the very industry supply chains and regulatory activities that the exception is intended to safeguard. To avoid such anticipated harms, these commenters asked the Postal Service either to accept Business/Regulatory Purposes exception applications in advance of the final rule, or else to defer the mailing ban until applications can be approved. In the April 2021 Guidance, the Postal Service explained that it would not accept early applications, as it was yet undetermined to what extent the exceptions would be available for ENDS products at all and on what terms. 86 FR at 20288. It is tautological that the Postal Service cannot announce and give effect to an exception to a mailing ban before the ban takes effect; prior to the ban, mailability is the rule, not an exception. As for accepting and processing applications in advance of the final rule, the course of intra- and interagency deliberations over the final rule—particularly in light of the voluminous number and range of public comments—required an extraordinary amount of time to process, to the point where any early acceptance period would have been too short to provide the substantial buffer that commenters sought. Nor is the Postal Service at liberty to further defer the effective date simply for the sake of a small group of pro-ENDS commenters, for the reasons discussed in section III.A.3. As it was, the same complex deliberations required far more time to complete the final rule than Congress had allotted in the POSECCA, and the policy interests evident in the statutory text and legislative history—none of which include solicitude toward industry supply chains or regulatory activities—do not support additional, discretionary delay beyond what was necessary to complete the final rule.[19]

Out of similar concerns over at least temporary disruption of industry supply chains, two ENDS industry commenters proposed that the Postal Service allow applicants to continue mailing ENDS products within the scope of the exception while awaiting approval of their application, subject to a sworn certification of eligibility, a bond or other security, or a provisional eligibility number provided by the Postal Service. The Postal Service declines to adopt this proposal as inconsistent with the aforementioned statutory requirements that the mailing ban take effect immediately and that the Postal Service verify the sender and recipient's eligibility prior to permitting any mailing under the Business/Regulatory Purposes exception.

Even if 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II) were arguably ambiguous as to whether verification may happen after acceptance or even after delivery, the Postal Service considers the only reasonable interpretation to be that verification must occur prior to acceptance. Congress clearly expressed its intent that verification of the recipient occur prior to delivery: 18 U.S.C. 1716E(b)(3)(B)(ii)(VI) requires package markings apprising Postal Service personnel that a given mailing "may be delivered only to a permitted government agency or business." Hence, "permitted" status must be ascertained as a condition precedent to delivery. Moreover, the exception is available "only" to eligible businesses and government agencies. 18 U.S.C. 1716E(b)(3)(A). The exception therefore may not be used to justify a mailing to or from an ineligible entity, regardless of whether the entity is the subject of a pending application. Because eligibility is not determined until it is determined, the presumption must necessarily be that a mailing is ineligible until demonstrated to be eligible, not the other way around. Moreover, the Postal Service is mindful that the Business/Regulatory Purposes exception is carved out from the general rule that ENDS products "shall not be deposited in or carried through the mails." *Id.* at (a)(1). As such, the narrow construction typically due exceptions, discussed in the preceding section, militates against a liberal presumption of eligibility on the sheer basis of a mailer's self-certification or payment of a bond. Even if such a presumption were not inconsistent with the statute, the Postal Service would decline to adopt it as a policy matter, given the undue opportunity for abuse that it would present.

The same commenters urged the Postal Service to streamline or eliminate the process for updates to approved applications, which, the commenters argued, should not require a further application and approval process. The requirements for approval of updated applications were set forth and explained in the Postal Service's 2010 final rule implementing the PACT Act. As the Postal Service explained then, the PACT Act charges the Postal Service with verifying the eligibility of senders and addressees pursuant to the Business/Regulatory Purposes exception, and so mailers must be responsible for maintaining the accuracy of all information in their applications and await verification of eligibility before any mailing may be treated as permissible under the exception. 76 FR at 29666.

Indeed, an update may be just as substantive as the original application (*e.g.*, the addition of parties or products), and it may materially change circumstances relevant to mailability. Even updates to a single entry on the form can be material: A change of address could be legitimate or used to mask an ineligible party; "legally operating" status can hinge on rescission or extension of a permit; and a change in product composition may change its status vis-à-vis controlled-substance or hazardous-materials rules. Vetting only an initial application but not updates to it would invite efforts to evade review through overreliance on unreviewed updates, in violation of both the letter and the spirit of 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II).

Nothing about the statutory verification requirement has changed since 2010, and so there is no basis to rethink the need to verify updated applications. That said, as noted earlier, the Postal Service will undertake to explore possibilities for streamlining the application process, including updates to applications, through automation and digitization.

Some pro-ENDS commenters opined that the centralized application process imposes red tape that favors large industry actors and poses undue obstacles to smaller businesses. While

[19] Moreover, it is difficult to see how the proposal to delay effectiveness until applications can be approved would work in practice. The Postal Service cannot predict how many applications it will receive, their timing and pacing, or their extensiveness, and so it cannot predict how long it will take to process even an initial batch of applications.

the Postal Service is sympathetic to the challenges faced by small and medium-sized enterprises, Congress has mandated that use of the Business/Regulatory Purposes exception be conditioned on Postal Service verification of eligibility. The PACT Act's verification requirements apply to all entities sending or receiving items under the exception, without distinction as to size. The Postal Service considers the alternative to centralized verification—verification at the point of acceptance and delivery of each mailing—to pose similar obstacles in terms of paperwork burden, as the sender or recipient would still need to compile and present the same license, permit, and other documentation to demonstrate eligibility. The only difference would be that the sender and recipient would have to do so for each and every mailing, rather than on a less frequent basis under the centralized process. It is difficult to see how the decentralized-verification alternative would be superior in terms of reducing administrative burden for small and medium-sized enterprises, given Congress's requirement of eligibility verification in all cases. That said, smaller businesses may benefit from proportionally faster processing times (within the bounds of application processing as discussed later in this section), to the extent that their applications involve fewer parties and products than those of larger businesses.

Two ENDS industry commenters suggested that the Postal Service provide a checklist for applicant documentation. Simultaneously to the final rule, the Postal Service is issuing a distinct version of its application form to account for ENDS products. The amended form will include detailed instructions and documentation requirements, as well as supporting worksheets.

Two ENDS industry commenters requested that the Postal Service confirm that it would process applications on a "first in, first out" (FIFO) basis, in the interest of equal treatment for all businesses. The PCSC generally uses a FIFO system for each stage of application processing, although the precise sequencing of application processing may be complicated somewhat by the expanded distribution of workload discussed earlier in this section.[20] It is certainly not the case that applications will be prioritized according to business size, industry reputation, or other applicant-specific circumstances.

State and local attorneys general proposed that the Postal Service share applications with State and local law enforcement officials to spread out the investigative workload. The Postal Service appreciates the suggestion and is willing to consider possibilities for enhancing application processing via intergovernmental and/or interagency information-sharing, subject to feasibility, appropriate protections for third-party information, and other pertinent conditions. The Postal Service regards such intergovernmental cooperation as part of what should be the normal administration of the PACT Act, see 18 U.S.C. 1716E(g), and looks forward to further dialogue with partners outside of the ambit of this rulemaking.

State and local attorneys general also proposed that the Postal Service use State and local governments' lists of licensees to verify eligibility. This suggestion is facially reasonable, but the Postal Service is unaware of any consolidated data source that would enable efficient and fair incorporation of such a resource into the application review process. Here, too, the Postal Service welcomes further dialogue with its intergovernmental partners about potential enhancements to PACT Act administration.

4. Documentation of Legally Operating Status

To support verification of eligibility as legally operating under 18 U.S.C. 1716E(b)(3)(A) and (b)(3)(B)(ii)(I), preexisting Publication 52 section 472.221.a required an applicant to submit information about its legal status, any applicable licenses, and authority under which it operates; information about the legal status, any applicable licenses, and operational authority for all entities to which the applicant's mailings under the exception would be addressed; and all locations where mail containing cigarettes and smokeless tobacco would be presented.

Some ENDS industry stakeholders expressed concern that the documentation requirements were geared exclusively toward tobacco licensing and would prejudice mailers of non-nicotine-related ENDS products. This concern is unfounded. Nothing in either 18 U.S.C. 1716E(b)(3)(A) or Publication 52 section 472.221.a is specific to tobacco or nicotine licensing. Instead, the statute conditions eligibility on the sender and recipient having "all *applicable* State and Federal Government licenses or permits": In other words, any license or permits that entitle the sender or recipient to engage in business activities relating to the product being shipped, whatever that product may be. 18 U.S.C. 1716E(b)(3)(A) (emphasis added). Similarly, Publication 52 section 472.221.a frames the documentation requirements solely in terms of licenses, permits, and authority, without specific reference to tobacco or nicotine or to documentation used exclusively with tobacco or nicotine. The existing language therefore requires no change to accommodate licensing, permit, or other documentation that may demonstrate legal authority to engage in business dealings concerning any or all types of ENDS products relevant to a shipment.

Insofar as the concern may pertain to a separate phrase in 18 U.S.C. 1716E(b)(3)(A)—"engaged in tobacco product manufacturing [or other specified types of business activity]"—it is evident that Congress used "tobacco product" in the PACT Act as a catch-all term encompassing all PACT Act-covered products, regardless of actual tobacco content. See 86 FR at 10219. To be sure, the phrase's import was clearer prior to POSECCA, when all PACT Act-covered products were derived from tobacco. But even after POSECCA's inclusion of non-tobacco-related ENDS products, see *supra* section III.D.1, the intent remains sufficiently clear. Given the thorough reliance on "tobacco product" throughout the PACT Act, construing the somewhat antiquated phrase literally as covering only bona fide tobacco-derived products and excluding non-tobacco-based ENDS products would vitiate the very language whereby Congress has now subjected to the PACT Act ENDS products related to delivery of any "substance," including non-tobacco-derived substances. Indeed, the POSECCA places ENDS products within the definition of "cigarette;" however linguistically awkward this may be, it is evident that "cigarette" is now a term of art signaling the PACT Act's application to both tobacco and non-tobacco products. It is reasonable to extend the same understanding to "tobacco product," within which "cigarettes" are subsumed. Thus, the only reasonable construction faithful to the POSECCA's text and intent is to treat "tobacco product" not as a term of limitation, but

[20] For example, if multiple analysts are conducting initial review of a batch of applications received on the same day, a later-filed application may advance in the review queue before an earlier-filed one that is still being reviewed by a different analyst. It would remain the case that any given reviewer will operate on a FIFO basis, however.

rather as a catch-all term encompassing all products subject to the PACT Act.[21]

In any event, the instance of "tobacco product" in 18 U.S.C. 1716E(b)(3)(A) cabins only the activity-based classes of entities eligible for the exception, and not the nature of the licenses or permits under which they may operate. Rather, licenses and permits go to whether the entity—whatever its market and field of activity—is legally operating.[22] As such, a cigarette manufacturer, for example, must have licenses and permits relating to cigarette manufacture, but whether it is legally operating may additionally depend on more general business licensure not specifically related to cigarettes. The same is true of an ENDS-related business. Indeed, the business activity that is the subject of an ENDS-related Business/Regulatory Purposes application may implicate multiple levels of licensure. For example, consider a business engaged in ENDS distribution and applying for the Business/Regulatory Purposes exception in connection with CBD-related products: "All applicable State and Federal Government licenses or permits" bearing on "legally operating" status might include a general operating license, permission to distribute ENDS products, and permission to distribute hemp-derived (*e.g.*, CBD) products, among other things, to the extent that any such licenses are required by applicable State or Federal law.

Certain other ENDS industry commenters inquire about a situation where neither Federal nor State law imposes any particular license or permit requirements on the same of a given ENDS product. The commenters propose that an applicant be permitted to simply cite a State statute allowing general business operations. The Postal Service appreciates the novelty of the situation, which would not have arisen with respect to the comprehensively regulated products previously subject to the PACT Act. As noted earlier, the PACT Act requires verification of all applicable State and Federal Government licenses or permits. If there are no applicable licenses or permits upon which "legally operating" status as to the relevant business activity depends, then that is that. At the very least, however, it seems unlikely that any State's laws would permit an applicant business to operate without a general business license. To the extent that the applicant's relevant business activity is not subject to any other license or permit requirements, then the applicant should be prepared to attest to and document that circumstance, either affirmatively or in response to further PCSC inquiry. Particularly where no other documentation may exist, a government-issued certificate of good standing may be helpful, although not necessarily dispositive. Applicants are reminded that they bear the burden of proof in establishing eligibility to the satisfaction of the PCSC, and applications will likely be processed faster if applicants affirmatively provide robust information about their legal status up front.

It should be noted that the same verification requirements apply with respect to all senders and recipients under the exception, regardless of their status as business actors or government agencies. See 18 U.S.C. 1716E(b)(3)(A), (b)(3)(B)(ii)(I)–(II). At the same time, however, only businesses' eligibility is conditioned upon "legally operating" status as evidenced by licenses and permits, compare *id.* at (b)(3)(A)(i) with *id.* at (b)(3)(A)(ii), and indeed, government agencies are not typically subject to licensure by other governmental bodies. Nevertheless, because the Postal Service is required to verify eligibility for governmental senders and recipients, applicants must provide the Postal Service with sufficient information to determine that the relevant governmental entity is an eligible one, and not merely an ineligible entity using a name identical to or resembling that of a bona fide governmental entity. Such information would include not only the entity's name and address, but also citations to the legal authority under which it operates.[23]

One ENDS business asked about how the documentation requirements would apply to contract research organizations and trade shows. The same principles would apply as discussed earlier in this section: To the extent that lawful operation of a contract research organization or trade show relating to the relevant PACT Act-covered products requires Federal or State licensing or permitting, then copies of such documentation must be included with an application concerning such a party. Again, particularly where other license or permit documentation may not exist, a government-issued certificate of good standing may be helpful, albeit not necessarily dispositive.

It is emphasized that the Postal Service is required not merely to collect Federal and State licenses and permits, but also to verify more broadly that a business is "legally operating" and "engaged in" the relevant business activity. This may require the submission of documentation beyond merely licenses and permits. For example, a university performing research on behalf of ENDS industry participants may need to submit not only copies of relevant licenses and permits, but also grant or contract documentation indicating that the research is within the scope of a legally authorized undertaking.

State and local attorneys general proposed that the Postal Service require applicants to provide information about the products that they intend to ship under the Business/Regulatory Purposes exception. The product suggestion is well-taken, given the various other regulatory and mailability concerns apart from the PACT Act that may pertain to certain ENDS products. The new application form and worksheet incorporate requirements for applicants to provide brand names and descriptions of each product that they intend to ship, as well as additional supporting documentation regarding products that contain lithium batteries, nicotine, THC, or CBD and any other ENDS liquids or solutions.

State and local attorneys general also recommended that applicants be required to certify that they will ship only between authorized persons (*i.e.*, persons whom the Postal Service has verified as eligible). While the concern for attestation is valid, the Postal Service believes that it is already adequately addressed, to the point where attestation at the point of acceptance would be redundant. The Business/Regulatory Purposes application form requires the customer to completely list all intended recipients and to certify as to the entries'

[21] To promote clarity, however, the Postal Service will use a different terminological approach in its regulations. See *infra* section III.J.3.

[22] It is possible that the commenters' concern arises not from the portion of the PACT Act that governs mailability, but from the separate portion that governs delivery sales more generally via modification of the Jenkins Act. See 15 U.S.C. 376a(a)(3)(B) (requiring delivery sellers to comply with "all State, local, tribal, and other laws generally applicable to sales of cigarettes and smokeless tobacco," including "licensing and tax-stamping requirements"). But that provision applies only to "delivery sales" to consumers. See 15 U.S.C. 375(5). Except for intrastate shipments within Alaska and Hawaii, such sales are beyond the scope of the exceptions to the PACT Act's mailing ban, and so they cannot be effectuated through the mails. As such, if the Jenkins Act provision is the basis for the commenters' concern, then it appears to be largely inapposite in this context. As noted in section III.C.3, inquiries about the application of Jenkins Act requirements to delivery-sale-related postal shipments of ENDS products within Alaska and Hawaii should be directed to ATF.

[23] While the Postal Service will retain the preexisting rule permitting waiver, upon request, of application requirements for mailings sent by State or Federal Government agencies, such waivers are not available to business applicants sending to government agencies.

completeness and accuracy. Any materially false or fraudulent statement or omission in the application could subject the applicant to liability under the False Claims Act. See 18 U.S.C. 1001(a). Furthermore, the PACT Act makes clear that the exception does not cover a shipment to an ineligible party, and so a shipment to such a party could subject the shipper to liability under the PACT Act. Moreover, the new rules, like the former rules, require shippers to present their PCSC eligibility determination letter to acceptance personnel for verification of the sender and addressee's eligibility. Here, too, presentment of false or misleading information, or concealment of relevant information, could subject a shipper to False Claims Act liability. As such, there does not appear to be any clear incremental value in adding a redundant attestation at the point of acceptance, let alone such value as might outweigh the administrative costs of doing so.

5. Qualifying Postal Service Products

Several pro-ENDS commenters asked the Postal Service not to limit the use of the Business/Regulatory Purposes exception to shipments via Priority Mail Express with Hold for Pickup service, but rather to allow such shipments via Priority Mail as a more affordable alternative. This concern appears to refer to the PACT Act rules initially implemented in 2010, and not to the current rules. Although Priority Mail Express with Hold for Pickup service was the only combination of services available at the time of original PACT Act implementation in 2010 that could permit the Postal Service to fulfill the PACT Act's age-verification, identity-verification, and tracking requirements, see 75 FR at 29665–29666, the subsequent creation of Adult Signature service enabled the Postal Service to expand the range of available product combinations to Priority Mail Express or Priority Mail with Adult Signature service. See Adult Signature Services, 76 FR 30542 (2011); Publication 52 section 472.222.a. Hence, the Postal Service has long since offered Priority Mail–based options. In this rulemaking, no commenter expressed opposition to the continued availability of Priority Mail Express or Priority Mail with Adult Signature Service for shipments under the Business/Regulatory Purposes exception, and the Postal Service is aware of no reason to restrict such availability in the context of ENDS products.

Upon further consideration, however, it is apparent that Hold for Pickup is now an inferior alternative for fulfilling the PACT Act's verification requirements. Unlike Adult Signature service, Hold for Pickup does not inherently require age or identity verification; rather, personnel must be instructed and expected to identify when a particular Hold for Pickup item requires such verification, based on mailers' compliance with the marking requirement. Because Adult Signature service now provides a more effective means to ensure verification, the Postal Service is discontinuing the option of Priority Mail Express with Hold for Pickup service for mailings under the Business/Regulatory Purposes exception, as well as all other PACT Act exceptions.

6. Methods of Tender

The Postal Service's preexisting PACT Act regulations require Business/Regulatory Purposes shipments to be tendered via a face-to-face transaction with a Postal Service employee, other than through package pickup by a letter carrier. Publication 52 section 472.222.a. A number of ENDS industry commenters asked the Postal Service to reconsider what they characterized as a requirement to tender at a Post Office and to allow Pickup on Demand, package pickup, or business mail acceptance for excepted shipments. Some such commenters noted that the purported requirement is not grounded in the text of the PACT Act.

The commenters misperceive somewhat the import of the face-to-face transaction requirement. For customers using the Business/Regulatory Purposes exception, only Pickup on Demand and package pickup are precluded; nothing in Postal Service regulations prohibits tender at a business mail entry unit or at authorized acceptance locations at a Post Office other than the retail counter, so long as a Postal Service employee accepts the items via an in-person, face-to-face encounter. But see DMM section 503.8.1.3 (requiring tender at a retail counter for customers using Adult Signature service to mail under the Certain Individuals exception). To promote clarity, the final rule includes explicit mentions of retail and/or business mail acceptance locations. The Postal Service hopes that this clarification should help to dispel the commenters' fears of bottlenecks at retail counters.

That said, the Postal Service declines to reconsider the prohibition on Pickup on Demand and package pickup. The centralized application process is intended to streamline the extent of verification that would otherwise be required upon acceptance pursuant to 18 U.S.C. 1716E(b)(3)(B)(ii)(I)–(II), but it cannot supplant acceptance verification entirely. Something must be done to associate the PCSC's determination of eligibility with a given mailing: otherwise, the Postal Service personnel faced with an apparent mailing of a prohibited product have no way to determine its legitimacy, defeating the whole purpose of PCSC verification. For this reason, while a mailer need not submit the entire dossier of eligibility documentation with each mailing, the mailer must at least show a Postal Service employee the PCSC's determination of eligibility, so that the Postal Service can be assured that the package may lawfully be accepted.

Pickup on Demand and package pickup do not provide adequate assurance that the face-to-face interaction necessary to connect PCSC authorization with a given package will occur in all cases. Much of the customer convenience underlying Pickup on Demand and package pickup is in the fact that packages may be left passively for a carrier to pick up *without* the need for in-person interaction. If Pickup on Demand and package pickup services were made available subject to a requirement for face-to-face interaction and verification, then this would raise secondary questions of how a carrier would know when the requirements apply and, more importantly, how the Postal Service could guard against circumvention by customers who do not engage in the requisite request for face-to-face pickup. Moreover, requiring carriers to take the time for face-to-face verification would increase the time required for carriers to service their routes, with negative effects on efficiency and service to other customers.[24] Because allowing Pickup on Demand and package pickup for excepted mailings would diminish the fulfillment of the Postal Service's obligations under both the PACT Act (*i.e.*, verification of eligibility prior to acceptance) and its governing statutes more generally, the Postal Service determines that Pickup on Demand and package pickup remain unacceptable.

7. Delivery Requirements

In addition to ensuring that the addressee is eligible to receive shipments under the Business/Regulatory Purposes exception, the PACT Act requires the Postal Service to ensure (1) that delivery is made only to a verified employee of the addressee; (2) that the receiving employee be verified to be at least the minimum age for

[24] As noted in section III.G.3, the Postal Service is statutorily obligated to pursue economy and efficiency in its operations.

purchase or sale of the relevant products; and (3) that the receiving employee be required to sign for the mailing. 18 U.S.C. 1716E(b)(3)(B)(ii)(II), (VII). Accordingly, the Postal Service's PACT Act regulations have required recipients to show proof of employment status with the addressee business or government agency; to show proof of age; and to sign the return receipt. Publication 52 section 472.223. The Postal Service did not propose to change these requirements.

Some ENDS industry commenters asked that delivery options be expanded from Priority Mail Express with Hold for Pickup service to allow carrier delivery. As discussed in section III.G.5, this request has long since been fulfilled. The Postal Service in 2011 expanded the range of available services to include Priority Mail Express or Priority Mail with Adult Signature service. Unlike Hold for Pickup, which requires a recipient to retrieve a package from a local Post Office, Adult Signature service can be fulfilled by a letter carrier. As such, the Postal Service's longstanding regulations already include carrier delivery options. As also noted in section III.G.5, however, the Postal Service has now determined to discontinue the availability of the Hold for Pickup option; this does not affect the availability of Adult Signature options that are compatible with carrier delivery.

One ENDS industry association recommended that the final rule expressly contemplate a signed letter from an employer as proof of employment. The Postal Service recognizes that the preexisting PACT Act regulations are not specific on this point, and that lay readers may benefit from additional clarity. Therefore, the final rule offers examples of acceptable employment documentation, including an employee identification badge or card, a recent letter on company or agency letterhead attesting to the recipient's employment, or any other documentation that the local postmaster deems to be of comparable reliability. In addition, where delivery is made to a business address, the carrier will be permitted to infer employment status from such factors as the recipient's uniform and presence at a reception desk or retail counter.

Finally, State and local attorneys general asked that the Postal Service bar delivery of shipments under the Business/Regulatory Purposes exception to Post Office Box or private mailbox addresses. The Postal Service declines to do so, for the reasons discussed in section III.G.2.

H. Certain Individuals Exception

As extended to ENDS, this exception allows individual adults to mail a limited number of lightweight packages containing ENDS products for noncommercial purposes. 18 U.S.C. 1716E(b)(4)(A). Some pro-ENDS commenters requested clarification on whether the return of damaged ENDS products to the manufacturer is covered by this exception. By way of clarification, the statute requiring this exception expressly includes the return by an individual of damaged or unacceptable goods to the manufacturer. *Id.* This language is mirrored in Publication 52 section 472.23, which the final rule extends to ENDS.

For additional clarity, the final rule adds language making explicit the permissibility of returning damaged or unacceptable products under this exception. The new language also clarifies the application of the exception's noncommercial-purpose condition to returns of damaged or unacceptable products, in that a product return remains noncommercial so long as any value offered to the sender is limited to the consumer's original outlays for the returned product and the cost of its return. Any additional exchange of value would not merely restore the consumer to their status quo ante; it would be tantamount to a higher-priced sale and thus no longer a noncommercial transfer.

Noting the noncommercial-purpose requirement, some ENDS industry commenters sought clarification regarding whether used disposable ENDS products, which they claim have no commercial value and are similar to damaged products, would be included as "damaged or unacceptable" goods under this exception if returned to manufacturers or other businesses for recycling.

The Certain Individuals exception allows shipments by individuals regardless of the type of recipient or the specific reason for mailing (subject to various limitations, including the noncommercial-purpose condition). Although the statute expressly lists the return of damaged or unacceptable products as an example, the use of "including" before this statutory phrase makes clear that it is merely illustrative, not exhaustive.

As noted earlier in this section, the Certain Individuals exception does contain a requirement that the mailing be "for noncommercial purposes." *Id.* As the commenters maintain, the depleted merchandise is effectively scrap with no intrinsic commercial value to the consumer. Thus, this exception permits the mailing of used ENDS products for recycling purposes only so long as no net commercial value, such as a rebate, credit, or discount on future purchases, is offered to the mailer in exchange for the used or depleted merchandise. This clarification is reflected in new language expressly discussing the possibility of recycling-oriented shipments under this exception. It is possible that some arrangements involving the recycling of used merchandise might not constitute a commercial exchange and therefore might be permissible under the Certain Individuals exception, such as where the merchandise is merely loaned to an individual user subject to a deposit payment that is refundable upon return of the material. Persons seeking guidance about whether a particular program would constitute a legitimate use of the Certain Individuals exception are encouraged to seek a mailability ruling pursuant to Publication 52 part 215.

One commenter reasoned that, because the return of damaged or unacceptable goods to the manufacturer is expressly allowed under this exception, the manufacturer should be allowed to use the exception to mail warranty replacement goods to adult consumers. However, the Certain Individuals exception provides only for adult "individuals" to mail ENDS for "noncommercial purposes." *Id.* The exception thus does not authorize shipments by businesses (or other organizational entities) for any purpose, not even to fulfill a repair or replacement triggered by a consumer's use of the exception. Nor does any other PACT Act exception permit business-to-individual mailings for such purposes.

A Federal agency partner inquired whether the availability of the Certain Individuals exception for products exchanged as gifts could be construed as allowing businesses to distribute free samples, notwithstanding the FDA's general ban on free samples of tobacco products. See 21 CFR 1140.16(d). The Postal Service emphasizes that its mailability regulations, including those administering the PACT Act, do not supersede any other applicable regulation that might restrict or prohibit a given transfer, distribution, or other activity effected through the mails. See Publication 52 part 412 ("The mailer is responsible for ensuring that all Postal Service requirements, as well as all federal and state laws and local ordinances that apply to the shipment of an article of restricted matter, have been met."). That said, as the name indicates, the Certain Individuals exception is not available for any and all noncommercial

shipment of PACT Act-covered products, but rather only for such shipments by individuals. As such, while gifts from one individual to another may be within the exception's scope, it does not permit businesses to distribute free samples to consumers. Nor does any other exception permit promotional samples to consumers.[25]

Some anti-ENDS commenters suggested that this exception should be altogether abolished or disallowed, reasoning in one instance that the return of damaged or unacceptable ENDS products through the mail by individuals unlikely to be aware of hazmat requirements poses health risks to Postal Service employees. As discussed in section III.A.2, absent a legal impediment to its application to ENDS, the Postal Service lacks a delegation of legislative authority to disallow this or any other PACT Act exception on policy grounds.

Moreover, hazardous-materials concerns are already addressed through comprehensive mailing requirements in Publication 52. Those requirements have applied to individual mailers of ENDS products since long before the POSECCA, and they will continue to apply to mailings under the Certain Individuals exception. The hazardous-materials rules will continue to function to protect the health and safety of all who handle the mail. ENDS industry actors are strongly encouraged to promote awareness of all relevant mailing restrictions and requirements, including hazardous-materials rules, among ENDS consumers. See DMM section 601.9.4.1 (advertising, promotional, and sales matter soliciting or inducing the mailing of nonmailable hazardous materials is itself nonmailable).

Some anti-ENDS commenters recommended that mailers using the exception be required to sign a sworn, written statement or provide other verification that the recipient is above the age of 21, as opposed to the oral affirmation required under the preexisting rules and the proposed rule. See Publication 52 section 472.231.d. These commenters purported that such a measure is necessary because underage recipients continue to access mailed products that are putatively nonmailable under the PACT Act.

Such a requirement would be superfluous and unnecessarily burdensome. Age verification is already required at delivery. 18 U.S.C. 1716E(b)(4)(B)(ii)(V)–(VI). By contrast, the mailer is required merely to "affirm that the recipient is not a minor." *Id.* at (b)(4)(B)(ii)(II). To the extent that any minors allegedly continue to receive mailings of products made nonmailable under the PACT Act, the commenters have pointed to no evidence that this is due to a deficiency in administration of the Certain Individuals exception.[26] Therefore, this recommended measure does not appear to address a demonstrable shortcoming in the Certain Individuals exception, let alone to do so in a way that would meaningfully improve compliance.

A coalition of State and local attorneys general urged the Postal Service to impose a host of additional conditions on this exception by reference to their proposals under the Business/Regulatory Purposes exception. Although it was not entirely clear from the comment, the recommended additional conditions presumably include requiring product identification, certification of mailer and recipient eligibility, exclusion of delivery to Post Office Boxes and commercial mail receiving agencies ("CMRAs"), and signature upon delivery. These commenters argued that delivery provisions set out in 15 U.S.C. 376a(b)(4)(ii) should apply because they assert that 18 U.S.C. 1716E(b)(4)(B), supposedly lacking comparably stringent age verification protocols, does not go far enough to prevent illegal deliveries.

As noted in section III.A.2, the Postal Service has no discretion to impose additional conditions that Congress did not specify in 18 U.S.C. 1716E(b)(4)(B). If anything, the contrast with measures that Congress simultaneously adopted through amendments to the Jenkins Act indicates that Congress did not intend for such measures to govern mailability. As such, the final rule maintains the age-verification and delivery requirements set out for this exception in Publication 52 section 472.23.

An industry coalition suggested that the Postal Service allow prepaid mailing labels to be used for this exception, so that consumers would not bear the costs of returns to manufacturers. As explained in section III.G.5, the Postal Service has determined that Adult Signature service permits the fulfillment of the Postal Service's verification responsibilities under the PACT Act. At present, Adult Signature service is not available in conjunction with domestic return services that would allow for the use of prepaid mailing labels in this manner. See DMM ex. 503.1.4.1, .1.4.3; Postal Regulatory Comm'n, Mail Classification Schedule sections 2120.5, 2645.1.1.d (last edited Oct. 3, 2021), available at *https://go.usa.gov/xFmHg.*

I. Consumer Testing and Public Health Exceptions

The Consumer Testing exception allows "legally operating cigarette manufacturer[s]" (and their legally authorized agents) "to mail cigarettes to verified adult smoker[s] solely for consumer testing purposes." 18 U.S.C. 1716E(b)(5)(A). The exception is subject to a number of conditions regarding manufacturer permitting, cigarette quantity, shipment frequency, tax compliance, payments from the manufacturer to recipients (not the other way around), age and identity verification, tracking and delivery confirmation, and recordkeeping, among other things. *Id.* at (b)(5)(A)–(C).

The Public Health exception permits Federal agencies "engaged in the consumer testing of cigarettes for public health purposes" to mail "cigarettes" in the same manner as manufacturers under the Consumer Testing exception,

[25] The Consumer Testing exception does permit the distribution of cigarettes to individual consumers solely for testing purposes, subject to various conditions and, again, only to the extent consistent with applicable laws and regulations. As discussed in section III.I, the Consumer Testing exception does not apply to smokeless tobacco or ENDS products.

[26] The academic literature cited by these commenters is inapt. One cited study purports to present findings about a lack of age verification for postal deliveries of e-cigarettes in 2014 in violation of the PACT Act, but neither the PACT Act nor any age-verification condition on mailing applied to e-cigarettes at that time. See generally Rebecca S. Williams et al., "Electronic Cigarette Sales to Minors Via the Internet," 169 *JAMA Pediatrics* e1563 (2015). The other allegedly relevant article claims that Postal Service letter carriers did not attempt to conduct age verification for deliveries of cigarettes by online businesses (not individuals, such as might be relevant to the Certain Individuals exception). Rebecca S. Williams et al., "Cigarette Sales to Minors Via the Internet: How the Story Has Changed in the Wake of Federal Regulation," 26 *Tobacco Control* 415 (2017). That article focuses on the consumers' interactions with online vendors and the Postal Service. As recipients, of course, consumers' knowledge or behavior is not transparent to the Postal Service; rather, from the Postal Service's perspective, the mailer (here, the internet vendor) is responsible for compliance with mailing requirements. Publication 52 section 212. The article provides no basis to think that the mailers gave the Postal Service (and thus letter carriers) any indication, let alone a reasonable one, to perceive that the contents of their packages might be nonmailable or require age verification. Indeed, the researchers expressly allowed minor test subjects to misrepresent their age and use their parents' drivers' licenses to bypass age-verification questions. Rebecca S. Williams et al., "Cigarette Sales to Minors Via the Internet." Notably, another study cited by the commenters attests that nearly 90 percent of youth access to tobacco products (including ENDS products) occurs via a third-party intermediary (*e.g.*, one who purchased them either lawfully or fraudulently), and not via an attempt by the underage user to order and obtain delivery the products directly. Sherry T. Liu, "Youth Access to Tobacco Products in the United States, 2016–2018," 5 *Tobacco Regulatory Science* 491 (2019).

except that the payment requirement is waived. *Id.* at (b)(6).

As relevant to both exceptions, "consumer testing" is limited to "formal data collection and analysis for the specific purpose of evaluating the product for quality assurance and benchmarking purposes of cigarette brands or sub-brands among existing adult smokers." *Id.* at (b)(5)(D).

In the notice of proposed rulemaking, the Postal Service noted that the use of "cigarettes" in these provisions raises an interpretive question. On the one hand, the POSECCA subsumes ENDS products within the term "cigarettes." 15 U.S.C. 375(7). On the other hand, the exceptions are confined to packages containing "not more than 12 packs of cigarettes (240 cigarettes)"—quantities that denote standard packaging of combustible cigarettes but not ENDS products—and Congress did not amend those provisions to indicate how the quantity limits should apply to ENDS products. 18 U.S.C. 1716E(b)(5)(A)(ii), (C)(ii)(III). The Postal Service tentatively opined that it would be reasonable to construe the lack of accommodation for ENDS products here as rendering the exceptions inapplicable to ENDS products, and the Postal Service invited views and proposed alternative standards from commenters. 86 FR at 10220.

1. Testing by Manufacturers

Public-health commenters generally opposed extending the Consumer Testing exception to ENDS manufacturers. One group of public-health organizations agreed with the notice of proposed rulemaking, in that the wide variety of ENDS packaging and Congressional silence on the matter indicate that Congress did not intend the exception to cover ENDS products. Another public-health organization noted that ENDS products do not have the same degree of standardization as cigarettes: For example, an ENDS pod containing 5 percent nicotine liquid may contain a roughly comparable amount of nicotine to 1–1.5 packs of combustible cigarettes, but more of the combustible cigarettes' nicotine is wasted, and less delivered to the user, due to so-called "sidestream smoke." Moreover, ENDS liquids' sizes and concentrations vary widely. A third such organization raised policy objections regarding the likelihood that ENDS shipments would contain hazardous materials, would promote dangerous product returns under the Certain Individuals exception, and would pose difficulties in policing companies' representations about bona fide consumer testing.

On the other hand, one public-health organization, two law students, and certain ENDS industry commenters advocated for making the exception available to ENDS manufacturers. ENDS industry commenters relied on the POSECCA's inclusion of ENDS products within the term "cigarette," concluding that ENDS products' entitlement to the exception must precede construction of the quantity condition, rather than the other way around. One such commenter, after repeating its general view that Congress did not intend to make ENDS products nonmailable, pointed out that consumer testing is necessary for ENDS manufacturers to fulfill requirements for FDA authorization. These and other commenters proposed various approaches to the quantity condition:

- *Nicotine-content equivalency:* Limit liquids to 12 units or cartridges, as the purported equivalent to 12 packs of cigarettes (based on the assumption that one 5 percent–nicotine ENDS pod equals one pack of cigarettes); either no limit on devices, or limit devices to the amount necessary to enable the use of that quantity of liquid.
- *Nicotine-consumption equivalency:* The quantity needed to supply the average user for the same period as 240 cigarettes. For example, if the average smoker consumes 14 cigarettes per day, then 240 cigarettes equates to 17 days of average consumption.[27] According to this commenter, most human studies of CBD use dosages ranging between 20 and 1,500 milligrams per day.[28] Thus, a median dosage of 740 milligrams per day would translate into 12,580 milligrams for 17 days.
- *Weight limit:* 5 pounds.
- *Package limit:* One package, regardless of contents, as the Postal Service allegedly cannot investigate the contents of shipments anyway; defer to FDA as to limits of consumer tests themselves.
- *Size limit:* Package dimensions equivalent to a package containing 12 packs of combustible cigarettes. This commenter submitted that one pack is typically 3.5 inches by 2.25 inches by 0.88 inch, for a volume of 6.93 cubic inches, hence 12 packs would be 83.16 cubic inches. The commenter noted that these external characteristics are objective and observable, thereby averting the need to open a package and inspect contents.
- *To be determined:* Collaborate with FDA and CDC to devise an appropriate equivalency standard, which may evolve with further data.

The Postal Service appreciates these thoughtful suggestions, which are discussed in greater depth later in this section. Upon further review, however, it is unnecessary to evaluate the suitability of a quantity standard for ENDS products in connection with the Consumer Testing exception. Beyond the interpretive difficulties posed by the quantity limit, Congress has provided at least two other indications of legislative intent that the Consumer Testing exception applies only to combustible cigarettes and not to ENDS products, notwithstanding their technical inclusion within the term "cigarette" generally. After all, even statutorily defined terms can give way where context indicates that Congress intended a different meaning. See, *e.g., Int'l Primate Prot. League* v. *Adm'rs of Tulane Educ. Fund,* 500 U.S. 72, 80, 83 (1991); *In re Korean Air Lines Co.,* 642 F.3d 685, 692–93 (9th Cir. 2011).

First, the exception is available only to "cigarette manufacturer[s]" with a permit "issued under section 5713 of the Internal Revenue Code of 1986." *Id.* at (b)(5)(A)(i). The only entities eligible for such permits are manufacturers and importers of cigars, cigarettes, smokeless tobacco, pipe tobacco, and roll-your-own tobacco, with "cigarette" restricted here to rolls of tobacco wrapped in paper or another substance. 26 U.S.C. 5702(b)–(c), 5713(a). This definition does not describe ENDS products, and so manufacturers of ENDS products are not subject to the Internal Revenue Code section 5713 permit requirement. Accordingly, ENDS manufacturers are not within the ambit of manufacturers eligible to use the mails under the Consumer Testing exception. Here, too, the POSECCA contains no amendment expanding the scope of eligible manufacturers to cover ENDS.

Second, the exception refers repeatedly to cigarettes in connection with a "smoker." 18 U.S.C. 1716E(b)(5)(A), (b)(5)(C)(ii)(II)(aa), (b)(5)(D)(ii). This language clearly denotes combustion, rather than the sub-combustion-level heating that occurs in most ENDS products.[29] The

[27] See CDC, Press Release, Smoking Is Down, But Almost 38 Million American Adults Still Smoke, Jan. 18, 2018, *https://go.usa.gov/x6qSt* (2016 data).

[28] Sian Ferguson, "CBD Dosage: Figuring Out How Much to Take," *Healthline,* Aug. 1, 2019, *https://www.healthline.com/health/cbd-dosage.*

[29] "E-cigarettes purportedly do not produce a combusted smoke; rather, they deliver an aerosol containing nicotine and other tobacco-related compounds." Megan J. Schroeder & Allison C. Hoffman, "Electronic Cigarettes and Nicotine Clinical Pharmacology," 23 *Tobacco Control* ii30 (2014), *https://tobaccocontrol.bmj.com/content/tobaccocontrol/23/suppl_2/ii30.full.pdf.* "Smoking" and "vaping" are frequently placed in opposition to one another in popular discourse. See, *e.g.,* Julia Savacool, "Vaping Vs. Smoking: Is One Better for

POSECCA contains no amendment that expands the term "smoker" to encompass the manner in which ENDS products are consumed.

It should be noted that the Consumer Testing exception is unique among the PACT Act's exceptions in that it pertains specifically to "cigarettes" and not to the full range of "mailings" or "tobacco products" covered by the PACT Act. Compare *id.* at (b)(2)–(4) with *id.* at (b)(5). Prior to the POSECCA, it was therefore clear that the Consumer Testing exception was confined to combustible cigarettes and did not apply to smokeless tobacco. While this history alone might not be relevant if Congress had used broader language in the Consumer Testing exception, Congress's retention of combustible-cigarette-specific conditions in the post-POSECCA Consumer Testing exception shows Congress's continuing intent that the exception apply only to combustible cigarettes, and not to other products that might now be encompassed within the otherwise-applicable statutory definition of "cigarettes."

Against this backdrop regarding Congress's intent to apply the Consumer Testing exception only to combustible cigarettes and not to ENDS products, it is all the more clear that the quantity limit of "12 packs of cigarettes (240 cigarettes)" is intended to govern only combustible cigarettes, in which context such quantities are commonplace, and not ENDS products, which are not so standardized. The language itself suggests this conclusion; the context solidifies it.

While the commenters have proposed a range of original ideas for a potential equivalency standard, the Postal Service finds no occasion to consider application of such a standard here, where Congress's intent to exclude ENDS products from the exception is clear. That decision is buttressed by the fact that no proposed equivalency standard is self-evident or compelling.

Proposals focused on the exterior of the package, rather than its contents, would impose virtually no limit on the amount or type of ENDS products sent in an ostensible consumer testing shipment. This unfettered latitude is far from Congress's design of limiting the quantity of product *within* a package.

Proposals focused on the amount of nicotine fail to account for the multiple layers of variability that complicate such an exercise: The range of nicotine content among combustible cigarettes,[30] the range of nicotine delivered to smokers [31] and users of nicotine-related ENDS products,[32] and the range of nicotine contained in ENDS products, which may contain as little as zero nicotine or be used with a limitless quantity of nicotine-containing solution, and which may vary even within the same brand and batch.[33] The difficulties in comparability are further compounded when considering how to equate combustible cigarettes with ENDS products related to non-nicotine substances, such as CBD.[34] And the ranges of variation increase still further when scaled up from a single cigarette to 240. Thus, it does not appear that an equivalency standard can be readily devised to reliably translate 240 cigarettes into some comparable number of ENDS products. The apparent impossibility of shoehorning ENDS products into the 240-cigarette limit underscores the conclusion—already apparent from other conditions of the Consumer Testing exception—that Congress intended this exception to be available only for combustible cigarettes and not for ENDS.

For these reasons, the Postal Service concludes that the PACT Act does not make the Consumer Testing exception available for ENDS products. It should be noted that the Intra-Alaska/Intra-Hawaii exception would permit the mailing of ENDS products for any purpose, including consumer testing, with the only restriction being that the mailing occur entirely within Alaska or Hawaii. Otherwise, barring further legislative change, such activities must employ transportation and delivery methods that do not involve the mails.

2. Testing by Federal Agencies

Two of the public-health organizations that opposed allowing the Consumer Testing exception for ENDS products nonetheless favored allowing the Public Health exception. One such commenter analogized the situation to the restrictions on mailing dangerous goods, which contain exceptions for scientific-use mailings, see 18 U.S.C. 1716(c), (e), and suggested that the Postal Service make the exception available only upon agreement with the relevant Federal agency. Federal agency partners with which the Postal Service consulted also expressed an interest in making the Public Health exception available for ENDS products, in order

Your Lungs? Here's What Experts Say," *Parade*, Feb. 20, 2021, *https://parade.com/1093720/julia-savacool/vaping-vs-smoking;* Scott Roberts Law, "What's the Difference Between Smoking and Vaping?," *Michigan Cannabis Business Blog*, May 14, 2020, *https://scottrobertslaw.com/whats-the-difference-between-smoking-and-vaping;* Nick English, "I Started Vaping to Quit Smoking, and It Was a Huge Mistake," *Men's Health*, Oct. 22, 2018, *https://www.menshealth.com/health/a23937726/vaping-vs-smoking.* Pro-ENDS commenters engaged in the same tendency when touting ENDS use as a beneficial alternative to combustible cigarettes. Two industry associations even styled themselves as promoters of "smoke-free alternatives" and "smoking alternatives."

[30] The nicotine content of combustible cigarettes in the United States has been measured to range from 7.2 to 13.4 mg per cigarette, or about ±30 percent around the mean of 10.2 mg per cigarette. Lynn T. Kozlowski et al., "Filter Ventilation and Nicotine Content of Tobacco in Cigarettes from Canada, the United Kingdom, and the United States," 7 *Tobacco Control* 369, 370 (1998), *https://tobaccocontrol.bmj.com/content/tobaccocontrol/7/4/369.full.pdf;* see also Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 FR 11818, 11826 (2018) (10–14 mg of nicotine per cigarette in the United States, per Kozlowski et al. and others).

[31] One study measured nicotine delivery from the combustible cigarettes surveyed as averaging 1.04 mg ±0.36 mg, or a range of about 35 percent. Neal L. Benowitz & Peyton Jacob III, "Daily Intake of Nicotine During Cigarette Smoking," 35 *Clinical Pharmacology & Therapeutics* 499 (1984), available at *https://ascpt.onlinelibrary.wiley.com/doi/abs/10.1038/clpt.1984.67;* see also 83 FR at 11826 (1.1–1.7 mg nicotine yield per cigarette)). In the Benowitz/Jacob study, cigarette smokers' daily nicotine intake averaged 37.6 mg ±17.7 mg at 1 standard deviation, but ranged overall from 10.5 to 78.6 mg, for a total range of more than ±75 percent around the median.

[32] The amount of nicotine emitted depends on multiple variables: Device power, nicotine concentration, ratio of propylene glycol to vegetable glycerin, and puff duration. Kathleen Stratton et al., Public Health Consequences of E-Cigarettes 92–94 (Nat'l Acads. of Scis., Eng'g, & Med. 2018), *https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf;* Soha Talih et al., "Transport Phenomena Governing Nicotine Emissions from Electronic Cigarettes: Model Formulation and Experimental Investigation," 51 *Aerosol Sci. & Tech.* 1, 8–13 (2016); Ivan Gene Gillman et al., "Effect of Variable Power Levels on the Yield of Total Aerosol Mass and Formation of Aldehydes in E-Cigarette Aerosols," 75 *Reg. Toxicology & Pharmacology* 58, 60 (2016); Maciej L. Goniewicz et al., "Nicotine Content of Electronic Cigarettes, Its Release in Vapour and Its Consistency Across Batches: Regulatory Implications," 109 *Addiction* 500, 503 (2014). Although Gillman et al. describe the amount of total aerosol produced, the same percent range should apply to the amount of nicotine aerosolized, given the homogeneity of constituents throughout a solution. Variability in nicotine delivered by ENDS does not end with nicotine emitted, however; the amount delivered to a user's bloodstream also depends on user- and product-specific factors. See generally Schroeder & Hoffman, "Electronic Cigarettes and Nicotine Clinical Pharmacology."

[33] Stratton et al., Public Health Consequences of E-Cigarettes 89–92; Goniewicz et al., "Nicotine Content of Electronic Cigarettes," 109 *Addiction* at 502.

[34] With respect to the proposal to equate CBD to combustible cigarettes based on daily use, even the CBD-dosage figures provided by the commenter present a range that is so wide (20–1,500 mg/day) as to render the commenter's focus on the average essentially meaningless. Moreover, the scholarly article referenced in the commenter's popular source does not discuss whether these dosages are representative of therapeutic practice; rather, they are characterized only as quantities that have been shown to be tolerated by humans from a safety perspective. Kerstin Iffland & Franjo Grotenhermen, "An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies," 2 *Cannabis & Cannabinoid Research* 139, 140 (2017), *https://go.usa.gov/x6cWG,* cited in Ferguson, "CBD Dosage."

for them to carry out testing activities that they consider necessary for effective regulation. Law-student commenters asserted that Congress likely intended to permit continued Federal testing of ENDS products for public-health regulation, which one such commenter submitted is unlikely to contribute materially to youth-access and other policy concerns that motivated the POSECCA and the PACT Act. Although ENDS industry commenters did not express views specifically about the Public Health exception, the linkage between the Public Health and Consumer Testing exceptions suggests that such commenters' views on the availability of the Consumer Testing exception would likewise carry over to the Public Health exception.

The Postal Service reiterates that it must be guided by the parameters and policy decisions expressed in the statute; Congress did not authorize the Postal Service to make its own policy decisions about whether any exception, including the Public Health exception, ought to be extended to ENDS products. Particularly given that lack of policy discretion, the Postal Service is not at liberty to speculate about what Congress might have intended regarding public-health testing of ENDS products by Federal regulatory agencies, in the absence of any statutory language or legislative history clearly addressing the question.

Like the Consumer Testing exception, the statutory language establishing the Public Health exception, which Congress likewise did not amend in the POSECCA, makes clear that the exception applies only to combustible cigarettes and not to ENDS products.

First, the Public Health exception repeatedly uses the term "consumer testing," a defined term restricted to testing involving "smokers." 18 U.S.C. 1716(b)(5)(D)(ii), (b)(6). As discussed in the preceding section, the plain meaning of "smoker" indicates that the context is combustible cigarettes, not ENDS products.

Second, the Public Health exception allows Federal agencies to "mail cigarettes under most of the same requirements, restrictions, and rules and procedures that apply to consumer testing mailings of cigarettes by manufacturers under" the Consumer Testing exception. *Id.* at (b)(6).[35] Among those applicable requirements is that the entity mailing any shipments verify "that the recipient is an adult established smoker": a term that, again, indicates application only to combustible cigarettes and not to ENDS products. *Id.* at (b)(5)(C)(ii)(II)(aa).

Third, the quantity limit discussed in the preceding section also governs the Public Health exception in the same manner as the Consumer Testing exception. As discussed in the preceding section, the quantity limit reinforces the conclusion that only combustible cigarettes, and not ENDS products, are amenable to these exceptions.

Given these clear indications of Congressional intent and the Postal Service's general lack of statutory authority over the scope of PACT Act exceptions, the Postal Service finds no basis to treat the two exceptions as differing in scope due to policy reasons that were not expressed by Congress.[36] It may be that Federal regulatory agencies, like manufacturers, will continue to conduct consumer testing without using the mails, or via use of the mails only within Alaska and Hawaii (as permitted by the Intra-Alaska/Intra-Hawaii exception). To the extent that Federal agencies find those options to be insufficient, then Congress, not the Postal Service, is the appropriate outlet for policy concerns regarding this statutory scheme.

3. Testing by Public-Health Researchers

Certain public-health-oriented commenters urged the Postal Service to permit the mailing of ENDS products from independent researchers or research organizations—not manufacturers or Federal agencies—to individuals for purposes of federally-funded public health research.

As explained in section III.A.1, the Postal Service lacks statutory authority to create new exceptions. Congress provided narrow exceptions for consumer testing only by manufacturers and Federal agencies, and not by any other entity. Moreover, as explained in the preceding two sections, even those exceptions do not cover ENDS products. Therefore, other than mailings entirely within Alaska and Hawaii (as authorized by the Intra-Alaska/Intra-Hawaii exception), researchers must find ways to conduct their consumer testing that do not involve use of the mails. To the extent that a policy case can be made for this use of the mails, that case should be directed to Congress, which has reserved to itself the discretion to modify or augment the PACT Act's exceptions.

J. Other Issues

1. International, Military, and Diplomatic Mail

Except for the Intra-Alaska/Intra-Hawaii exception, the PACT Act's exceptions are not expressly confined to domestic mail. As the Postal Service explained in the 2010 rulemaking concerning PACT Act implementation, however, the complex verification requirements for the PACT Act's exceptions, combined with the strict consequences of any noncompliance, render it impracticable, if not impossible, for these requirements to be fulfilled as to mail originating or destinating outside of the United States. 75 FR at 29665; 75 FR at 24535. In the notice of proposed rulemaking, the Postal Service proposed to maintain the same approach to the exceptions in the context of ENDS products, except potentially with respect to any products that may eventually be covered by the tobacco-cessation/therapeutic exclusion. 86 FR at 10219.

One group of public-health-oriented commenters applauded the disallowance of exceptions for international mail and the extension of that policy to ENDS products. Contrariwise, one ENDS manufacturer asserted that the policy violates the statute, which, according to the commenter, frames the exceptions in terms that provide an affirmative entitlement to mail without restriction to domestic mail. The commenter noted that the Business/Regulatory Purposes exception expressly encompasses businesses involved in "export" and "import," see 18 U.S.C. 1716E(b)(3)(A)(i), and opined that the statutory conditions for each exception

[35] One requirement is specifically excepted in the statute. Moreover, it is also reasonable to construe the Internal Revenue Code permit requirement as inapplicable to Federal regulatory agencies, given Congress's clear intent that they be eligible to mail under the Public Health exception notwithstanding their ineligibility for such permits.

[36] Regarding one commenter's comparison to 18 U.S.C. 1716(c)–(e) as a suggested basis for decoupling the Consumer Testing and Public Health exceptions vis-à-vis their applicability to ENDS products, the comparison is inapt. First, that statute is distinct from the PACT Act, which expressly provides that the same requirements apply to activities conducted under the Consumer Testing and Public Health exceptions. Second, 18 U.S.C. 1716(c)–(e) expressly confer discretion upon the Postal Service over the mailability of dangerous items for scientific purposes; the PACT Act does not provide such discretion. Third, 18 U.S.C. 1716(c)–(e) do not concern the mailing of otherwise nonmailable items to individuals, as the Consumer Testing and Public Health exceptions do; rather, the mailings covered by those provisions are more analogous to mailings under the PACT Act's Business/Regulatory Purposes exception. See 18 U.S.C. 1716(c) (shipments of live scorpions "to be used for purposes of medical research or for the manufacture of antivenom"); *id.* at (d) (shipments of poisonous drugs and medicines from manufacturers or dealers to licensed medical professionals); *id.* at (e) (shipments of poisons for scientific use between manufacturers, dealers, laboratories, and Federal, State, or local government agencies).

can be applied to international as well as domestic mail, without any statutory basis for distinction on the basis of feasibility. One Federal agency partner also asked the Postal Service to reconsider the restriction, in the interest of facilitating effective Federal regulation of foreign parties' tobacco and ENDS products.

The final rule maintains the approach outlined in the notice of proposed rulemaking. The issue is not whether the statute expressly addresses international mail or whether it expressly provides for feasibility-based discretion. Rather, the statutory exceptions permit mailing only to the extent that the Postal Service is able to verify certain things about the mailer and/or recipient. See, *e.g.*, *id.* at (b)(3)(B)(ii)(I)–(II), (b)(3)(B)(ii)(VII), (b)(4)(B)(ii)(I)–(II), (b)(4)(B)(ii)(V). In contrast to private-sector delivery carriers' integrated international networks, the Postal Service does not collect or deliver international mail outside of the United States (other than in the Freely Associated States); it must rely on foreign postal operators and other third-party agents to perform acceptance and delivery abroad. Given the specificity of the statutory verification obligations and their lack of extraterritorial applicability to or contemplation of foreign postal operators and agents, the Postal Service is unable to fulfill, and is not confident in its ability to ensure reliable fulfillment of, the verification tasks upon which these exceptions condition mailability. To the extent that the Postal Service cannot ensure verification, then the statute bars exceptional mailability for the relevant class of shipments.

As the industry commenter observes, the Business/Regulatory Purposes exception is available to legally operating businesses "engaged in tobacco product . . . export [and] import." *Id.* at (b)(3)(A)(i). But these descriptors are used only to define the class of businesses that may be eligible to mail to other eligible parties under the exception; it does not, by itself, establish entitlement to use the mails for export and import activities. Thus, upon fulfilling all of the conditions for the exception, an export business could receive ENDS products from a domestic manufacturer or wholesaler, for example, and an import business could send ENDS products to domestic wholesalers and distributors. To the extent that the Postal Service can verify all required facts about these senders and recipients, their shipments are mailable under the exception. But because the Postal Service cannot conduct the statutorily required verification for overseas parties, the exporter's exports and importer's imports cannot themselves qualify for use of the mails. Those legs of the products' journey must be accomplished through commercial export and import channels, not through the international mail channel.

In response to the Federal agency partner's concern regarding effective regulation, the Postal Service is sympathetic to this policy interest. Again, however, Congress has imposed verification conditions for use of the mails that the Postal Service is unable to fulfill with respect to international shipments. Non-postal delivery channels may be available to facilitate the transfer of samples and covered items between foreign businesses and U.S. regulators. To the extent that use of the mails would be necessary or expedient to effective regulation, it is for Congress to weigh whether that policy interest warrants relaxation of the PACT Act's verification mandates, creation of a new exception, or some other legislative accommodation.

Certain pro-ENDS commenters urged the Postal Service to ensure that ENDS products will be mailable to U.S. military service members overseas on the same terms as cigarettes and smokeless tobacco. As stated in the notice of proposed rulemaking, the PACT Act exceptions have long been inapplicable to "mail *presented at* overseas Army Post Office (APO), Fleet Post Office (FPO), or Diplomatic Post Office (DPO) locations and destined to addresses in the United States." 86 FR at 10219 (emphasis added). This is because these overseas acceptance locations are operated not by the Postal Service, but by the Department of Defense's Military Postal Service Agency (MPSA) and by the Department of State. Although U.S. postal laws and regulations apply to U.S. mail operations in these locations, it was determined that the acceptance conditions for the PACT Act's exceptions cannot reliably be fulfilled at these overseas sites.

Upon further review and interagency consultation, it appears that the same is true for the PACT Act exceptions' requirements of age, employment, and identity verification at the place of delivery. See 18 U.S.C. 1716E(b)(3)(B)(ii)(II), (b)(3)(B)(ii)(VII), (b)(4)(B)(ii)(V),[37] (b)(5)(C)(ii)(VI)–(VII). The postal services that enable fulfillment of these requirements—Adult Signature Required and Adult Signature Restricted Delivery—are not currently available for items sent to APO/FPO/DPO addresses. Because the verification requirements cannot reliably be fulfilled upon delivery to APO/FPO/DPO addressees, shipments to such addressees are incompatible with the statutory criteria for the exceptions.

[37] Under the Certain Individuals exception, the Postal Service is not itself required to perform the age verification, so long as it duly transfers the items to MPSA. 18 U.S.C. 1716E(b)(4)(B)(ii)(VI). However, the age-verification requirement remains, pursuant to a standalone condition that MPSA would be obliged to fulfill. *Id.* at (b)(4)(B)(ii)(V).

2. Reasonable Cause

The PACT Act bars the acceptance or transmission of mailed packages as to which the Postal Service "knows or has reasonable cause to believe contains" matter made nonmailable by the PACT Act. 18 U.S.C. 1716E(a)(1). "Reasonable cause" can be based upon certain public statements of intent to mail nonmailable items or the presence of a person on the Noncompliant List. *Id.* at (a)(2). Under the Postal Service's longstanding PACT Act regulations, the presence of reasonable cause imposes on the mailer a burden of establishing eligibility to mail. Publication 52 section 472.1.

In the notice of proposed rulemaking, the Postal Service noted that the statute's use of "includes" before these enumerations of "reasonable cause" plainly indicates that the list is illustrative, rather than exhaustive, and the Postal Service proposed to make explicit in its regulations the possibility that other indicia regarding a package, individually or in combination with other packages, may give rise to reasonable cause. 86 FR at 10219. In the highly circumstantial context of ENDS products, the Postal Service further proposed to elaborate on the burden-shifting principle by calling for affirmative, credible, and verifiable indications of mailability in order to dispel the presumed nonmailability of such products. *Id.* at 10219–10220.

Some anti-ENDS commenters expressed general support for these changes, and no party expressed opposition. Therefore, the Postal Service adopts the proposed changes in this final rule.

State and local attorneys general, a public-health organization, and a law student proposed enumerating additional bases for identifying parties whose association with a package may give rise to reasonable cause:

- Identification of a party in scientific journal articles about ENDS products;
- Involvement of an ENDS manufacturer or distributor in litigation;
- Public statements on social media;
- Other media sources;

- The presence of markings on a package pursuant to section 2A(b)(1) of the Jenkins Act;
- Lists of entities licensed by a State or local government to engage in tobacco or ENDS industry activities;
- The use of a Post Office Box or CMRA; and
- A mailer's past practice of sending or receiving items made nonmailable under the PACT Act.

The Postal Service finds it unnecessary to incorporate these suggestions into the final rules. Statements in social media and other media are covered by 18 U.S.C. 1716E(a)(2)(A) and existing Publication 52 section 472.1(a). Information on a mailpiece (*e.g.*, Jenkins Act markings and address information) would be among the indicia taken into account under the new provision. So, too, would a mailer's past practices, insofar as the new provision accounts for information about a mailing "in combination with other packages."

Because the list of "reasonable cause" indicia in Publication 52 section 472.1 is merely illustrative, the other proposed information sources remain potentially available, even if they are not expressly enumerated. To the extent that any relevant information not only exists at large, but is brought to the actual attention of Postal Service personnel authorized to determine how to interpret and act upon that information, then that awareness may reasonably justify the Postal Service's treatment of associated mailings as nonmailable, absent contrary information sufficient to dispel reasonable cause.

One law-student commenter expressed concern that the Noncompliant List may be unreliable, given the purported ease with which listed actors could rebrand or establish a new address. The Postal Service is not responsible for maintaining the Noncompliant List. However, it should be noted that section 2A(e)(1)(C) of the Jenkins Act directs the Attorney General to update and distribute the Noncompliant List at least once every four months, and related provisions require the Attorney General to include entities identified by State, local, and Tribal governments and to maintain the accuracy and completeness of the list. Moreover, no provision bars other parties from identifying inaccuracies or suggesting updates to the Attorney General.

State and local attorneys general requested a point of contact for non-Postal-Service law-enforcement actors, the industry, and the general public to report suspicious mailing behavior. The Postal Inspection Service (*https://www.uspis.gov*) is the law-enforcement component of the Postal Service, and suspicious mailing behavior may be reported through the Postal Inspection Service hotline (1–877–876–2455). Mailing addresses for local Postal Inspection Service division offices can be found at *https://postalpro.usps.com/ppro-tools/inspection-service*.

One law-student commenter encouraged the Postal Service to ensure that relevant personnel are trained and given up-to-date information about the Noncompliant List and market research on ENDS mailers. The Postal Service has internal processes to communicate such information to relevant personnel, and it will take this comment under advisement in administering those internal communications.

Another law-student commenter proposed that a suspected ENDS mailer be required to furnish a sworn certification of mailability, punishable by a fine. The Postal Service finds such a measure to be unnecessary. Under the reasonable cause standard, mailability is based on indicia of suspicion—a collection of facts indicating for and against mailability—weighed in the administrative and law-enforcement discretion of Postal Service personnel. It is difficult to conceive of why facts tending in one direction should require the submission of paperwork when other facts would not. Moreover, the making of materially false statements or representations to the Postal Service is punishable under 18 U.S.C. 1001, regardless of whether the person has made a sworn declaration or received specific notice of potential punishment. As such, the Postal Service does not perceive any practical benefit that would arise from this suggestion.

3. Terminology

In the notice of proposed rulemaking, the Postal Service discussed the semantic difficulties posed by the POSECCA's technical inclusion of ENDS within the relevant statutory definition of "cigarettes." 86 FR at 10219. While this has a pronounced legal effect—generally subjecting ENDS to the same legal treatment as combustible cigarettes—there are clear differences in the two types of products, particularly given the broad scope of POSECCA-covered ENDS products. Hence, using the term "cigarette" in Publication 52 to denote ENDS products as well as combustible cigarettes might not offer sufficient clarity to a lay reader. The Postal Service proposed to use "tobacco products" as a catch-all term to encompass combustible cigarettes, smokeless tobacco, and ENDS products, due to Congress's use of that term in the PACT Act (and the lack of any amendment to that usage in the POSECCA). In doing so, the Postal Service acknowledged that even "tobacco products" is imperfect as applied to ENDS products, many of which do not derive from tobacco, and solicited commenters' suggestions.

Commenters presented various views, often independent of their position on ENDS products generally. Some commenters accepted and even agreed with "tobacco products" as a catch-all term, noting that at least some ENDS liquids contain tobacco-derived nicotine and that Congress intended ENDS to be regulated in the same manner as cigarettes and smokeless tobacco. Others supported a slightly disaggregated catch-all term, such as "tobacco and vapor products," "cigarettes and alternative tobacco products," "nicotine products and delivery devices," or "tobacco and nicotine-related delivery products." Still other commenters opposed the use of a catch-all term, but rather proposed a continued serial listing ("cigarettes, ENDS, and smokeless tobacco"). This last group opposed the use of an umbrella term for various reasons: ENDS products might not be thought of as "tobacco products;" "tobacco products" is a term with special significance but a different scope in other legal contexts; and ENDS products should not be equated with cigarettes due to purported differences in their level of harmfulness.

Upon consideration of these views, the Postal Service agrees that the umbrella term "tobacco products," while consistent with statutory usage, might pose an undue risk of misleading lay readers of the regulations. Notwithstanding the post-POSECCA PACT Act's continued use of "tobacco products" as an apparent (albeit undefined) umbrella term, catch-all terms relying on "tobacco" or "nicotine" do not adequately capture the wide range of ENDS products covered by the POSECCA. Of the proffered options, "tobacco and vapor products" best captures the distinction between cigarettes and smokeless tobacco, on the one hand, and potentially non-nicotine-based ENDS products, on the other hand. Yet even it has its shortcomings: It elides the degree of overlap between the two categories, and the level of generality may sacrifice clarity.

The Postal Service has determined that the well-taken semantic concerns can be avoided through use of the more generic, all-encompassing term "covered products" to refer collectively to cigarettes, smokeless tobacco, and

ENDS products subject to the PACT Act.[38] At the same time, because certain requirements pertain uniquely to ENDS products, the final rule treats ENDS products as a standalone category of covered products, rather than subsuming them within the definition of "cigarette" as the POSECCA does. Although this terminological approach differs formally from the statutory framework, the Postal Service is confident that its regulations yield the same functional result. To the extent of any inadvertent conflict, however, the statute would naturally control.

4. Communications

Three ENDS industry commenters asked the Postal Service to issue an updated Field Information Kit regarding the mailability of ENDS products, similar to the ones that it issued upon implementing the original and earlier amended PACT Act. See Postal Service, Field Information Kit: PACT Act, Postal Bulletin No. 22,287, June 17, 2010, at 3–17, *https://about.usps.com/postal-bulletin/2010/pb22287/pdf/pb22287.pdf;* Postal Service, Field Information Kit: PACT Act, Postal Bulletin No. 22,292, Aug. 26, 2010, at 3–18, *https://about.usps.com/postal-bulletin/2010/pb22292/pdf/pb22292.pdf.* One law student also recommended that the Postal Service set up web pages to educate the public about the new requirements, as well as trainings for employees.

In conjunction with this **Federal Register** notice, the Postal Service is issuing a Field Information Kit. Like its 2010 counterparts, the Field Information Kit contains training materials and job aids to be distributed to Postal Service employees, as well as background information and frequently asked questions for both employees and the public. The Postal Bulletin is available at *https://about.usps.com/postal-bulletin/2021.*

5. Enforcement

A group of State and local attorneys general asked the Postal Service not to return to sender matter made nonmailable under the PACT Act, but to seize and destroy it instead. These commenters adverted to ongoing litigation that some of them have brought on this issue. See generally *City of New York* v. *U.S. Postal Serv.,* No. 1:19–CV–05934 (E.D.N.Y. filed Oct. 22, 2019). Because this matter is the subject of ongoing litigation, the Postal Service declines to address it at this time.

One ENDS consumer expressed skepticism that the POSECCA will be enforceable, to the extent that vendors send products below the supposed weight threshold for Postal Service enforcement without publicly advertising or marking their product. While it is conceivable that some illegal activity will evade detection in any law-enforcement scheme, each of the commenter's premises is false. First, there is no weight threshold for Postal Service enforcement of mailability; the Postal Service can and does enforce mailability laws regardless of weight, shape, or other mailpiece characteristics. Second, a vendor that does not advertise its sales is unlikely to remain a vendor for long. Third, the presence of identifying markings is not a prerequisite for detection of nonmailable matter; indeed, few shippers of the substantial quantities of nonmailable contraband detected by the Postal Inspection Service and its Federal law-enforcement partners transparently indicate the illicit contents that they are shipping.

Finally, a commercial mailing agent asked for clarification of its duty to enforce the POSECCA and PACT Act and its liability for its customers' mailings. As already provided in Postal Service regulations, all mailers, including mail service providers and mailing agents, must comply with applicable Postal Service laws and regulations governing mailability and preparation for mailing, as well as non-postal laws and regulations on the shipment of particular matter. Publication 52 section 212. In other words, a mail service provider or mailing agent, as a mailer on behalf of a third party, is liable for violations of mailing laws in the same manner as any other mailer. Mail service providers and mailing agents may limit their liability risk by taking robust measures to identify attempts to use their services for unlawful purposes.

6. Availability of Rules' Text

Some commenters urged the Postal Service to make the text of the proposed or new rules available as soon as possible. At the time of the notice of proposed rulemaking, Publication 52 was incorporated by reference in 39 CFR 113.2. As such, the Office of the Federal Register did not permit the text of revisions or proposed revisions to Publication 52 to appear in the attendant **Federal Register** notice. In the interest of transparency and facilitating informed public comment, the Postal Service posted the proposed rules' text on its website and directed readers of the **Federal Register** notice of proposed rulemaking to that posting. This afforded commenters a reasonable opportunity to review the proposed revisions, and several of the comments demonstrate that their authors did so. Subsequently, the Postal Service, in consultation with the Office of the Federal Register, amended Title 39, CFR, and the DMM to clarify the status of Publication 52. 86 FR 53220. As a result of those changes, the text of revisions to Publication 52 is now permitted to be published with the attendant **Federal Register** notice, as is the case with this final rule.

Three ENDS industry commenters urged the Postal Service to publish the text of the final rules in advance of formal publication. It is unclear what this suggestion is supposed to mean. The Postal Service is unaware of any rulemaking practice whereby a final rule is published twice, once "informally" and once "formally." There is only publication of the final rule, which, in this case, immediately triggers the nonmailability of ENDS products. If the commenters' idea is that the Postal Service should publish the rules first and the response to comments later, then this, too, does not appear to comport with regular Federal rulemaking practices, and it might raise concerns about due process and APA compliance. As such, the Postal Service has opted for consistency with normal practices, while attempting to enhance awareness and clarity through issuance of the April 2021 Guidance.

7. Updates

One law student recommended that the Postal Service periodically review the final rule for potential revisions to account for subsequent research regarding ENDS products. The commenter suggested that the review occur one year after the end of the FDA's period for premarket tobacco product applications and every three years thereafter.

The Postal Service appreciates that research on the public-health risks and benefits arising from ENDS products, as well as the market for ENDS products itself, is in a state of rapid evolution. This final rule itself is likely to have its own effects on the ENDS market and on public health.

As discussed in section III.A, however, this rulemaking is not an

[38] The Postal Service recognizes that the FDA uses the term "covered tobacco product" in reference to ENDS products subject to FDA regulation as "deemed" tobacco products. See 21 CFR 1140.3. As discussed in section III.C.1, the scope of such FDA-regulated ENDS products differs from the scope of PACT Act-covered products. Given the explicit definitions in each set of regulations and the differing regulatory contexts, the Postal Service is confident that readers of Publication 52 chapter 47 will understand "covered products" to mean products covered by that chapter and the PACT Act, and not "covered tobacco products" for purposes of 21 CFR part 1140.

instance of policy discretion by the Postal Service, such as the Postal Service might revisit as facts and policy considerations change. The Postal Service is fulfilling a severely circumscribed statutory command to make ENDS products nonmailable except in certain limited circumstances. The decision about the public-health risks and benefits was made by Congress. While further scientific research may alter Congress's policy decision, the Postal Service does not anticipate that it will bear on the limited manner in which it is carrying out Congress's mandate. As such, the Postal Service also does not anticipate a need to revisit this final rule on the basis of further scientific research.

That said, the Postal Service may eventually have other reasons to revisit this final rule, such as further changes in applicable law; evolution in the ENDS market; further guidance from ATF on the scope of covered ENDS products; potential FDA approval of ENDS products for tobacco-cessation or other therapeutic uses; advances in technology that may facilitate alternative methods for administering the Business/Regulatory Purposes exception; and the development of regulatory and enforcement experience regarding ENDS products. Because these (and other, unforeseen) circumstances are not predictable, the Postal Service finds it imprudent to prescribe a schedule of revisions at this time.

IV. Explanation of Changes From Proposed Rule

The final rule includes substantive revisions and additions to Publication 52, as well as non-substantive corrections for consistency and organization, such as extensive renumbering to accommodate substantive revisions.

Material substantive revisions from the proposed rule that are incorporated throughout the final rule include the following:

- "Covered products," defined in section 471.6 as any cigarette, smokeless tobacco, or ENDS, replaces "tobacco products" where applicable.
- Marking requirements for mailings under nonmailability exceptions are revised to provide options for distinguishing among covered products and eligible recipients where applicable.
- Application requirements for the Business/Regulatory Purposes, Consumer Testing, and Public Health exceptions are revised to (1) allow for submission of applications by email to a specified Postal Service email address; (2) require submission of specified Postal Service forms and/or worksheets; (3) clarify that copies of licenses may be furnished (in lieu of originals); (4) clarify the timeframe (*i.e.*, at least 15 days) for updating application materials prior to mailings to or from parties to which the updated information relates; and (5) clarify that Postal Service personnel will have access to current lists of authorized senders/recipients under applicable exceptions.
- Application requirements for the Business/Regulatory Purposes and Public Health exceptions are revised to specify that the PCSC Director may suspend, modify, or rescind discretionary waivers for federal or state government agencies of certain application requirements.
- Mailing requirements for the Business/Regulatory Purposes and Consumer Testing exceptions are revised to require that a current PCSC eligibility letter be presented at acceptance, to acknowledge that lists of authorized senders and recipients will be made available to acceptance personnel, and to clarify that such mailings may be tendered at retail or BME locations.
- Mailing requirements for the Business/Regulatory Purposes and Certain Individuals exceptions are revised to reflect current Postal Service offerings by requiring the use of a combination of Priority Mail Express or Priority Mail with Adult Signature Required or Adult Signature Restricted Delivery. Mailing requirements for the Consumer Testing and Public Health exceptions are similarly revised to require the use of a combination of Priority Mail Express or Priority Mail with Adult Signature Restricted Delivery.[39] For all exceptions, the former option of Priority Mail Express with Hold for Pickup is deleted.
- Delivery requirements for the Business/Regulatory Purposes and Consumer Testing exceptions are revised to clarify that mailings lacking the PCSC eligibility number in the return block will not be released to recipients.
- Delivery requirements for the Certain Individuals and Consumer Testing exceptions are revised to clarify that the minimum age of recipients must be confirmed by Postal Service personnel before mailings may be released or delivered to recipients.

[39] The PACT Act conditions use of the Consumer Testing and Public Health exceptions on delivery only to the named recipient. See 18 U.S.C. 1716E(b)(5)(A), (b)(5)(C)(ii)(VI)–(VII). This condition can be fulfilled via the use of Adult Signature Restricted Delivery, which restricts delivery to the named addressee, but not Adult Signature Required, which does not.

Discrete substantive revisions include the following:

- The proposed definition of "e-liquid" in proposed section 471.3 is deleted as redundant.
- A consolidated definition of "minimum age," defined as 21 years of age, or older where required by local law for acceptance or delivery, is added in section 471.9.
- General provisions regarding nonmailability and reasonable cause in proposed 472.1 are reorganized as sections 472.1 and .2. The circumstances giving rise to nonmailability are delineated more specifically; the treatment of nonmailable matter found in the mails and not seized is clarified through a cross-reference to general provisions on that topic; and clarification is made that nonmailable covered products must not be accepted, forwarded, or delivered.
- The "reasonable cause" standard for Postal Service personnel in proposed section 472.1 is clarified to allow consideration of any potentially relevant circumstances.
- A new section 473.b clarifies that the PACT Act exceptions do not apply to mail from the United States to APO, FPO, or DPO addresses. As explained in section III.J.1, the postal services necessary to reliably fulfill the PACT Act exceptions' verification requirements are not currently available at such locations, and at this time, there does not appear to be any sufficiently reliable alternative means of ensuring that those requirements are fulfilled. In conformance with this change, provisions are removed from the Certain Individuals section that had formerly prescribed how shipments can be made to APO/FPO addresses.
- A new section 473.1.e consolidates the requirement, common to all PACT Act exceptions, that all excepted shipments must be tendered through a face-to-face transaction with a Postal Service employee. For clarity, the requirement is framed here in the negative, as a prohibition on all other entry methods, and enumerates examples of prohibited entry methods.
- Language is added to the preamble of the Business/Regulatory Purposes exception provisions to clarify not only the types of parties eligible to mail under the exception, but the specific sender-addressee pairings permitted by the PACT Act (*i.e.*, business-to-business, business-to-government, or government-to-business, but not government-to-government).
- Application requirements for the Business/Regulatory Purposes exception are further revised to include additional required information relating to (1) the

nature of the relevant business(es); and (2) for ENDS only, brand name(s) and product description(s), including information sufficient to confirm mailability under other applicable provisions (*e.g.*, restrictions related to hazardous materials or controlled substances).

• Delivery requirements for the Business/Regulatory Purposes exception are revised to provide examples of methods for verifying a recipient's employment. Specifically, proof of employment may take the form of an employee identification card or badge containing the name and phone number of the employer/agency along with the name of the employee; a signed letter on employer/agency letterhead; or any form of identification the postmaster deems to be of comparable reliability. Further clarification is made that employee status may be inferred by Postal Service personnel based on observable factors.

• Provisions are added regarding the Certain Individuals exception to emphasize the noncommercial-purpose requirement and to clarify how it applies in the context of returns of damaged or unacceptable merchandise and of used products sent for recycling.

• Application requirements for the Consumer Testing exception are revised to require submission of a copy of the permit issued under 26 U.S.C. 5713. Conversely, language is added to the Public Health exception provision to clarify that a manufacturer's permit is not required for government agencies applying under that exception.

• The additional requirements set out in proposed section 472.27 are relocated to section 472.3 and revised to clarify the applicability of other laws and regulations.

• Mailers' requirements to retain eligibility documentation under applicable nonmailability exceptions are increased from three to six years to align with potentially applicable statutes of limitations and are set out separately in section 472.4.

• Revisions and additions are made to clarify that applicants bear the burden, during initial determinations or appeals, of establishing eligibility for each sender and recipient, and must submit additional documentation as necessary. Further clarification is made that the PCSC Director may approve or deny applications in whole or with respect to certain mailers or recipients, and that eligibility may be suspended, modified, or revoked, in whole or in part, for failure to comply with applicable laws or regulations.

• A new section 474.1 is added to clarify that ATF administers the relevant statutory definition of ENDS and the exclusion of FDA-approved tobacco-cessation and therapeutic products. Persons interested in interpretive guidance concerning these two subjects are advised to contact ATF at the listed address, with a copy to the PCSC.

• The statutory exclusion of FDA-approved tobacco cessation/therapeutic products from the definition of ENDS in proposed section 471.2 is set out separately in section 474.2, and a requirement is added for persons who believe that a product qualifies for this exclusion to submit documentation to ATF, with a copy to the PCSC.

Joshua J. Hofer,

Attorney, Ethics & Legal Compliance.

The Postal Service adopts the following changes to Publication 52, *Hazardous, Restricted, and Perishable Mail,* incorporated by reference into Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM), section 601.8.1, which is further incorporated by reference in the Code of Federal Regulations. 39 CFR 111.1, 111.3. Publication 52 is also a regulation of the Postal Service, changes to which may be published in the **Federal Register**. 39 CFR 211.2(a). Accordingly, for the reasons stated in the preamble, the Postal Service amends Publication 52 as follows:

* * * * *

4 Restricted Matter

* * * * *

[Revise title of 47 to read as follows:]

47 Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems

* * * * *

471 Definitions

[Revise the last sentence of 471.1 to read as follows:]

471.1 Cigarette

* * * The term cigarette includes roll-your-own tobacco and excludes cigars.

* * * * *

[Revise the title of 471.4 to read as follows:]

471.4 Roll-Your-Own Tobacco

* * * * *

[Renumber 471.5 through 471.6 as 471.7 through 471.8, respectively, and insert after 471.4 the following:]

471.5 Electronic Nicotine Delivery System (ENDS)

Any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device. ENDS include but are not limited to, electronic cigarettes (e-cigarettes), electronic hookahs (e-hookahs), electronic cigars (e-cigars), vape pens, advanced refillable personal vaporizers, and electronic pipes. Any reference to ENDS also includes any component, liquid, part, or accessory of an ENDS device, regardless of whether the component, liquid, part, or accessory is sold or provided separately from the device.

471.6 Covered Product

For purposes of chapter 47, any cigarette, smokeless tobacco, or ENDS.

* * * * *

[Add after 471.8, as renumbered, the following:]

471.9 Minimum Age

21 years of age (the federal minimum age for the sale or purchase of covered products), or such higher age that a state or municipality may impose for the legal sale or purchase of covered products at the place of acceptance or delivery, as appropriate.

* * * * *

[Revise 472 to read as follows:]

472 Covered Products Generally Nonmailable

472.1 General

The following are nonmailable:

a. Shipments of covered products described in 473.1.a through .e.

b. Shipments of covered products that are not described in 473.1.a through .e and that do not qualify for an exception under 473.2 through .6.

c. Shipments of covered products that are not described in 473.1.a through .e and that would generally qualify for an exception under 473.2 through .6, but for a failure to meet one or more conditions for the applicable exception. For example, a recipient may fail to be verified as being of at least the minimum age (see 473.34.a, .44.a, .54.a), or a Return Receipt may be absent or may lack the mailer's eligibility number (see 473.32.b, .52.c).

472.2 Treatment of Nonmailable Covered Products

472.21 Refusal of Acceptance and Transmission

The Postal Service will not accept, forward, or deliver any package that it knows, or has reasonable cause to believe, contains nonmailable covered products. If the Postal Service reasonably suspects that a mailer is tendering nonmailable covered products, then the mailer bears the burden of proof in establishing eligibility to mail.

472.22 Seizure and Forfeiture

Nonmailable covered products deposited in the mail are subject to seizure and forfeiture. Any nonmailable covered products seized and forfeited shall be destroyed or retained by the federal government for the detection or prosecution of crimes or related investigations and then destroyed.

472.23 Disposition of Nonmailable Covered Products Not Seized and Forfeited

Any nonmailable covered products not seized and forfeited shall be handled in accordance with 216 and 414.

472.24 Penalties

Persons involved in the shipment or attempted shipment of nonmailable covered products may be subject to seizure and forfeiture of assets, criminal fines, imprisonment, and civil penalties.

472.3 Reasonable Cause To Suspect Covered Products

Among any other potentially relevant circumstances, the Postal Service has reasonable cause to suspect the presence of covered products based on:

a. A statement on a publicly available website, or an advertisement, by any person that the person will mail matter which is nonmailable under this section in return for payment;

b. The fact that the mailer or other person on whose behalf a mailing is being made is on the U.S. Attorney General's List of Unregistered or Noncompliant Delivery Sellers; or

c. Any other characteristics of a package or label, individually or in combination with other packages or labels, that reasonably indicate the likely presence of covered products.

472.4 Applicability of Other Laws and Regulations

Shipments permitted under 473 are subject to all other applicable federal, state, and local laws and regulations. For example, ENDS that consist of or contain controlled substances (including cannabis and cannabis derivatives), drug paraphernalia, lithium batteries, liquids, or any toxic or flammable substance (*e.g.*, nicotine, diacetyl (butane-2,3-dione), propanol, and other components of ENDS liquids) may be subject to prohibitions, restrictions, or additional requirements stated elsewhere in this publication. Mailers, recipients, and applicants are solely responsible for complying with all applicable Postal Service regulations and other federal, state, and local laws when mailing covered products.

472.5 Recordkeeping

Mailers, recipients, and applicants must maintain records to establish compliance with the requirements in 473 for a 6-year period and must make such records available to the Postal Service upon request.

* * * * *

[Insert after 472 the following:]

473 Mailability Exceptions

473.1 Scope of Exceptions

Covered products are mailable if one of the conditions in 473.2 through 473.6 is met. These exceptions do not apply to the following:

a. Mail treated as domestic under DMM 608.2.2.

b. Mail sent to Air/Army Post Office (APO), Fleet Post Office (FPO), or Diplomatic Post Office (DPO) addresses.

c. Mail presented at APO, FPO, or DPO installations and destined to addresses in the United States.

d. International mail as defined in DMM 608.2.3.

e. Mail presented outside of a face-to-face transaction with a Postal Service employee at a Postal Service retail or business mail acceptance location. Examples of prohibited entry methods include, but are not limited to, Pickup on Demand; package pickup; an Approved Shipper location or other third-party acceptance location; a Contract Postal Unit; a Village Post Office; and placement in a customer mailbox, collection box, or Postal Service lobby drop.

473.2 Intra-Alaska and Intra-Hawaii Shipments

Intra-Alaska and intra-Hawaii shipments of covered products are mailable, provided that such mailings:

a. Are presented in a face-to-face transaction with a Postal Service employee within the state, and not through any entry method prohibited under 473.1.e;

b. Destinate in the same state of origin;

c. Bear a valid complete return address that is within the state of origin; and,

d. Are marked with the following exterior marking on the address side of the mailpiece, with the relevant type of item selected: "INTRASTATE SHIPMENT OF [CIGARETTES/SMOKELESS TOBACCO/ENDS]."

473.3 Exception for Business/Regulatory Purposes

Eligibility to mail and to receive mail under the business/regulatory purposes exception is limited to federal and state government agencies and legally operating businesses that have all applicable state and federal government licenses or permits and are engaged in the manufacturing, distribution, wholesale, export, import, testing, investigation, or research of covered products. Mailings under this exception are permitted only for business purposes between eligible businesses or for regulatory purposes between such businesses and eligible government agencies. Mailability is further restricted to mailings that comply with all conditions in 473.31 to 473.34.

473.31 Application

Each customer seeking to mail covered products under the business/regulatory purposes exception must submit a complete application (PS Form 4615 or 4615E, as appropriate) and, for ENDS, complete Worksheets 4615–EM and 4615–ER as appropriate, along with all supporting documentation requested on those forms and worksheets.

a. Along with any other information requested on PS Form 4615 or 4615E and Worksheets 4615–EM and 4615–ER, the applicant must furnish:

1. Information about its legal status, copies of any applicable licenses, and authority under which it operates.

2. Information about the legal status, copies of any applicable licenses, and operational authority for all recipients to which the mailings under this exception will be addressed.

3. All locations where mail containing covered products will be presented.

4. For each business mailer and/or recipient, the nature of the relevant business activities (*e.g.*, manufacturing, wholesale, distribution, testing, investigation, import, export).

5. The brand name and a description of each product intended to be mailed. For ENDS, descriptions must include information about the source of any CBD; the concentration of any THC; and safety data sheets or technical specification documentation for any hazardous materials (*e.g.*, lithium batteries, nicotine, diacetyl (butane-2,3-dione), propanol).

b. The applicant is responsible for establishing the eligibility of each sender and recipient and for the accuracy, completeness, and currency of all information provided in the application.

c. Applications must be submitted as follows:

1. For cigarettes and smokeless tobacco (PS Form 4615): by email to *MDA@usps.gov*.

2. For ENDS (PS Form 4615E and Worksheets 4615–EM and 4615–ER): by email to *MDA@usps.gov*.

d. The Director, PCSC, will make a determination of eligibility to mail under the business/regulatory purposes exception. The mailer bears the burden of establishing eligibility and must furnish any additional supporting documentation requested by the Director, PCSC, upon request as necessary to establish eligibility. The Director, PCSC, may approve or deny an application in its entirety or only with respect to certain mailers and/or recipients. A number is assigned to each letter of eligibility.

e. The applicant must update the information in its application, including any updated documentation, in a timely manner, as necessary, at least 15 days prior to conducting any mailing to or from an entity to which the information pertains.

f. Upon written request by a state or federal agency, the Director, PCSC, may, in his or her discretion, waive certain application requirements for mailings entered by the requesting state or federal agency for regulatory purposes. The Director, PCSC, may suspend, rescind, or modify any waiver at any time.

g. Any determination of eligibility to mail under this exception shall lapse if the authorized mailer does not tender any mail under this exception within any 3-year period. After that time, the affected mailer must apply for and receive new authorization for any mailings under this exception.

473.32 Mailing

All mailings tendered under the business/regulatory purposes exception must:

a. Use one of the following combinations of services:

1. Priority Mail Express with Adult Signature Required or Adult Signature Restricted Delivery service (see DMM 503.8.0).

2. Priority Mail with Adult Signature Required or Adult Signature Restricted Delivery service.

b. Be accompanied by a Domestic Return Receipt (PS Form 3811). The sender's address block must bear the eligibility number issued by the PCSC and be made returnable to the address as shown below:

PCSC, PACT MAILING OFFICE, USPS ELIGIBILITY NO. XX–00–0000, 90 Church St., Ste. 3100, New York, NY 10007–2951.

c. Bear the following marking, with the relevant type of item and recipient selected: "[CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING—DELIVER ONLY TO EMPLOYEE OF ADDRESSEE [BUSINESS/AGENCY] UPON AGE VERIFICATION" on the address side of the mailpiece.

d. Bear the business or government agency name and full mailing addresses of both the sender and recipient, both of which must match exactly those listed on the authorized mailer's application on file with the Postal Service.

e. Be entered at a retail and/or business mail acceptance location specified in the application and authorized by the PCSC.

473.33 Entry and Acceptance

Mailings under the business/regulatory purposes exception must be entered under the following conditions:

a. Covered products must be tendered via a face-to-face transaction with a Postal Service employee. Applicable mailings may not be tendered through any entry method prohibited under 473.1.e.

b. The mailer must present Postal Service acceptance personnel with the following:

1. For shipments of cigarettes and/or smokeless tobacco, a letter from the PCSC showing that the PCSC has authorized the mailer, addressee, and acceptance location.

2. For shipments of ENDS:

i. A letter from the PCSC showing that the PCSC has authorized the mailer and has not withheld authorization as to the addressee;

ii. A PCSC-approved Worksheet 4615–EM showing that the PCSC has authorized the mailer and the acceptance location; and

iii. A PCSC-approved Worksheet 4615–ER showing that the PCSC has authorized the addressee.

473.34 Delivery

Mailings bearing the marking for business/regulatory purposes are eligible for delivery only to a verified employee of the addressee business or government agency under the following conditions:

a. The recipient must be an adult of at least the minimum age (see 471.9) at the place of delivery. The recipient's age must be verified by a postal employee before releasing or delivering the item to the recipient. The recipient must furnish proof of age via a driver's license, passport, or other government-issued photo identification that lists age or date of birth.

b. The recipient must demonstrate status as an employee of the business or government agency identified as the addressee on the mailing label. Proof of employment may take the form of an employee identification badge or card issued by the employer and including the employee's name, the employer's name, and the employer's telephone number; a signed letter on company or agency letterhead from a supervisor or human relations office attesting to the recipient's current employment; or any other form of identification that the postmaster deems to be of comparable reliability. Where delivery is made to a business address, employment status may be inferred from the carrier's observation of such factors as the recipient's uniform and presence at a reception desk or retail counter.

c. Once the recipient's age and identity as an employee of the addressee are established, the recipient must sign for receipt of delivery and in the appropriate signature block of PS Form 3811.

473.4 Exception for Certain Individuals

The exception for certain individuals permits the mailing of small quantities of covered products by individual adults for noncommercial purposes. Mailability is further restricted to mailings that comply with all conditions in 473.41 to 473.44. Eligible shipments may be made to any type of recipient (individual, business, government, or other organization).

473.41 Noncommercial Purposes

Noncommercial purposes may include, but are not limited to, the following:

a. Covered products exchanged as gifts between individual adults. For purposes of this rule, "gifts" do not include covered products purchased by one individual for another from a third-party vendor through a mail-order transaction, or the inclusion of covered tobacco products at no additional charge with other matter pursuant to a commercial transaction.

b. Damaged or unacceptable covered products returned by a consumer to the manufacturer or other business. For purposes of the noncommerciality requirement, the manufacturer or other business may provide the consumer with a refund, credit, replacement product, or other form of value in exchange for the damaged or unacceptable covered product, so long as it does not exceed the amount that the consumer paid for the damaged or unacceptable product plus the cost of return shipping for the damaged or unacceptable product.

c. Used covered products sent by a consumer to a manufacturer or other business for recycling. For purposes of this rule, the consumer must not receive anything of value (*e.g.*, a discount, credit, or rebate) in exchange for a returned item.

473.42 Mailing

No customer may send or cause to be sent more than 10 mailings under this exception in any 30-day period. Each mailing under the certain individuals exception must:

a. Weigh no more than 10 ounces.

b. Use one of the following combinations of services:

1. Priority Mail Express with Adult Signature Required or Adult Signature Restricted Delivery service (see DMM 503.8.0).

2. Priority Mail with Adult Signature Required or Adult Signature Restricted Delivery service.

c. Bear the full name and mailing address of the sender and recipient on the Priority Mail Express or Priority Mail label.

d. Bear the following exterior marking on the address side of the mailpiece, with the relevant type of item selected: "PERMITTED [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING—DELIVER ONLY UPON AGE VERIFICATION."

473.43 Entry and Acceptance

Mailings under the certain individuals exception must be entered under the following conditions:

a. Covered products must be tendered via a face-to-face transaction with a Postal Service employee. Applicable mailings may not be tendered through any entry method prohibited under 473.1.e.

b. The individual presenting the mailing must furnish a driver's license, passport, or other government-issued photo identification that lists age or date of birth. The name on the identification must match the name of the sender appearing in the return address block of the mailpiece. The customer must be an adult of at least the minimum age at the place of acceptance (see 471.9).

c. For mailings addressed to an individual, at the time the mailing is presented, the customer must orally confirm that the addressee is an adult of at least the minimum age at the place of delivery (see 471.9).

473.44 Delivery

Mailings bearing the marking for certain individuals are eligible for delivery only under the following conditions:

a. The recipient receiving or signing for the article must be an adult of at least the minimum age at the place of delivery (see 471.9). This must be confirmed by postal employees before releasing or delivering the item to the recipient. The recipient must furnish proof of age via a driver's license, passport, or other government-issued photo identification that lists age or date of birth.

b. Once age is established, the recipient must sign for receipt of delivery.

473.5 Consumer Testing Exception

The consumer testing exception permits a legally operating cigarette manufacturer or a legally authorized agent of a legally operating cigarette manufacturer to mail cigarettes to verified adult smokers solely for consumer testing purposes. The manufacturer for which mailings are entered under this exception must have a permit, in good standing, issued under 26 U.S.C. 5713. The consumer testing exception applies only to cigarettes and not to smokeless tobacco or ENDS. Mailability is further restricted to mailings that comply with all conditions in 473.51 to 473.54.

473.51 Application

Each person seeking to mail cigarettes under the consumer testing exception must submit a complete application (PS Form 4616), along with all supporting documentation requested on that form, by email to *MDA@usps.gov*. For each application, the following conditions must be met:

a. The applicant must furnish the following information:

1. A copy of the relevant manufacturer's permit issued under 26 U.S.C. 5713.

2. If the applicant is an agent of a manufacturer, complete details about the agency relationship with the manufacturer.

3. All locations where mail containing cigarettes for consumer testing will be presented.

b. As part of its application, the applicant must certify in writing that it will comply with the following requirements:

1. Any recipient of consumer testing samples of cigarettes is an adult established smoker.

2. No recipient has made any payment for the cigarettes.

3. Every recipient will sign a statement indicating that the recipient wishes to receive the mailings.

4. The manufacturer or the legally authorized agent of the manufacturer will offer the opportunity for any recipient to withdraw the recipient's written statement at least once in every 3-month period.

5. Any package mailed under this exception will contain no more than 12 packs of cigarettes (maximum of 240 cigarettes) on which all taxes levied on the cigarettes by the state and locality of delivery have been paid and all related state tax stamps or other tax-payment indicia have been applied.

c. The application must be submitted to the Director, Pricing and Classification Service Center (PCSC) via email to *MDA@usps.gov*. The applicant bears the burden of establishing eligibility.

d. The applicant must provide any requested copies of records establishing compliance to the Director, PCSC, and/or the Director, Product Classification (see 214 for address), upon request, no later than 10 business days after the date of the request.

e. The Director, PCSC, will make a determination of eligibility to mail under the consumer testing exception. The Director, PCSC, may approve or deny an application in its entirety or only with respect to certain mailers and/or recipients. A number is assigned to each letter of eligibility.

f. An applicant or authorized mailer must update the information in its application with the Director, PCSC, as necessary, in a timely manner upon becoming aware of a change in application information, not later than 15 days prior to conducting any mailing, for as long as it continues to mail under the consumer testing exception.

g. Any determination of eligibility to mail under this exception shall lapse if the authorized mailer does not tender any mail under this exception within any 3-year period. After that time, the mailer must apply for and receive new authorization for any further mailings under this exception.

473.52 Mailing

All mailings under the consumer testing exception:

a. Must be limited in tobacco content to no more than 12 packs of cigarettes (maximum 240 cigarettes) on which all taxes levied on the cigarettes by the destination state and locality have been paid and all related state tax stamps or other tax-payment indicia have been applied.

b. Must use one of the following combinations of services:

1. Priority Mail Express with Adult Signature Restricted Delivery service (see DMM 503.8.0).

2. Priority Mail with Adult Signature Restricted Delivery service.

c. Be accompanied by a Domestic Return Receipt (PS Form 3811). The sender's address block must bear the eligibility number issued by the PCSC and be made returnable to the address as shown below:

PCSC, PACT MAILING OFFICE, USPS ELIGIBILITY NO. XX–00–0000, 90

Church St., Ste. 3100, New York, NY 10007–2951.

d. Must bear the following marking: "PERMITTED CIGARETTE MAILING—DELIVER ONLY TO ADDRESSEE UPON AGE VERIFICATION" on the address side of the mailpiece.

e. Must bear the name and full mailing addresses of both the mailer and recipient, both of which must match exactly those listed on the authorized mailer's application on file with the Postal Service.

f. May not be addressed to an addressee located in a state that prohibits the delivery or shipment of cigarettes to individuals in the destination state.

g. May be sent only to an addressee who has not made any payment for the cigarettes, is being paid a fee for participation in consumer tests and has agreed to evaluate the cigarettes and furnish feedback to the manufacturer in connection with the consumer test.

h. May not exceed more than one package from any one manufacturer to an adult smoker during any 30-day period.

i. Must be entered at a retail and/or business mail acceptance location specified in the application and authorized by the PCSC.

473.53 Entry and Acceptance

Mailings under the consumer testing exception must be entered under the following conditions:

a. Covered products must be tendered via a face-to-face transaction with a Postal Service employee. Applicable mailings may not be tendered through any entry method prohibited under 473.1.e.

b. The mailer must present Postal Service acceptance personnel with a letter from the PCSC showing that the PCSC has authorized the mailer and acceptance location.

473.54 Delivery

Mailings bearing the marking for consumer testing are eligible for delivery only to the named addressee under the following conditions:

a. The recipient signing for the article must be an adult of at least 21 years of age. The recipient's age must be verified by a postal employee before releasing or delivering the item to the recipient. The recipient must furnish proof of age via a driver's license, passport, or other government-issued photo identification that lists age or date of birth. The name on the identification must match the name of the addressee on the Priority Mail Express or Priority Mail label.

b. Once the recipient's age and identity are established, the recipient must sign for receipt of delivery and in the appropriate signature block of PS Form 3811.

473.6 Public Health Exception

Federal government agencies involved in the consumer testing of tobacco products solely for public health purposes may mail cigarettes (this does not apply to smokeless tobacco or ENDS) under the mailing standards of 473.5, except as follows:

a. The federal agency is not required to have a manufacturer's permit issued under 26 U.S.C. 5713.

b. The recipient is not required to be paid a fee for participation in consumer tests.

c. Upon written request, the Director, PCSC, may waive certain application requirements for mailings entered by the requesting federal agency. The Director, PCSC, may suspend, rescind, or modify any waiver at any time.

473.7 Suspension or Revocation of Eligibility

Eligibility to mail under one or more exceptions in 473.2 through .6 may be suspended or revoked by the Director, PCSC, in the event of failure to comply with any applicable law or regulation. A customer may appeal an adverse initial decision to the Director, Product Classification (see 214 for address). The mailer bears the burden of proof in establishing eligibility in any appeal of a suspension or revocation decision and of furnishing all supporting documentation when requested. Decisions by the Director, Product Classification, to revoke a customer's eligibility under any exception may be appealed to the Judicial Officer under 39 CFR part 953.

* * * * *

474 Additional Guidance

474.1 Interpretative Guidance

The definitions in 471.1 through. 5 and the exclusion in 474.2 are pursuant to section 1 of the Jenkins Act (15 U.S.C. 375), which is administered by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF). Interpretative guidance regarding these provisions may be requested by contacting ATF at the following address, with a copy to the Pricing and Classification Service Center (PCSC) (see 213 for address): Bureau of Alcohol, Tobacco, Firearms and Explosives, 99 New York Avenue NE, c/o 90 K St. NE, Ste. 250, Washington, DC 20226.

474.2 Exclusion of Products Approved for Tobacco Cessation or Therapeutic Purposes

A product is excluded from the definition of ENDS in 471.5 (15 U.S.C. 375(7)(C)) if:

a. It is approved by the Food and Drug Administration for sale as a tobacco cessation product or any other therapeutic purpose; and

b. Is marketed and sold solely for such purposes.

Any party who believes that a product to be sent through the mails qualifies for this exclusion should provide appropriate documentation to ATF at the address in 474.1, with a copy to the PCSC.

[FR Doc. 2021–22787 Filed 10–20–21; 8:45 am]

BILLING CODE P

Field Information Kit

Prevent All Cigarette Trafficking (PACT) Act of 2009

Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems (ENDS) as Nonmailable Matter

What: On June 29, 2010, smokeless tobacco and cigarettes became nonmailable in most circumstances. Effective October 21, 2021, electronic nicotine delivery systems (ENDS) products are likewise nonmailable in most circumstances.

WHEN: A final rule to implement these changes related to the inclusion of ENDS products is being published in the *Federal Register* on October 21, 2021 and becomes effective on the same day.

WHY: These new rules result from legislation enacted on December 27, 2020. This legislation includes ENDS products within the scope of the Prevent All Cigarette Trafficking (PACT) Act of 2009, which prohibits cigarettes and smokeless tobacco in the mail except under certain conditional exceptions.

DETAILS:
Under the new rules, the following matter is generally nonmailable, except in limited circumstances. **Note:** Cigars are not subject to these rules.

- **Cigarettes**, meaning:
  - Rolls of tobacco wrapped in paper or in any substance not containing tobacco.
  - Rolls of tobacco wrapped in a tobacco-containing substance but likely to be offered to, or purchased by, consumers as a cigarette; or
  - Roll-your-own tobacco (tobacco or wrappers offered to, or purchased by, consumers for making cigarettes or cigars).

- **Smokeless tobacco**, meaning:
  - Tobacco intended to be placed in the oral or nasal cavity; or
  - Tobacco otherwise consumed without being combusted.

- **Electronic nicotine delivery systems ("ENDS")**, meaning:
  - Electronic devices that, through an aerosolized solution, deliver nicotine, flavor, or any other substance to the user inhaling from the device; or
  - Any component, liquid, part, or accessory of an ENDS device, regardless of whether it is shipped separately from the device.

  Note: Examples of ENDS devices include e-cigarettes, e-hookahs, e-cigars, e-pipes, vape pens, or advanced refillable personal vaporizers. Despite the name, ENDS are nonmailable regardless of whether they contain or are used with nicotine.

The following types of shipments of cigarettes, smokeless tobacco, and ENDS are **ineligible for any exception and are always nonmailable**, regardless of markings or other indications:

- Mail accepted via any carrier, contractor, or third-party acceptance method. Prohibited acceptance methods and locations for cigarettes, smokeless tobacco, and ENDS include Pickup on Demand, Package Pickup, customer mailboxes or collection boxes, a Community Post Office, a Contract Postal Unit, a Village Post Office, an Approved Shipper, and any other contractor- or third-party-operated acceptance location;

- Inbound international mail;

- Outbound international mail;

- Overseas military and diplomatic mail (i.e., mail to, from, or between APO/FPO/DPO addresses); or

- Mail to, from, or between the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

The **exceptions** under which cigarettes, smokeless tobacco, or ENDS **may be mailed** are as follows:

- **Intra-Alaska/Intra-Hawaii:** Shipments entirely within Alaska or Hawaii.

- **Business/Regulatory Purposes:** Shipments transmitted between authorized businesses for business purposes, or between authorized businesses and government agencies for regulatory purposes. This exception requires pre-authorization of the sender and recipient by the Pricing and Classification Service Center (PCSC).

- **Certain Individuals:** Infrequent, lightweight shipments mailed by adult individuals.

- **Consumer Testing/Public Health (cigarettes only):** Cigarettes sent by authorized manufacturers to adults for consumer testing purposes, and shipments sent by authorized federal agencies to consumers for public health purposes. This exception requires pre-authorization of the sender by the PCSC.

<u>The following rules are conditions for excepted mailings:</u>

- All shipments must bear a **unique marking** on the address side of the package.

- All shipments must be presented in **face-to-face transactions** with postal acceptance employees, therefore package pickup services are **not permitted**. If

a customer uses an electronic postage payment method such as **Click-N-Ship®**, the package must be tendered at a Post Office™ facility or business mail acceptance location. Shipments may not be tendered at contract retail units, commercial mail receiving agencies, or other third-party locations.

- Except for intra-Alaska shipments and intra-Hawaii shipments, all shipments must be sent by **Priority Mail Express or Priority Mail service with an Adult Signature service.**

- Except for intra-Alaska shipments, intra-Hawaii shipments, and other shipments between approved businesses, **absolutely no retail or ecommerce sales transactions** of cigarettes, smokeless tobacco, or ENDS may use the mail for delivery.

- Cigarettes, smokeless tobacco, and ENDS are **prohibited in inbound and outbound international mail**, **overseas military and diplomatic (APO/FPO/DPO) mail**, and mail to, from, within, or between **ZIP Codes in the Freely Associated States (i.e., 96939–96944, 96960, or 96970)**.

- Except for intra-Alaska and intra-Hawaii shipments, **age verification must be completed for all cigarettes, smokeless tobacco, and ENDS shipments** prior to delivery, and in some cases prior to acceptance. The federal minimum age for these purposes is **age 21** in all states and U.S. territories and possessions. Higher minimum age requirements may apply in certain locations, based on local law.

What you need to know: Familiarize yourself with the contents of this communications package on revisions to the PACT Act. Several service talks have been developed specifically for delivery operations and retail associates.

All packages must meet the requirements listed in the "PACT Act Acceptance and Delivery Procedures." The following items appear below and are available at *https://blue.usps.gov/retail/policy-procedures/service-talks/domestic-service-talks.htm*

- "PACT Act Acceptance and Delivery Procedures" for each of the exceptions indicated above.
- "PACT Act FAQs" for all employees who accept or deliver packages.
- "PACT Act Acceptance and Delivery Rules" Job Aid.

Acceptance Service Talk

Mailability of Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems

Effective October 21, 2021, electronic nicotine delivery systems (ENDS) are generally nonmailable, similar to cigarettes and smokeless tobacco.

For mailability purposes, ENDS are defined as electronic devices that aerosolize a solution of nicotine, flavor, or any other substance and deliver the vapor to the user inhaling from the device. Despite the name, ENDS are not limited to products containing or intended to be used with nicotine. Examples include e-cigarettes, e-hookahs, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes. For mailability purposes, ENDS also include any component, liquid, part, or accessory of ENDS, regardless of whether it is shipped separately from the device.

The law spells out limited circumstances in which cigarettes, smokeless tobacco, and ENDS can be mailed. Even under these exceptions, several restrictions apply.

Mailings must be tendered in a face-to-face transaction with a Postal Service employee at a retail facility or Business Mail Entry Unit (BMEU). They cannot be tendered via Post Office lobby drops or other non-face-to-face methods, and they cannot be tendered at Contract Postal Units or third-party acceptance locations.

Cigarettes, smokeless tobacco, and ENDS are prohibited in international mail; mail to and from APO/FPO/DPO addresses; and mail to, from, within, and between ZIP Codes in the Freely Associated States (i.e., 96939–96944, 96960, or 96970).

In domestic mail, cigarettes, smokeless tobacco, and ENDS are permitted only in the following circumstances:

- **Intra-Alaska/Intra-Hawaii:** Shipments entirely within Alaska or Hawaii.
- **Business/Regulatory Purposes:** Shipments transmitted between ENDS/tobacco industry businesses authorized by the Postal Service's Pricing and Classification Service Center (PCSC), or between such businesses and federal or state agencies for regulatory purposes.
- **Certain Individuals:** Infrequent, lightweight shipments mailed by age-verified adult individuals.
- **Consumer Testing/Public Health:** Limited shipments by cigarette manufacturers or federal agencies pre-authorized by the PCSC to individuals for testing purposes. This applies only to cigarettes, and not to smokeless tobacco or ENDS.

How does this change to the PACT Act affect retail employees?
Retail employees must ensure that mailers comply with PACT Act requirements. Customers claiming one of the exceptions are required to put identifying markings on their packages. Where this is the case, or where there are other indications that a customer is mailing cigarettes, smokeless tobacco, or ENDS, you must evaluate whether the customer has complied with the requirements for one of the exceptions. If not, then the package is nonmailable and should be refused.

Acceptance Procedures

Business/Regulatory Purposes Exception

1. Mailings must be presented to a postal employee in a face-to-face transaction. Post Office lobby drops, Contract Postal Units, third-party acceptance locations, Pickup on Demand, Package Pickup, and other carrier-based acceptance methods are not available.
2. Check for this marking on address side (with the mailer using whichever terms in brackets apply): **"[CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING-DELIVER ONLY TO EMPLOYEE OF ADDRESSED [BUSINESS/AGENCY] UPON AGE VERIFICATION"**
3. Verify that postage has been prepaid via Click-N-Ship, PC Postage, Permit Imprint, or an IBI postage meter.
4. Verify that the mailer has used the following combination of products: (1) **Priority Mail Express or Priority Mail**, with (2) **Adult Signature Required or Adult Signature Restricted Delivery**.
5. Verify that the mailpiece includes the name and full mailing addresses for both the sender and recipient.
6. Verify that both the sender and recipient identified on the package are businesses and/or government agencies.
7. Ask the mailer for the mailer's authorization letter from the PCSC and worksheets showing authorized mailers, recipients, and acceptance locations.
8. Verify that the mailer, recipient, and acceptance location are listed as authorized in the letter and/or worksheets, and that the letter does not identify the recipient as unauthorized.
9. Verify the mailer's information by checking the "Mailers with Authorized Cigarettes, Smokeless Tobacco or ENDS Business/Regulatory Exceptions" list published weekly in a *Retail Digest* (also available on https://blue.usps.gov/mail-acceptance/_xls/PACT%20ACT%20Authorized%20Mailers%20List.xlsx).
10. Advise the mailer that the mailer must additionally purchase Return Receipt service using PS Form 3811, *Domestic Return Receipt*. Advise the mailer that the return receipt must bear the mailer's eligibility number issued by the Pricing and Classification Service Center (PCSC) in the return address block; include the addressee's full name and address; and be made mailable to the address illustrated below:

    PCSC PACT Mailing Office
    USPS Eligibility No. [insert PCSC authorization number]
    90 Church Street, Suite 3100
    New York, NY 10007-2951

11. If steps 1 through 10 have been completed successfully and no other mailability issues are apparent, accept the package. If the mailer has failed to comply with any step, or if you cannot verify that the PCSC has authorized the mailer, recipient, and acceptance location, refuse the package.

Certain Individuals Exception

1. Mailings must be presented to a postal employee in a face-to-face transaction. Post Office lobby drops, Contract Postal Units, third-party acceptance locations, Pickup on Demand, Package Pickup, and other carrier-based acceptance methods are not available.
2. Check for the following marking on the address side (with the mailer using whichever terms in brackets apply): **"PERMITTED [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING-DELIVER ONLY UPON AGE VERIFICATION"**
3. Verify that the package weighs no more than 10 ounces.
4. Ask the customer to confirm that the package is not being sent for commercial purposes.
5. Verify that postage has been prepaid via Click-N-Ship, PC Postage, Permit Imprint, or an IBI postage meter.
6. Verify that the mailer has used the following combination of products: (1) **Priority Mail Express or Priority Mail**, with (2) **Adult Signature Required or Adult Signature Restricted Delivery.**
7. Check that the shipping label bears the full name and address for both the sender and the addressee.
8. Ask the mailer to present government-issued photo identification that lists age or date of birth, such as a driver's license or passport.
9. Check that the name on the identification matches the sender name on the Priority Mail Express or Priority Mail label.
10. Verify that the mailer is at least 21 years of age (or any higher minimum age that local law sets for the sale or purchase of the relevant products).
11. If the addressee is an individual, ask the mailer to orally confirm that the addressee is an adult of at least the minimum age for the legal sale or purchase of cigarettes, smokeless tobacco, or ENDS products at the place of delivery.
12. If you are aware that the mailer has mailed 10 or more such packages in the last 30 days, advise the mailer that the package cannot be mailed at this time.
13. If steps 1 through 11 have been completed successfully and no other mailability issues are apparent, accept the package. If the mailer has failed to comply with any step, or if you cannot verify the mailer's identity and/or age, refuse the package.

Consumer Testing/Public Health

1. Mailings must be presented to a postal employee in a face-to-face transaction. Post Office lobby drops, Contract Postal Units, third-party acceptance locations, Pickup on Demand, Package Pickup, and other carrier-based acceptance methods are not available.
2. Check for marking on address side: **"PERMITTED CIGARETTE MAILING—DELIVER ONLY TO ADDRESSEE UPON AGE VERIFICATION"**
3. Ask the mailer to confirm that the package contains no more than 12 packs (240 cigarettes) and does not contain smokeless tobacco or ENDS.
4. Verify that postage has been prepaid via Click-N-Ship, PC Postage, Permit Imprint, or an IBI postage meter.

5. Verify that the mailer has used the following combination of products: (1) **Priority Mail Express or Priority Mail**, with (2) **Adult Signature Restricted Delivery**. **Note:** Adult Signature Required is not an eligible service with this marking.
6. Check that the shipping label bears the full name and address for both the sender and the addressee.
7. Verify that the sender identified on the package is a government agency or business and that the addressee is an individual.
8. Ask the mailer for the mailer's authorization letter from the PCSC and worksheets showing authorized mailers and acceptance locations.
9. Verify that the mailer and acceptance location are listed as authorized in the letter and/or worksheets, and that the letter does not identify the recipient as unauthorized.
10. Verify the mailer's information by checking the "Mailers with Authorized Cigarettes, Smokeless Tobacco or ENDS Business/Regulatory Exceptions" list published weekly in a *Retail Digest* (also available https://blue.usps.gov/mail-acceptance/_xls/PACT%20ACT%20Authorized%20Mailers%20List.xlsx).
11. Advise the mailer that the mailer must additionally purchase Return Receipt service using PS Form 3811, *Domestic Return Receipt*. Advise the mailer that the return receipt must bear the mailer's eligibility number issued by the Pricing and Classification Service Center (PCSC) in the return address block; include the addressee's full name and address; and be made mailable to the address illustrated below:

    PCSC PACT Mailing Office
    USPS Eligibility No. [insert PCSC authorization number]
    90 Church Street, Suite 3100
    New York, NY 10007-2951

12. If you are aware that the mailer has mailed a package to the same addressee in the last 30 days, advise the mailer that the package cannot be mailed at this time.
13. If steps 1 through 11 have been completed successfully and no other mailability issues are apparent, accept the package. If the mailer has failed to comply with any step, or if you cannot verify that the PCSC has authorized the mailer and acceptance location, refuse the package.

Intra-Alaska/Intra-Hawaii Exception — Personnel in Alaska and Hawaii only

1. Mailings must be presented to a postal employee in a face-to-face transaction. Post Office lobby drops, Contract Postal Units, third-party acceptance locations, Pickup on Demand, Package Pickup, and other carrier-based acceptance methods are not available.
2. Check for marking on address side (with the mailer using whichever terms in brackets apply): **"INTRASTATE SHIPMENT OF [CIGARETTES/SMOKELESS TOBACCO/ENDS]."**
3. Check that the return address is complete, valid, and located in your state.

4. Verify that delivery address is in your state.
5. If steps 1 through 4 have been completed successfully and no other mailability issues are apparent, accept the package. If the mailer has failed to comply with any step, or if you cannot verify that both addresses are in your state, refuse the package.

Note: Not all mailings tendered in Alaska or Hawaii fall under this exception. If a mailpiece contains cigarettes, smokeless tobacco, or ENDS and is tendered in Alaska or Hawaii for delivery out of state, it can be mailable only if it meets the conditions for one of the other exceptions above.

No Exceptions Apply

If the mailing does not qualify for one of the exceptions above, inform the mailer that it cannot be mailed under U.S. law.

In addition, do not accept the item if any of the following is true:

- The package has a foreign return or delivery address.
- The package has an APO, FPO, or DPO return or delivery address.
- The package has a return or delivery address with a ZIP Code in the Freely Associated States (i.e., 96939–96944, 96960, or 96970), or is being mailed in one of those ZIP Codes.
- The package was tendered via a private mailbox, collection box, Postal Service lobby drop, Approved Shipper, Contract Postal Unit, Village Post Office, or other method besides a face-to-face transaction with a postal employee at a Postal Service retail location or BMEU.

Delivery Service Talk

Mailability of Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems

Effective October 21, 2021, electronic nicotine delivery systems (ENDS) are generally nonmailable, similar to cigarettes and smokeless tobacco.

For mailability purposes, ENDS are defined as electronic devices that aerosolize a solution of nicotine, flavor, or any other substance and deliver the vapor to the user inhaling from the device. Despite the name, ENDS are not limited to products containing or intended to be used with nicotine. Examples include e-cigarettes, e-hookahs, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes. For mailability purposes, ENDS also include any component, liquid, part, or accessory of ENDS, regardless of whether it is shipped separately from the device.

The law spells out limited circumstances in which cigarettes, smokeless tobacco, and ENDS can be mailed. Even under these exceptions, the following restrictions apply.

Mailings must be tendered in a face-to-face transaction with a Postal Service employee at a retail facility or Business Mail Entry Unit (BMEU). They cannot be tendered via Pickup on Demand, Package Pickup, or any other method of acceptance by a letter carrier.

You may see packages with one of the following markings (with the customer using one of the terms in each set of brackets):

- **[CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING — DELIVER ONLY TO EMPLOYEE OF ADDRESSED [BUSINESS/AGENCY] UPON AGE VERIFICATION**
- **PERMITTED [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING—DELIVER ONLY UPON AGE VERIFICATION**
- **PERMITTED CIGARETTE MAILING—DELIVER ONLY TO ADDRESSEE UPON AGE VERIFICATION**

These mailings must use an Adult Signature service, and any such mailings with a business or government return address must also have a Return Receipt (PS Form 3811) returnable to the Pricing and Classification Service Center. If mailing with one of these markings has the necessary services, then delivery should be attempted, subject to verification that the recipient is at least 21 years old. If the mailing is missing one of these services, then it is nonmailable and generally should be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

If a marking instructs you to deliver only to an addressee (in conjunction with Adult Signature Restricted Delivery) or to the addressee's employee, then such restrictions apply as well.

If delivery cannot be made to a person meeting the relevant criteria, then a PS Form 3849 notice should be left, and the package returned to the local Post Office.

[For offices outside of Alaska and Hawaii:] The marking "INTRASTATE SHIPMENT OF [CIGARETTES/SMOKELESS TOBACCO/ENDS]" is specific to shipments within Alaska and Hawaii only. It is invalid anywhere else. If you see a mailing with this marking, then the package is nonmailable and generally should be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

[For offices in Alaska and Hawaii only:] You may also see packages marked as follows: **INTRASTATE SHIPMENT OF [CIGARETTES, SMOKELESS TOBACCO, or ENDS].** If you see a package with this marking, check to ensure that the return address is in our state. If so, then the package is mailable and should be delivered. These packages are mailable even if the shipper has not used an Adult Signature service or Return Receipt, and you do not need to verify anything at delivery, unless the shipper has opted to use such a service. If you see a package with an "INTRASTATE" marking but with an out-of-state return address, then it is nonmailable and generally should be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

[All offices:] Only domestic mail can be eligible for the mailability exceptions. Cigarettes, smokeless tobacco, and ENDS are prohibited in international mail; mail to and from APO/FPO/DPO addresses; and mail to, from, within, and between ZIP Codes in the Freely Associated States (i.e., 96939–96944, 96960, or 96970).

Finally, any domestic mailings with invalid markings, or with other indications that the contents are cigarettes, smokeless tobacco, or ENDS, are nonmailable and generally should be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

Any questions should be directed to your supervisor.

Delivery Procedures

Business/Regulatory Purposes Exception

1. Check for marking on address side: "[CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING—DELIVER ONLY TO EMPLOYEE OF ADDRESSEE [BUSINESS/AGENCY] UPON AGE VERIFICATION." (The mailer should have chosen one of the items in each set of brackets.)
2. Make sure that the mailing is associated with Adult Signature service and has a return receipt. If the package does not have either of these services, return the package to sender with a report to the PCSC, treat as dead mail, or refer to the Inspection Service, as applicable. See MI [NUMBER] for further instructions.
3. Make sure that the return address to the PCSC on the return receipt includes the mailer's eligibility number in the return address block, as shown in the illustration below.

   PCSC PACT Mailing Office
   USPS Eligibility No. XX-00-0000
   90 Church Street, Suite 3100
   New York, NY 10007-2951

   If the eligibility number is missing on the return receipt, return the package to sender with a report to the PCSC, treat as dead mail, or refer to the Inspection Service, as applicable. See MI [NUMBER] for further instructions.
4. At the point of delivery, ask the recipient to present (a) government-issued photo identification that lists age or date of birth, such as a driver's license or passport and (b) proof of employment with the named addressee. Proof of employment may be any of the following:
   a. An employee identification badge or card with the employee's name, employer's name, and employer's phone number;
   b. A signed letter from a supervisor or human resources office on company letterhead;
   c. Any other form of identification that your postmaster deems to be sufficiently reliable; or
   d. If delivery is made at the business's address, observation of such factors as the recipient's uniform and presence at a reception desk or retail counter.
5. Verify that the recipient is at least 21 years of age (or any higher minimum age that local law sets for the sale or purchase of the relevant products).
6. Verify that the recipient is an employee of the named addressee.
7. If the recipient cannot be verified as being an employee or at least the minimum age, then a PS Form 3849 notice should be left, and the package returned to the local Post Office.
8. If the recipient is verified as being an employee and at least the minimum age, advise the recipient to sign for receipt of delivery and in the appropriate signature blocks of PS Form 3811.

Certain Individuals Exception

1. Check for the following marking on the address side: "**PERMITTED [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING—DELIVER ONLY UPON AGE VERIFICATION"** (The mailer should have chosen one of the items in brackets.)
2. Ask the recipient to present government-issued photo identification that lists age or date of birth, such as a driver's license or passport.
3. Verify that the recipient is at least 21 years of age (or any higher minimum age that local law sets for the sale or purchase of the relevant products).
4. If the recipient cannot be verified as being at least the minimum age, then a PS Form 3849 notice should be left, and the package returned to the local Post Office.
5. If the recipient is verified as being at least the minimum age, advise the recipient to sign for receipt of delivery.

Consumer Testing/Public Health Exception

1. Check for marking on address side: **"PERMITTED CIGARETTE MAILING—DELIVER ONLY TO ADDRESSEE UPON AGE VERIFICATION"**
2. Make sure that the mailing is associated with Adult Signature Restricted Delivery service and has a return receipt. If the package does not have either of these services, return the package to sender. **Note:** Adult Signature Required is not an eligible service with this marking.
3. Make sure that the return address to the PCSC on the return receipt includes the mailer's eligibility number in the return address block, as shown in the illustration below.

   PCSC PACT Mailing Office
   USPS Eligibility No. [insert PCSC authorization number]
   90 Church Street, Suite 3100
   New York, NY 10007-2951

   If the eligibility number is missing on the return receipt, return the package to sender with a report to the PCSC, treat as dead mail, or refer to the Inspection Service, as applicable. See MI [NUMBER] for further instructions.
4. At the point of delivery, ask the recipient to present government-issued photo identification that lists age or date of birth, such as a driver's license or passport.
5. Verify that the recipient is the addressee named on the package. If the recipient cannot be verified as the addressee, then a PS Form 3649 notice should be left and the package returned to the local Post Office.
6. Verify that the recipient is at least 21 years old. If the recipient is verified as the addressee but is not at least 21 years old, then the item is nonmailable and must be returned to sender with a report to the Pricing and Classification Service Center, treated as dead mail, or referred to the Inspection Service, as applicable. See MI [NUMBER] for further instructions.
7. If the recipient is verified as being the addressee and at least 21 years old, advise the recipient to sign for receipt of delivery.

Intra-Alaska/Intra-Hawaii Exception—Personnel in Alaska and Hawaii Only

1. Check for marking on address side: "**INTRASTATE SHIPMENT OF [CIGARETTES/SMOKELESS TOBACCO/ENDS]**" (The mailer should have chosen one of the items in brackets.)
2. Verify that the delivery address is in the same state as the return address and acceptance site.
3. If the return address or acceptance site is out of state, then the item is nonmailable and must be returned to sender with a report to the Pricing and Classification Service Center, treat as dead mail, or refer to the Inspection Service, as applicable. See MI [NUMBER] for further instructions.
4. No forwarding of intra-state exception shipments is permitted to out-of-state addresses.

Note: *Not all mailings delivered in Alaska or Hawaii fall under this exception. If a mailpiece for delivery in Alaska or Hawaii bears a marking for one of the other exceptions below, follow the appropriate tasks for that marking.*

No Exceptions Apply

Cigarettes, smokeless tobacco, and ENDS are prohibited in international mail; mail to APO/FPO/DPO addresses; and mail to, from, and between ZIP Codes in the Freely Associated States (i.e., 96939–96944, 96960, or 96970).

In any of these situations, or in any other situation not covered by an exception above where cigarettes, smokeless tobacco, or ENDS are indicated or within plain sight, in or on a domestic mailpiece, do not deliver the item. See MI [NUMBER] for further instructions.

Packages Presented for Collection

Under most circumstances, cigarettes, smokeless tobacco, and ENDS are nonmailable. Even under exceptions that permit mailing, these shipments must be entered in a face-to-face transaction with Postal Service retail or business mail acceptance personnel. Under no circumstances are cigarettes, smokeless tobacco, or ENDS eligible for carrier-based collection methods.

Carriers must refuse acceptance of any package presented by a customer, via Pickup on Demand or Package Pickup, in a mailbox or collection box, or at an Approved Shipper– or contractor-operated location, if the carrier knows or has reasonable cause to believe that the package contains cigarettes, smokeless tobacco, or ENDS.

If a carrier inadvertently accepts such a package and identifies it as such later, the item is nonmailable and must generally be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

Frequently Asked Questions

For All Audiences

1. ***When does the law about ENDS mailings take effect?***
   ENDS are generally nonmailable effective October 21, 2021.

2. ***Can people still order cigarettes, smokeless tobacco, or ENDS online?***
   There is no general ban on online sales of cigarettes, smokeless tobacco, or ENDS. However, such items cannot be shipped by U.S. mail from online vendors, except within Alaska and within Hawaii. In all other situations (including shipments into or out of Alaska or Hawaii), customers must ensure that the items will not be shipped by U.S. mail. Non-postal carrier options may be available; the Postal Service cannot advise what restrictions might apply for other carriers.

3. ***Why is the Postal Service making cigarettes, smokeless tobacco, and ENDS nonmailable?***
   The Postal Service is implementing mailability restrictions mandated by Congress and the President. Specifically, in 2010, the Prevent All Cigarette Trafficking Act (or PACT Act) was enacted, which made cigarettes and smokeless tobacco nonmailable, with some exceptions. Legislation enacted in December 2020 made ENDS subject to the PACT Act as well.

4. ***What are electronic nicotine delivery systems or ENDS?***
   Electronic nicotine delivery systems (ENDS) are defined in the law as "any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device." Note that, despite the name, ENDS are not limited to products containing or intended to be used with nicotine. Examples include e-cigarettes, e-hookahs, e-cigars, vape pens, and electronic pipe. For mailability purposes, ENDS also include any component, liquid, part, or accessory of ENDS, regardless of whether it is shipped separately from the device.

5. ***If the PACT Act talks about "electronic nicotine delivery systems," why can't people mail ENDS liquids that don't contain nicotine and products that aren't used with nicotine?***
   Although Congress used the phrase "electronic nicotine delivery systems," the law makes clear that the relevant products are not limited to those containing or used with nicotine. Instead, for mailability purposes, ENDS include any electronic device that, through an aerosolized solution, delivers nicotine, flavor, *or any other substance* to the user inhaling from the device, as well as parts, liquids, components, and accessories for such devices (even if shipped separately).

6. ***Are <u>all</u> cigarettes, smokeless tobacco, and ENDS nonmailable now?***

These items are nonmailable under most circumstances. They are always nonmailable in inbound and outbound international mail; overseas military and diplomatic mail (i.e., mail to, from, and between APO/FPO/DPO addresses); and mail to, from, and between the Federated States of Micronesia, the Republic of the Marshall Islands, and Palau. For other types of domestic shipments, cigarettes, smokeless tobacco, and ENDS are nonmailable unless the sender and addressee have met various conditions and requirements. Among other things, except for shipments entirely within Alaska or within Hawaii, cigarettes, smokeless tobacco, and ENDS cannot be mailed to consumers as part of a sales transaction. See Chapter 47 of Publication 52, *Hazardous, Restricted, and Perishable Mail* (Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems).

7. ***If a postal customer qualifies for an exception allowing the shipment of cigarettes, smokeless tobacco, or ENDS, is there an age restriction for the mailer or addressee?***
   The federal minimum age to purchase cigarettes, smokeless tobacco, and ENDS is 21, although state and local governments may set higher minimum ages. In most instances where cigarettes, smokeless tobacco, and ENDS may be mailable, federal law requires verification of the mailer and recipient's age as a condition for accepting and delivering the package.

8. ***If a postal customer qualifies for an exception allowing the shipment of cigarettes, smokeless tobacco, or ENDS, can the customer use Package Pickup or Pickup on Demand service? What about leaving the package in the mailbox, a collection box, or Post Office lobby drop?***
   No. All such shipments must be tendered in face-to-face transactions with postal employees at a retail or business mail acceptance location. They are not allowed to be tendered through any other method. Federal law requires the Postal Service to verify that the sender and addressee qualify for an exception, and that cannot be done without a face-to-face transaction to review the customer's authorization.

9. ***If a postal customer qualifies for an exception allowing the shipment of cigarettes, smokeless tobacco, or ENDS, why does the customer have to use only certain combinations of services (Priority Mail Express or Priority Mail, plus an Adult Signature service and, in some cases, Return Receipt service)?***
   Federal law requires that all shipments of cigarettes, smokeless tobacco, or ENDS (except for intrastate shipments in Alaska or Hawaii) be sent with a service that provides tracking and confirmation of delivery, and that the Postal Service verify the recipient's age, employment, and/or identity as a condition for delivery. The postal products that meet these criteria are Priority Mail Express with Adult Signature service and Priority Mail with Adult Signature service. Regarding return receipts, see FAQ #12.

10. May postal customers send or receive cigarettes, smokeless tobacco, or ENDS in international mail?

No. Cigarettes, smokeless tobacco, and ENDS are prohibited in inbound and outbound international mail. Postal customers should not solicit mailings of such items from foreign businesses.

11. Can postal customers in the United States send cigarettes, smokeless tobacco, or ENDS to overseas U.S. military or diplomatic locations, or vice versa?

No. The PACT Act's exceptions require verification of age, employment, and/or identity at the point of acceptance and delivery. The postal services that enable fulfillment of these requirements—Adult Signature Required and Adult Signature Restricted Delivery—are not currently available for items mailed to or from APO/FPO/DPO addresses. Because verification cannot be performed, the law does not permit cigarettes, smokeless tobacco, or ENDS to be mailed to or from these addresses.

12. Why do business or government mailers mailing cigarettes, smokeless tobacco, or ENDS have to make their return receipts returnable to the PCSC rather than the sender?

By law, the Postal Service must collect and maintain records showing sender and recipient information for each shipment sent by business or government mailers (other than within Alaska or within Hawaii). The use of return receipts returnable to the PCSC provides a centralized way for the Postal Service to maintain records of these shipments.

13. Why do business and government mailers have to get advance approval from the PCSC to send cigarettes, smokeless tobacco, or ENDS?

By law, the Postal Service must verify that business and government shippers and addressees meet various statutory criteria before mailing cigarettes, smokeless tobacco, or ENDS. The Postal Service has determined that a centralized approval process is more efficient and convenient for customers than requiring them to provide complete eligibility documentation for every shipment.

14. Can manufacturers, related businesses, or government agencies mail smokeless tobacco and ENDS as part of a consumer test?

No, unless the shipping location and addressee are both in Alaska or both in Hawaii. In all other situations (including shipments into and out of Alaska or Hawaii), the law restricts consumer testing mailings to combustible cigarettes only.

15. If a postal customer has complied with the PACT Act rules for mailing ENDS, is there anything else that the customer should know?

Yes. Some ENDS products contain or are intended for use with federally controlled substances (including marijuana and marijuana derivatives),

regardless of whether those products are legal in the sender or addressee's state. Such products may be prohibited or restricted because they are controlled substances, regardless of the mailer's compliance with PACT Act rules. Refer customers to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Chapter 453 (Controlled Substances and Drugs).

In addition, some shipments of ENDS liquids (particularly liquids containing nicotine) and batteries may qualify as hazardous material/dangerous goods to which special labeling and packaging requirements apply. Refer customers to Publication 52, *Hazardous, Restricted, and Perishable Mail*, part 3 (Hazardous Materials), Chapters 348 (Corrosives) and 349 (Miscellaneous Hazardous Materials); part 4 (Restricted Matter), Chapter 453 (Controlled Substances and Drugs); and part 6 (International Mail).

Postal customers may also need to comply with applicable state and local laws.

16. Why is the Postal Service regulating cigarettes, smokeless tobacco, and ENDS? Isn't that the job of the Food and Drug Administration (FDA)?

The Postal Service is implementing mailability restrictions enacted by Congress and the President. See FAQ #3. These restrictions affect whether and how certain products can be sent through the U.S. postal system. By contrast, the FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect the public health, regardless of any particular distribution method used for such products. The Postal Service and FDA rules are based on different laws that vary in scope. Either or both sets of laws (as well as other laws) may bear on a particular product and situation. Mailers are responsible for ensuring that they are compliant with all applicable laws, including mailing rules and other agencies' regulations.

17. Whom can we contact with questions about cigarettes, smokeless tobacco, or ENDS mailings?

For general questions from individual customers, contact the local Post Office or email ProductClassification@usps.gov.
For business and government customers with questions about applications and eligibility letters, email MDA@usps.gov.
For all other questions from business or government customers, email PCSC@usps.gov.

For customers who believe their mailings to have been wrongly rejected, contact the PCSC (PCSC@usps.gov).

For questions about whether specific products are restricted as cigarettes, smokeless tobacco, or ENDS, contact the Bureau of Alcohol, Tobacco, Firearms and Explosives, with a copy to the PCSC:

Bureau of Alcohol, Tobacco, Firearms and Explosives
99 New York Avenue NE
c/o 90 K St. NE, Ste. 250
Washington, DC 20226

Pricing and Classification Service Center
90 Church St., Ste. 3100
New York, NY 10007-2951

For Postal Service Personnel

18. ***We are aware that retailers are sending cigarettes, smokeless tobacco, and ENDS sold to consumers by U.S. mail. Is this legal?***
It is only legal for intra-Alaska and intra-Hawaii shipments. In any other circumstance (including shipments from those states to other locations and vice versa), cigarettes, smokeless tobacco, and ENDS cannot be sold to consumers by mail. Refer customers to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Chapter 47 (Cigarettes, Smokeless Tobacco, and Electronic Nicotine Delivery Systems). Contact the Postal Inspection Service about the suspected unlawful mailing activity.

19. ***A local customer runs a business involving cigarettes, smokeless tobacco, or ENDS, and they want to make sure that they can continue using the mail to move inventory to and from other businesses in the industry. Can they use the mail for this?***
Generally, yes, but the sending business must first apply to the PCSC for authorization to ship to the receiving businesses. Refer the customer to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.3 (Exception for Business/Regulatory Purposes), for more information about mailing requirements.

20. ***A business mailer has presented us with a letter from the PCSC authorizing mailings of cigarettes, smokeless tobacco, or ENDS at our installation and seeks to mail containers using Priority Mail Express with Adult Signature service or Priority Mail with Adult Signature service. What else do they need to do?***
See Publication 52, *Hazardous, Restricted, and Perishable Mail* Sections 473.3 (Exception for Business/Regulatory Purposes), 473.5 (Consumer Testing Exception), and 473.6 (Public Health Exception), and the Acceptance Procedures contained in this Field Information Kit.

21. ***Marijuana has been decriminalized or legalized at the state or local level where I live. A customer has a business selling marijuana-based ENDS products, and they want to know whether they can still get deliveries from suppliers through the mail and/or use the mail to send their products to other businesses. What should I tell them?***
See FAQ #15. While other ENDS products might be mailable between businesses under certain conditions, this does not apply if the product qualifies as a controlled substance or drug paraphernalia under federal law. At this time, marijuana and most marijuana derivatives are still nonmailable controlled

substances, and ENDS intended for use with such substances can qualify as nonmailable drug paraphernalia. The federal laws governing use of the mails, including intrastate or local mailings, apply regardless of whether a product is legal under state or local law. The only exceptions are for hemp and hemp-based products (including cannabidiol (CBD)), if those products contain no more than 0.3 percent tetrahydrocannabinol (THC) by weight. Refer customers to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Chapter 453 (Controlled Substances and Drugs). Contact the Postal Inspection Service if you believe that a mailing contains controlled substances or drug paraphernalia, or that a customer is engaging in such mailings.

22. An individual adult customer in the United States wants to mail cigarettes, smokeless tobacco, or ENDS to a friend or relative in the United States. Is this allowed?

Generally, yes, if the shipment is not being sent for commercial purposes and the sender complies with a number of requirements prior to mailing. Refer the customer to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.4 (Exception for Certain Individuals), for more information about mailing requirements. The customer may also need to comply with applicable state and local laws.

23. An individual adult customer wants to mail cigarettes, smokeless tobacco, or ENDS to the manufacturer for warranty service or as part of a product recall. Is this allowed?

Generally, yes, if the sender is not receiving any value back from the manufacturer beyond what was paid for the item, plus return shipping, and the sender complies with a number of requirements prior to mailing. Refer the customer to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.4 (Exception for Certain Individuals), for more information about mailing requirements. The customer may also need to comply with applicable state and local laws.

24. An individual adult customer wants to mail used ENDS parts to a business that recycles used products. Is this allowed?

Generally, yes, if the sender is not receiving any value in exchange for the used goods and complies with a number of requirements prior to mailing. Refer the customer to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.4 (Exception for Certain Individuals), for more information about mailing requirements. The customer may also need to comply with applicable state and local laws.

25. A local Approved Shipper or Contract Postal Unit has customers who are mailing, or who are asking about mailing, cigarettes, smokeless tobacco, or ENDS. Is this okay?

No. See FAQ #8.

26. I found a package labeled as cigarettes, smokeless tobacco, or ENDS in a customer mailbox, collection box, or Postal Service lobby drop. What should I do with it?

See FAQ #8. If such a shipment is found in a customer mailbox, it must be refused. If it is found in a collection box or lobby drop, or if it is identified after retrieval from a customer mailbox, it generally must be returned to sender with a report to the Pricing and Classification Service Center. See MI [NUMBER] for further instructions.

27. One of our customers wants to schedule Pickup on Demand or Package Pickup of a shipment containing cigarettes, smokeless tobacco or ENDS. What should we do?

See FAQ #8. Advise the customer to present the package at the Post Office or a BMEU, because Pickup on Demand and Package Pickup service are not available for shipments containing cigarettes, smokeless tobacco or ENDS.

28. We are in Alaska or Hawaii and have customers that send groceries, including cigarettes, smokeless tobacco, and ENDS, through the mail. What should we tell them?

These customers should be advised that such shipments are mailable to customers within your state (AK and HI only). Refer the customer to Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments), for more information about mailing requirements.

29. We are in Alaska or Hawaii and are seeing packages marked with "INTRASTATE SHIPMENT OF" followed by cigarettes, smokeless tobacco, or ENDS. What are we supposed to do with these?

Shipments with this marking should be delivered as usual, if both the return and delivery addresses are within your state (AK and HI only).

For Individual Customers

30. I use ENDS products to help me quit smoking or for therapeutic reasons. Can I still get these products through the mail?

No, unless you are in Alaska or Hawaii and purchasing from a vendor located in and shipping from your state. In all other situations, the vendor can no longer use the mail to ship ENDS products that you buy. While the Food and Drug Administration (FDA) may have authorized the marketing of various ENDS products, it has not approved any ENDS products specifically for tobacco-cessation or therapeutic purposes. Without such FDA approval, individuals' uses, motivations, or beliefs regarding ENDS products have no effect on whether they are mailable.

31. I want to mail cigarettes, smokeless tobacco, or ENDS back to a manufacturer for warranty service or as part of a product recall. Is this allowed?

Generally, yes, if you are not receiving any value back beyond what was paid for the item, plus return shipping, and you comply with all applicable requirements prior to mailing. See Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.4 (Exception for Certain Individuals), for more information about mailing requirements. You may also need to comply with applicable state and local laws.

32. I want to mail used ENDS parts to a business that recycles used products. Is this allowed?

Generally, yes, if you are not receiving any value in exchange for the used goods and you comply with all applicable requirements prior to mailing. See Publication 52, *Hazardous, Restricted, and Perishable Mail*, Section 473.4 (Exception for Certain Individuals), for more information about mailing requirements. You may also need to comply with applicable state and local laws.

33. My carrier had a package of cigarettes, smokeless tobacco, or ENDS that I was expecting, but asked me for photo identification before giving it to me. Is this required?

Yes. Federal law requires the Postal Service to verify that recipients of packages containing cigarettes, smokeless tobacco, or ENDS are eligible adults.

34. I am planning to mail cigarettes, smokeless tobacco, or ENDS to a friend of mine (also in the United States) as a gift. What do I need to do?

If you and your friend are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.4 (Exception for Certain Individuals). Other restrictions may apply to ENDS products: see FAQ #15. You may also need to comply with applicable state and local laws.

For Business Customers

35. We are a company with all applicable licenses. We mail cigarettes, smokeless tobacco, and/or ENDS to other businesses and to regulatory agencies. What must we do to mail these products to other businesses in the industry and to government agencies?

If the shipping location and the recipient are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.3 (Exception for Business/Regulatory Purposes). Other restrictions may apply to ENDS products: see FAQ #15.

36. My business ships cigarettes, smokeless tobacco, or ENDS products to retailers. Are they eligible for the "business/regulatory purposes" exception?

Yes, retail businesses are engaged in "distribution" and therefore may qualify for the "business/regulatory purposes" exception, so long as they meet the other requirements for the exception. You may also need to comply with applicable state and local laws.

37. My company ships cigarettes, smokeless tobacco, or ENDS products to other offices within the company. Can we use the "business/regulatory purposes" exception for that?

Yes, if your company meets the requirements for the exception. You may also need to comply with applicable state and local laws.

38. I see that I need to list planned mailing locations in my "business/regulatory purposes" application. Do I have to go to the Post Office to mail everything? I'm worried that they will be overwhelmed.

No. While you must tender your mailings in a face-to-face transaction with a Postal Service employee, you can do so at a Postal Service business mail acceptance location, as well as at a Post Office or other Postal Service retail location.

39. My business has sent a "business/regulatory purposes" application to the PCSC. How long will it take to be processed?

Application processing time can depend on many factors, such as the volume of applications, their complexity, and the thoroughness of documentation that applicants provide up front. Due to the variability of all these factors, it is impossible to predict how long processing may take for any individual application.

40. I run a small business and have sent a "business/regulatory purposes" application to the PCSC. Will I have to wait until bigger businesses' applications are processed, even if they sent them later?

Applications are generally processed on a first-come, first-served basis. The timing of applications, not the size of a business, determines the order in which applications are processed.

41. What if one of my approved recipients has changed, or I need to mail to a business or governmental entity that isn't listed on my approval letter?

Use PS Form 4615 or PS Form 4615-E, along with Worksheets 4615-EM and 4615-ER, to provide any updated or new information to supplement your existing application. Be sure to provide complete documentation to show that your company and each addressee has all applicable federal, state, and/or local licenses and permits to engage in the relevant business operations.

42. I'm expecting a shipment of cigarettes, smokeless tobacco, or ENDS from a customer or a business in the industry. I received a notice saying that I

should retrieve a package at the Post Office because our business was closed when the carrier arrived. Why?
By law, shipments of cigarettes, smokeless tobacco, or ENDS can be delivered only upon verifying in a face-to-face transaction that the addressee is above age 21 and, in the case of the "business/regulatory purposes" exception, that the recipient is an employee of the addressee. You can retrieve the package at the Post Office or request redelivery through usps.com. If you wish to pick it up at the Post Office, take the PS Form 3849 that you received to the Post Office, along with government-issued photo identification and proof of employment. Once a Postal Service employee has verified your age and employment status, you will need to sign for receipt of delivery and in the appropriate block of the return receipt.

43. ***Is there a quantity or frequency limitation under the "business/regulatory purposes" exception?***
No.

44. ***We need to send replacement ENDS products or parts to customers seeking warranty service. Can we send the products or parts through the mail?***
Generally, no. It is legal only for intra-Alaska and intra-Hawaii shipments. In any other situation (including into or out of Alaska or Hawaii), cigarettes, smokeless tobacco, and ENDS cannot be mailed to consumers for replacement or repair.

45. ***Some of our customers use ENDS products to help them quit smoking or for therapeutic reasons. Can we use the mail to send ENDS products to these customers?***
No, unless you are in Alaska or Hawaii and shipping to a customer located in your state. In all other situations, you can no longer use the mail to ship ENDS products. While the Food and Drug Administration (FDA) may have authorized the marketing of various ENDS products, it has not approved any ENDS products specifically for tobacco-cessation or therapeutic purposes. Without such FDA approval, individuals' uses, motivations, or beliefs regarding ENDS products have no effect on whether they are mailable.

46. ***My business is in Alaska or Hawaii. Doesn't the PACT Act have an exception that allows me to send cigarettes, smokeless tobacco, or ENDS without having to get PCSC approval? And can't I receive them from other businesses without having to show identification and sign for delivery?***
Those things are true only for intra-state shipments, so long as you include a special marking on your shipments. If you are shipping to an out-of-state business, then you need to get PCSC approval and meet the other conditions under the "business/regulatory purposes" exception. The same is true for shipments that you receive from out of state.

47. My business needs to test ENDS products in order to get government approvals. Can I mail them to individual testers?

No, unless you are in Alaska or Hawaii and shipping to testers located in your state. Although the PACT Act has an exception for consumer testing, it applies only to combustible cigarettes, not ENDS products. See FAQ #14. You can still mail ENDS products to other businesses that perform testing, investigation, and research, so long as all the requirements for the "business/regulatory purposes" exception are met.

48. I work at a laboratory that researches the health effects of ENDS products. Can I mail ENDS to individual testers as part of my research?

No, unless you are in Alaska or Hawaii and shipping to testers located in your state. Although the PACT Act has an exception for consumer testing, it applies only to combustible cigarettes, not ENDS products. See FAQ #14.

49. We are a cigarette manufacturer, or an agent of a cigarette manufacturer, with all applicable licenses. We're conducting a consumer testing program. Can we send samples to testers through the mail?

Generally, yes. If the shipping location and the recipient are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.5 (Consumer Testing Exception). You may also need to comply with applicable state and local laws.

For Government Customers

50. My agency needs to send cigarettes, smokeless tobacco, or ENDS to another government agency, or to another office of my agency. Can we send them through the mail?

No, unless both agencies' addresses are within Alaska or within Hawaii. The PACT Act allows certain mailings between businesses and government agencies and, for combustible cigarettes only, between federal agencies and individual test subjects, but not between or within government agencies.

51. My agency has regulatory jurisdiction over foreign companies that need to send product samples of cigarettes, smokeless tobacco, or ENDS to my agency. Can they send them through the mail?

No. Cigarettes, smokeless tobacco, and ENDS cannot be mailed to the U.S. from abroad.

52. My agency needs to send samples of cigarettes, smokeless tobacco, or ENDS to a business, laboratory, or government agency in another country. Can we send them through the mail?

No. Cigarettes, smokeless tobacco, and ENDS cannot be mailed internationally.

53. My agency has regulatory jurisdiction over U.S. companies that need to send product samples of cigarettes, smokeless tobacco, or ENDS to my agency. Can they send them to us through the mail?

Generally, yes. If the shipping location and the recipient are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.3 (Exception for Business/Regulatory Purposes). Other restrictions may apply to ENDS products: see FAQ #15.

54. Can my agency use the mail to return a product sample of cigarettes, smokeless tobacco, or ENDS to a regulated business?

Generally, yes. If the shipping location and the recipient are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.3 (Exception for Business/Regulatory Purposes). Other restrictions may apply to ENDS products: see FAQ #15.

55. Can individuals in the U.S. use the mail to send samples of cigarettes, smokeless tobacco, or ENDS to my agency?

Yes. Individuals are allowed to send infrequent, lightweight packages of cigarettes, smokeless tobacco, or ENDS for noncommercial purposes, including to government agencies. Individuals in Alaska or Hawaii can also mail those products without restriction to government agencies located in their state. The individuals will need to comply with all applicable requirements in Publication 52, *Hazardous, Restricted, and Perishable Mail*, Sections 473.2 (Intra-Alaska and Intra-Hawaii Shipments) and 473.4 (Exception for Certain Individuals). Other restrictions may apply to ENDS products: see FAQ #15.

56. My agency requires businesses to test ENDS products in order to get government approvals. Can U.S. businesses mail their products to individual testers?

No, unless the business or its agent is located in Alaska or Hawaii and shipping to testers located in the same state. Although the PACT Act has an exception for consumer testing, it applies only to combustible cigarettes, not ENDS products. See FAQ #14. However, a regulated business can mail ENDS products to other businesses that perform testing, investigation, and research, so long as each of the businesses meets the criteria for the "business/regulatory purposes" exception. Other restrictions may apply to ENDS products: see FAQ #15.

57. My agency performs consumer testing to evaluate the health effects of ENDS products. Can we mail ENDS to individual testers in the U.S.?
No, unless you are in Alaska or Hawaii and shipping to testers located in your state. See FAQ #14.

58. My agency works with non-governmental research laboratories that perform consumer testing to evaluate the health effects of ENDS products. Can our partner laboratories mail ENDS to individual testers in the U.S.?
No, unless the laboratory is in Alaska or Hawaii and shipping to testers located in the same state. See FAQ #14.

59. My agency performs consumer testing to evaluate the health effects of cigarettes. Can we mail cigarettes to individual testers in the U.S.?
Generally, yes. If the shipping location and the recipient are both in Alaska or both in Hawaii, follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Sections 473.5 and .6 (Consumer Testing Exception; Public Health Exception). Note that the "public health" exception is available only to federal agencies, and not to state or local government agencies.

60. My agency requires businesses to test cigarettes in order to get government approvals. Can U.S. businesses mail cigarettes to individual testers?
Generally, yes. If the shipping location and the recipient are both in Alaska or both in Hawaii, businesses should follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.2 (Intra-Alaska and Intra-Hawaii Shipments). In all other situations (including shipments into or out of Alaska or Hawaii), businesses should follow the instructions in Publication 52, *Hazardous, Restricted and Perishable Mail*, Section 473.5 (Consumer Testing Exception). Note that the "consumer testing" exception is restricted to cigarette manufacturers and their agents.

61. My agency works with non-governmental research laboratories that perform consumer testing to evaluate the health effects of cigarettes. Can our partner laboratories mail cigarettes to individual testers in the U.S.?
No, unless the cigarettes are being shipped entirely within Alaska or within Hawaii. See FAQ #14. In all other situations, the "consumer testing" and "public health" exceptions permit shipments only by cigarette manufacturers, their agents, and federal agencies, but not by independent research laboratories. See Publication 52, *Hazardous, Restricted and Perishable Mail*, Sections 473.5 and .6 (Consumer Testing Exception; Public Health Exception).

— Customer Service Standardization,

Delivery and Post Office Operations, 10-21-21

PACT ACT – Job Aid

Mailable Cigarettes, Smokeless Tobacco and ENDS: Acceptance Rules

Exception	Type of Mailer	Priority Mail Express/Priority Mail Required?	Return Receipt to PCSC Required?	Requires Pre-Authorization?	Photo ID Required?	Special Marking Required?	Quantity Limit?	Frequency Limit?
Noncontiguous States (AK, HI)	Any	No	No	No	No	Yes [1]	No	No
Business/Regulatory	Business or Federal/State Government	Yes	Yes	PCSC letter required	No	Yes [2]	No	No
Certain Individuals	Individual only	Yes	No	No	Yes, sender at least minimum purchase age[5]	Yes [3]	≤10 oz.	≤10 mailings / 30 days
Consumer Testing/Public Health (cigarettes only)	Business or Federal Government	Yes	Yes	PCSC letter required	No	Yes [4]	≤12 packs of cigarettes (240 cigarettes)	≤1 mailing / 30 days per addressee

[1] INTRASTATE SHIPMENT OF [CIGARETTES/SMOKELESS TOBACCO/ENDS] (whichever bracketed term applies)
[2] [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING – DELIVER ONLY TO EMPLOYEE OF ADDRESSEE [BUSINESS/AGENCY] UPON AGE VERIFICATION (whichever bracketed terms apply)
[3] PERMITTED [CIGARETTE/SMOKELESS TOBACCO/ENDS] MAILING – DELIVER ONLY UPON AGE VERIFICATION (whichever bracketed term applies)
[4] PERMITTED CIGARETTE MAILING – DELIVER ONLY TO ADDRESSEE UPON AGE VERIFICATION
[5] Minimum legal age to purchase cigarettes, smokeless tobacco, and ENDS is age 21 in all states and U.S. territories and possessions, or any higher age that a state or municipality imposes.

Mailable Cigarettes, Smokeless Tobacco and ENDS: Delivery Rules

Exception	Type of Recipient	Adult Signature Required?	Photo ID Required?	Signature Requirement	Recipient Restriction
Intra-Alaska/Intra-Hawaii	Any	No	No	None	N/A
Business/Regulatory	Business or Federal/State Government	Yes	Yes, recipient at least minimum purchase age[5]	Sign for receipt of mailpiece and PS Form 3811	Only deliver to verified employee of named business or government addressee
Certain Individuals	Any	Yes	Yes, recipient at least minimum purchase age[5]	Sign for receipt of mailpiece	Deliver to addressee or adult agent
Consumer Testing/Public Health (cigarettes only)	Individual only	Yes (Adult Signature Restricted Delivery only)	Yes, recipient at least 21 years old	Sign receipt of mailpiece and PS Form 3811	Deliver only to named addressee

Stand-Up Talk

July 2021

Prevent All Cigarette Trafficking (PACT) Act

The PACT Act has been in effect since June 29, 2010. *(See Postal Bulletin 22287 in the archives).* The Act stipulates that cigarettes and smokeless tobacco — including roll-your-own cigarettes — are nonmailable matter for both inbound and outbound international mail. These products are prohibited regardless of *International Mail Manual* (IMM) individual country listings.

The PACT Act requires that USPS not accept or transmit any package from a mailer that is known — or suspected — to have contents as described. Actionable information includes any statement on a publicly available website, social media, or advertisement, or statements from persons indicating they will mail these prohibited items in exchange for payment.

The Inspection Service works with the Bureau of Alcohol, Tobacco, Firearms and Explosives; U.S. Customs and Border Protection; and other stakeholder agencies to identify and stop mailers from using USPS to ship this prohibited content.

TAKE ACTION

Set aside all international packages you have reasonable cause to believe contain content prohibited by the PACT Act. Reasonable cause is created when:

- Visual observation can be made of the contents from translucent or damaged coverings or packaging.
- The content description on a customs form is "cigarettes" or "gift."
- The packaging is lightweight and in the approximate dimensions of 12 inches by six inches by four inches.
- The brand name or a description is visible on the exterior packaging.

Stage identified packages in a designated area for the USPIS International Mail Security team. For non-International Service Center (ISC) locations, placard and dispatch containers of these packages to the attention of USPIS International Mail Security at the upstream ISC.

For additional information see Publication 52, section 472.1: Nonmailable cigarettes and smokeless tobacco deposited in the mailer are subject to seizure and forfeiture.

# # #