those injuries over time, inaction by voluntary standards organizations to address the blade-contact hazard effectively, and the high societal costs of these injuries, the Commission believes a performance requirement is necessary to reduce the unreasonable risk of blade-contact injuries on all table saws.

(2) *Later effective date.* The proposed rule would require an effective date that is 36 months after the final rule is published in the **Federal Register**. An effective date later than 36 months could further reduce the impact of the rule on manufacturers because it would allow them additional time to benefit from the development of new AIM technologies by diverse suppliers, spread the costs of developing or negotiating for the rights to use AIM technology, modify the design of their table saws to incorporate the AIM technology, and retool their factories for production. However, almost certainly, a later effective date would also delay the ubiquitous availability of table saws with AIM technology into the market. Because we anticipate that a longer period will not be necessary for commercial availability of AIM technologies from diverse suppliers, the Commission finds that a 36-month effective date from the issuance of a final rule is an appropriate length of time.

(3) *Exempt contractor and cabinet saws, or industrial saws, from a product safety rule.* The Commission considered whether to exempt certain types of saws commonly used by professional, commercial, or industrial users, based on their size, weight, power, or electrical specifications. Based on the severity of injuries and recurring hazard patterns of blade-contact injuries, coupled with the high societal costs of these injuries, though, a performance requirement is necessary to reduce the unreasonable risk of blade-contact injuries on all table saws. Moreover, there is no clear dividing line between consumer and professional saws.

(4) *Limit the applicability of the rule to some, but not all, table saws.* The Commission considered limiting the scope of the rule to a subset of table saws to allow manufacturers to produce both table saw models with AIM technology, and models without AIM technology. However, based on the severity of injuries and recurring hazard patterns of blade-contact injuries, coupled with the high societal costs of these injuries, the Commission finds that a performance requirement is necessary to reduce the unreasonable risk of blade-contact injuries on all table saws.

(5) *Information and education campaign.* The Commission considered whether to conduct an information and education campaign informing consumers about the dangers of blade-contact hazards, and the benefits of AIM technology. Although such a campaign could help inform consumers, without a performance requirement this approach would not be sufficient to address the unreasonable risk of blade-contact injuries on table saws.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–23898 Filed 10–31–23; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0179]

RIN 0910–AI75

Prior Notice: Adding Requirement To Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-Refusal and Post-Hold Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its prior notice regulations to add a requirement that the prior notice for articles of food arriving by international mail include the name of the mail service and a mail tracking number and add a requirement that prior notice and food facility registration information be submitted within a certain timeframe, after certain notices of refusal or hold have been issued (''post-refusal'' and ''post-hold'' submission). We are also proposing certain technical changes, including those that reflect expanded capabilities of the Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS) and the Prior Notice Systems Interface (PNSI). These amendments, if finalized, will improve program efficiency and better enable FDA to protect the U.S. food supply and public health.

DATES: Either electronic or written comments on the proposed rule must be submitted by January 30, 2024. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by January 2, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 30, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Comments

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0179 for ''Information Required in Prior Notice of Imported Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, at 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on the information collection under the PRA to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.''

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Peter Ajuonuma, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 301–796–2277, *Peter.Ajuonuma@fda.hhs.gov*.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–706–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA uses prior notice information to, among other things, determine what products should be inspected upon arrival into the United States. The proposed rule, if finalized, would: (1) amend § 1.281(b)(10) (21 CFR 1.281(b)(10)) to add a requirement for people submitting prior notice for articles of food arriving by international mail to provide the name of the mail service and the mail tracking number; [1] (2) amend §§ 1.283 and 1.285 (21 CFR 1.283 and 1.285) to add a requirement that prior notice be submitted within 10 calendar days from the date a notice of refusal or hold was issued and that food facility registration be submitted within 30 calendar days from the date a notice of refusal or hold was issued; and (3) make certain technical amendments.

To effectively carry out its responsibility to detect food articles offered for import that are adulterated or pose a public health risk, FDA must be able to identify and inspect food items that are imported by international mail. Receiving the name of the mail service and a mail tracking number for articles of food arriving by international mail would enable FDA to better coordinate with the U.S. Postal Service (USPS), U.S. Customs and Border Protection (CBP), and other Agencies, to track and inspect articles that have been identified as a possible bioterrorism risk. Currently, FDA does not receive the name of the mail service or tracking numbers for articles of food arriving by international mail. This makes it difficult for FDA to stop articles from being delivered to U.S. recipients that FDA believes pose a bioterrorism risk. Having the name of the mail service and tracking numbers for articles of food arriving by international mail would help FDA better plan its operations and stop such articles from being delivered.

Many foods are regularly imported by mail, and in FDA's experience, these foods can present similar risks to the U.S. food supply as other imported foods. Further, FDA's presence at international mail facilities supports that people are increasingly using the mail system to import foods, including foods that could pose a significant risk to public health. The use of the mail system to import food highlights the need for FDA to have the name of the mail service and tracking number to adequately monitor and refuse or hold specific food shipments.

Additionally, requiring a reasonable timeframe for post-refusal and post-hold submissions of prior notice and food facility registration may reduce the amount of time articles subject to refusal or holds are held at ports of entry, thus reducing associated monetary charges. It would also enable FDA to utilize its resources more effectively by delineating the post-refusal and post-hold submission timeframe. Without a date by which such submissions must be made, FDA has spent longer periods of time (*e.g.,* weeks and months) reviewing multiple replacement non-compliant prior notice or registration submissions.

Finally, regarding the technical changes to the regulations, FDA's PNSI was developed to receive prior notice information for import submissions that could not be accommodated in the Automated Commercial System (ACS), mainly mail and baggage submissions, and prior notice for foods refused under section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)). ACE, ACS's successor system, can now accommodate such submissions. Therefore, we also propose to amend § 1.280(a)(2) (21 CFR 1.280(a)(2)) to remove the requirement that prior notice of foods arriving by international mail be submitted through FDA PNSI. If finalized as proposed, prior notice for food arriving by international mail can be submitted through the PNSI or through the U.S. CBP ABI/ACE/ITDS. Further, we propose to amend § 1.281(a)(5)(iv),

[1] Note that FDA intends to consider enforcement discretion when there is no prior notice if the food is offered for import for non-commercial purposes with a non-commercial shipper. See Compliance Policy Guide ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' announced in the **Federal Register** on May 6, 2009 (74 FR 20955).

(b)(4)(iv), and (c)(5)(iv) to cross-reference product coding requirements for infant formula under § 106.80 (21 CFR 106.80). These regulations currently cross-reference § 106.90 (21 CFR 106.90) when referring to lot or code number requirements for infant formula. Section 106.90 establishes requirements related to current good manufacturing practice, while § 106.80 establishes product coding requirements for infant formula. Therefore, if finalized as proposed, § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) will be amended to refer to § 106.80 instead of § 106.90.

B. Summary of the Major Provisions of the Proposed Rule

FDA proposes to amend §§ 1.281(b)(10), 1.283(a)(6) and (c), 1.285(g) and (i), and 1.280(a)(2). Currently, § 1.281(b)(10), which applies to articles arriving by international mail, requires only the submission of the anticipated date of mailing. If this amendment is finalized as proposed, § 1.281(b)(10) will include an additional requirement to submit the name of the mail service and mail tracking number in the prior notice to FDA for food articles arriving by international mail.

Sections 1.283(a)(6) and (c) and 1.285(g) and (i), with few exceptions and if other requirements are met, require an article of food that has been refused under section 801(m) of the FD&C Act (no prior notice or inaccurate prior notice) or held under section 801(l) of the FD&C Act (importation from unregistered foreign facility that is required to register) to be treated as general order merchandise under CBP regulations if no prior notice is submitted or resubmitted, or no registration is provided. However, these sections do not provide a timeframe within which such submissions must be made. If this amendment is finalized as proposed, § 1.283(c)(1) and (2) will require submission or resubmission of prior notice within 10 calendar days from the date the notice of refusal was issued. We believe that 10 days is an appropriate timeframe because it allows time for certain persons who want to file a request for FDA review pursuant to § 1.283(d), to file their request, receive a response of the review decision, and submit or resubmit prior notice if necessary.

In addition, if finalized as proposed, § 1.285(i)(1) will require submission of a valid registration within 30 calendar days from the date a notice of hold was issued. We believe that 30 days is an appropriate timeframe in this context because it allows time to obtain and submit a valid registration if necessary. It also allows time to file a request for FDA review pursuant to § 1.285(j), receive a response of the review decision, and submit or resubmit registration if necessary. If a prior notice is not submitted or resubmitted, or a registration is not provided within the timeframe, these changes will require the article to be dealt with as set forth in CBP regulations relating to general order merchandise. Unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

FDA also proposes to amend § 1.280(a)(2). This regulation currently requires prior notice of articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACE/ITDS, to be submitted through FDA PNSI. At this time, there are no longer any transaction types that cannot be made through ABI/ACE/ITDS. Therefore, this proposed amendment would remove the requirement that only the FDA PNSI be used for the submission of prior notice for articles of food arriving by international mail. Finally, FDA proposes to amend § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) to refer to § 106.80 instead of § 106.90.

C. Legal Authority

Section 801(m) of the FD&C Act directs FDA to issue regulations requiring prior notice to FDA of an article of food that is imported or offered for import into the United States for the purpose of enabling such article to be inspected at ports of entry into the United States. Section 801(l) of the FD&C Act requires that an article of food that is imported or offered for import into the United States and that is from a foreign facility for which a registration has not been submitted to FDA under section 415 of the FD&C Act (21 U.S.C. 350d) be held at the port of entry for the article until the foreign facility is so registered. Additionally, section 701(b) of the FD&C Act (21 U.S.C. 371(b)) authorizes FDA and CBP to prescribe regulations for the efficient enforcement of section 801 of the FD&C Act.[2]

D. Costs and Benefits

We estimate the costs of the proposed rule, as accrued to submitters or transmitters of prior notices to read and understand the rule, and to gather and provide international mail tracking information, to be negligible. The proposed rule, if finalized, would not significantly increase costs to small entities. See the Preliminary Economic Analysis of Impacts for a detailed cost and benefit analysis.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
ABI	Automated Broker Interface.
ACE	Automated Commercial Environment.
CBP	U.S. Customs and Border Protection.
CPG	Compliance Policy Guide.
E.O.	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FSMA	FDA Food Safety Modernization Act.
GMP	Good Manufacturing Practice.
OMB	Office of Management and Budget.
PNSI	Prior Notice System Interface.
USPS	U.S. Postal Service.

III. Background

A. Introduction

FDA proposes to amend the prior notice regulation as follows: (1) amend § 1.281(b)(10) to add a requirement to provide the name of the mail service and mail tracking number for articles of food imported or offered for import by international mail; [3] (2) amend § 1.283(c) to require submission or resubmission of prior notice within 10 calendar days from the date the notice of refusal under section 801(m) of the FD&C Act was issued and § 1.285(i) to require submission of food facility registration within 30 calendar days from the date the notice of hold under section 801(l) of the FD&C Act was issued; and (3) amend § 1.280(a)(2) to remove the requirement that articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ACE,[4] be submitted through FDA PNSI, and amend § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) to cross-reference § 106.80 instead of § 106.90. Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188) added section 801(m) to the FD&C Act and requires FDA to establish regulations requiring the submission of prior notice of food that is imported or offered for import into the United States.

[2] In 2003, the U.S. Treasury Department transferred to the Department of Homeland Security its regulatory authority relating to the requirements for prior notice. See Department of Treasury Order No. 100–16.

[3] The prior notice regulation specifies that ''international mail'' means foreign national mail services and does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service (21 CFR 1.276(b)(8)).

[4] There are no longer any transaction types that cannot be made through ACE.

B. Need for the Regulation

The information in a prior notice enables FDA to target import inspections more effectively, thereby helping to protect our nation's food supply against terrorist acts and other public health emergencies. FDA regulations require that specific information about food articles imported or offered for import into the United States be submitted in advance of arrival of the food.

Currently, FDA does not require submission of the name of the international mail service or the mail tracking number for food articles imported by international mail; therefore, FDA has limited ability to track or locate the movement of food articles imported by international mail, which could pose a public health risk. Receiving the name of the mail carrier and the mail tracking number for food articles imported by international mail would assist FDA in conducting investigations and surveillance operations in response to a food-related emergency. Access to the name of the mail service and the tracking number would also enable FDA to act quickly to identify the affected food articles and prevent contamination of the food supply. It would also help to improve emergency response time, as FDA and other Agencies would be better equipped to identify, alert, and secure those facilities or entities that could be potentially impacted by a bioterrorism incident. Requiring the submission of this information would bolster FDA's efforts to prevent violative and potentially dangerous food shipments from entering the United States at international mail facilities, and also could help FDA to track, identify, inspect, and contain such shipments. With this information available, FDA could better utilize its resources and plan its operations, given its knowledge of the movement, location, and time of the food's arrival to the U.S. port of entry.

Providing the name of the international mail service and the tracking number in the prior notice will also enable FDA to effectively coordinate a quicker response with other Agencies in the event of any suspected act of bioterrorism or public health emergency. For instance, if FDA receives information indicating that a particular international mail package contains a food article that could be affected by a bioterrorist incident or other food-related public health emergencies, FDA alerts CBP and USPS about the food article and the potential risk it may pose. Knowing the tracking number of that suspected contaminated food and the mail service carrier would help FDA, CBP, and USPS to track the origin and location of the international mail. The mail package could then be more easily identified and separated from other foods or incoming mail to safely conduct inspection to determine the degree of risk the article of food poses. This would enable FDA to prevent the article of food from entering the U.S. food supply chain more swiftly.

Moreover, articles of food imported or offered for import without a prior notice or with inadequate prior notice are subject to refusal of admission or hold under section 801(m) of the FD&C Act. Articles of food imported or offered for import from an unregistered foreign food facility that is required to register are subject to being held under section 801(l) of the FD&C Act. If an article of food is refused admission under section 801(m) or held under section 801(l), certain persons may submit a request, within 5 calendar days of the refusal or hold, asking FDA to review whether the article is subject to the prior notice requirements, whether the information submitted in a prior notice is complete and accurate, or whether the facility associated with the article is subject to food facility registration requirements (§§ 1.283(d) and 1.285(j)). Alternatively, submitters or transmitters can attempt to come into compliance by submitting or resubmitting prior notice after refusal of admission (§ 1.283(c)), or by obtaining and providing a registration number for post-hold submissions (§ 1.285(i)). Requests for review under §§ 1.283(d) and 1.285(j) may not be used to submit or resubmit prior notice or obtain a registration number.

Currently, FDA regulations do not require a timeframe within which an article of food must be brought into compliance by submitting or resubmitting prior notice or submitting a registration number if the article of food is refused or held. As a result, when articles of food are refused or held under section 801(m)(1) or section 801(l) of the FD&C Act, they may be refused or held for several weeks while submitters or transmitters submit multiple replacement non-compliant prior notice or registration submissions to be reviewed by FDA. This practice consumes significant amounts of FDA reviewers' time and may lead to importers incurring large demurrage charges (*i.e.,* monetary charges due to a failure of goods to leave port).

C. History of the Rulemaking

The Bioterrorism Act amended the FD&C Act and created the requirement that FDA receive certain information about imported foods before their arrival in the United States. On February 3, 2003, FDA and the Department of Treasury (U.S. Customs Service) [5] issued a joint notice of proposed rulemaking (68 FR 5428), requiring submission to FDA of prior notice of human and animal food that is imported or offered for import into the United States. On October 10, 2003, FDA issued an interim final rule (68 FR 58974) that requires the submission to FDA of prior notice of food, including animal food, that is imported or offered for import into the United States. In 2008, 2011, and 2017, FDA finalized and issued amendments to the prior notice regulation (see 73 FR 66294, November 7, 2008, as amended at 76 FR 25542, May 5, 2011; 82 FR 15627, March 30, 2017) to further improve the implementation of the prior notice requirement.

For articles not arriving by international mail, the prior notice rule requires the submission of anticipated arrival information and planned shipment information to provide FDA with information necessary for planning examinations and communicating with CBP for enforcement and examination purposes (see § 1.281(a)(11) and (17), 68 FR 58974 at 59009 and 59011). Further, FDA requires the identification of the carrier because the information is necessary to enable FDA and CBP to identify the appropriate article of food for inspection or holding when the food arrives in the United States (see § 1.281(a)(16), 68 FR 58974 at 59011). The 2008 final rule added the ability, under § 1.281(a)(11), to submit the tracking number for food articles arriving by express consignment operator or carrier, as part of the anticipated arrival information of the food or planned shipment information (73 FR 66294 at 66297). In the 2017 amendment to the prior notice rule, we removed certain limitations regarding the submission of a tracking number (82 FR 15627 at 15628). In doing so, we reiterated the importance of the tracking number to learn the information that FDA needs to make entry determinations, such as port, date, and time of arrival. In the 2017 amendment, we also eliminated some requirements for submitting prior notice due to the expanded capabilities of ACE, such as the requirement to submit articles that have been refused under section 801(m)(1) of the FD&C Act or subpart I

[5] In March 2003, U.S. Customs Service was subsumed by the newly formed CBP (see Homeland Security Act of 2002, Pub. L. 107–296 (2002)) (*https://www.cbp.gov/about/history#:~:text=On%20March%201%2C%202003%2C%20U.S.,boundaries%20and%20ports%20of%20entry*).

in FDA PNSI. ACE can now accommodate this type of entry and others it previously could not, such as articles of food arriving through international mail and baggage entries. The amendments described in this proposed rule would further align the prior notice rule with requirements that exist for food not arriving by international mail and better reflect ACE's expanded capabilities.

In addition, in the 2003 interim final rule, we stated that under § 1.283(a)(6), if no prior notice, correction (*i.e.,* prior notice resubmission), or request for FDA review is submitted in a timely fashion, following a refusal under section 801(m) of the FD&C Act, the food will be dealt with as set forth in CBP regulations relating to general order merchandise, except that it may only be sold for export or destroyed as agreed to by CBP and FDA (68 FR 58974 at 59020 and 59021). Similarly, we stated that under § 1.285(g), if an article of food is placed under hold under section 801(l) of the FD&C Act and no registration or request for FDA review is submitted in a timely fashion, the food will be dealt with as set forth in CBP regulations relating to general order merchandise, except that it may only be sold for export or destroyed as agreed to by CBP and FDA (68 FR 58974 at 59076).

In the 2008 final rule, we ''made a minor change in the text of § 1.283(a)(6) by replacing the phrase, 'in a timely fashion,' with the phrase, 'in accordance with paragraph (d) [of § 1.283],' to clarify that the timeliness of a request for FDA review is found at paragraph (d) [of that section]. We made a similar change in § 1.285(g)'' (73 FR 66294 at 66370). That change requires requests for FDA review under §§ 1.283(d) and 1.285(j) to be submitted within 5 calendar days of the refusal or hold and removes the requirement that post-refusal and post-hold submissions be submitted in a timely fashion or be subject to any timeframe. However, §§ 1.283(a)(6) and 1.285(g) state that, if an article of food is refused or held under section 801(m) or (l) of the FD&C Act, and no prior notice is submitted or resubmitted, or no registration is provided, the food must be dealt with as set forth in CBP regulations relating to general order merchandise.

It is difficult for FDA to administer these provisions without a requirement for when the prior notice must be submitted or resubmitted or for when registration must be provided. There is currently no uniform and predictable date by which such submissions must be made before the article is treated as CBP general order merchandise. As such, there have been instances where articles are refused or held for prolonged periods of time (*e.g.,* weeks and months) while submitters or transmitters submit multiple replacement non-compliant prior notice or registration submissions that must be reviewed by FDA. This is not an effective use of FDA resources and personnel and can lead to the accumulation of large demurrage charges for those articles that are subject to hold or refusal. This proposed rule would amend such provisions by imposing a timeframe for post-refusal and post-hold submissions.

IV. Legal Authority

We are issuing this proposed rule under section 801(m) of the FD&C Act, which directs FDA to implement a regulation requiring prior notification to FDA of food that is imported or offered for import into the United States; section 801(l) of the FD&C Act, which requires that a food article being imported or offered for import into the United States that is from a foreign facility for which a registration has not been submitted under section 415 of the FD&C Act be held at the port of entry until the foreign facility is so registered; and section 701(b) of the FD&C Act, which authorizes FDA and CBP to jointly issue regulations for the efficient enforcement of section 801 of the FD&C Act.

In the 2003 interim final rule, we stated that the planned shipment information is necessary to ensure the effective enforcement of section 801(m) of the FD&C Act (68 FR 58974 at 59012). The tracking information is considered part of the planned shipment information as it is currently allowed to be submitted under § 1.281(a)(17). In both the 2003 and 2008 final rules, we explained that certain information not explicitly mentioned in section 801(m) of the FD&C Act is required for the efficient enforcement of the Bioterrorism Act (68 FR 58974 at 59001 and 73 FR 66294 at 66340). We now tentatively determine that, for articles of food arriving by international mail, the name of the mail service and the mail tracking number is necessary for the efficient enforcement of section 801(m) of the FD&C Act. Additionally, we tentatively determine that imposing a timeframe on post-refusal and post-hold submissions of prior notice and food facility registration is necessary for the efficient enforcement of sections 801(m) and 801(l) of the FD&C Act.

V. Description of the Proposed Rule

The proposed rule, if finalized, will amend §§ 1.281(b)(10) to require the submission of the name of the mail service and mail tracking number in the prior notice for articles of food sent by international mail. Currently, § 1.281(b)(10) requires only the submission of the anticipated date of mailing. If the proposed rule is finalized, § 1.281(b)(10) will include an additional requirement to submit the name of the international mail service used in mailing the article and the mail tracking number in the prior notice of the article to FDA, for food articles arriving by international mail. We believe international mail packages usually bear tracking numbers that could be used to track the mail or identify its country of origin. We welcome comments regarding any country where a tracking number is not issued for international mail.

The proposed rule will also amend §§ 1.283(a)(6) and (c), and 1.285(g) and (i)(1) to require post-refusal and post-hold submissions of prior notice to be submitted within 10 calendar days and post-refusal and post-hold submissions of registration be submitted within 30 calendar days from the date the notice of refusal or hold was issued. If the prior notice or registration requirements are not met within these timeframes, the article shall be dealt with as set forth in CBP regulations relating to general order merchandise. Unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed. We believe that 30 calendar days is an appropriate timeframe for registration submissions because it gives time to obtain and submit a valid registration, as well as time to file a request for review by FDA and receive a response of the review decision, and to submit the required information, if necessary. However, we are willing to consider other timeframes. Therefore, FDA invites public comment on whether 30 calendar days would be an appropriate timeframe for registration submission or if a different timeframe would be more appropriate. For comments suggesting a timeframe, we request an explanation of the reason.

If finalized, the proposed change to § 1.280(a)(2) will remove the requirement that articles of food arriving by international mail be submitted in FDA PNSI. This change will allow a prior notice submitter to use CBP's ABI/ACE/ITDS as an alternative to FDA PNSI to submit prior notice of articles of food imported or offered for import by international mail.

This proposal would also make technical amendments to § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) to correct a cross-reference in the regulation to § 106.80 instead of § 106.90.

VI. Proposed Effective Date

FDA is proposing that the final rule based on this proposal become effective 30 days after the date of publication in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed change to prior notice requirements would not significantly increase costs to small entities, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This proposed rule would amend existing prior notice regulations to require the submission of tracking information for food articles imported using international mail. To estimate costs and benefits associated with the proposed rule, we assume that the appropriate baseline is the state of the world with current prior notice regulations. We then compare the likely impacts of the proposed rule against this baseline. The costs of the proposed rule, if finalized, accrue to submitters or transmitters of prior notices for reading and understanding the rule and the additional time needed to gather and provide the tracking information. When annualized over a period of 10 years, we estimate these costs range from approximately $0.04 million to $0.50 million at a 3 percent rate of discount. At a 7 percent rate of discount, these costs range from approximately $0.04 million to $0.52 million. Our primary annualized estimates are approximately $0.27 million and $0.28 million at 3 and 7 percent rates of discount, respectively.

We estimate benefits in the form of cost-savings which accrue to transmitters of prior notices and to FDA. These cost-savings range in annualized value from approximately $0.04 million to $0.18 million for both 3 and 7 percent rates of discount. The primary annualized value is $0.09 million for both rates of discount. These estimates are summarized in table 1.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.09	$0.04	$0.18	2021	7	10	
	0.09	0.04	0.18	2021	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.28	0.04	0.52	2021	7	10	
	0.27	0.04	0.50	2021	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Small Business: None. Wages: Growth:							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; OMB Control No. 0910–0520—Revision.

Description: FDA is amending its regulations governing notification requirements for articles of food being imported or offered for import into the United States and is making corresponding changes to the information collection. Specifically, we are revising the data elements required in prior notice notifications under section 801(m) of the FD&C Act to include mail service name and mail tracking number.

FDA intends to use the information to better identify, track, contain, and inspect articles of food sent through international mail that it has reason to believe present a bioterrorism threat or public health concern. We believe having the name of the mail service and the mail tracking number will improve our ability to identify and prevent such food articles from entering the U.S. food supply, as well as reduce challenges associated with locating articles without this information.

Description of Respondents: Persons submitting prior notice for articles of food imported or offered for import into the United States.

Burden: FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Average number of responses per respondent	Total annual responses	Average one-time burden per respondent (in minutes)	Average burden per response (in minutes)	Total annual hours
1.281(b)(10)	5,460	143	781,219	30	4	54,811

Based on 2021 fiscal year data from our Online Reporting Analysis Decision Support System, we estimate that 26,200 persons submit prior notice through PNSI. We assume 5,460, or roughly 20 percent, are importing or offering for import articles of food by international mail. The proposed requirement to submit tracking information applies only to persons importing or offering for import articles of food by international mail. The number of prior notices for international mail entries per respondent per year ranges from 1 to approximately 5,000. The average number of prior notice submissions for international mail entries per person per year is approximately 143. Of the more than 18 million prior notices received by FDA per year, approximately 781,219 are identified as ''mail.''

We estimate a one-time average burden of 30 minutes per respondent to learn the new requirement and coordinate with mail services to establish best practices for receiving and providing the information. In addition to the one-time burden, we estimate an average recurring annual burden of 4 minutes per prior notice mail submission. The one-time total burden for all the 5,460 respondents amounts to 163,800 minutes (5,460 × 30). The total recurring burden for all the 781,219 mail entries is 3,124,876 minutes (781,219 × 4). Therefore, we estimate the average total annual recurring burden in hours to be 54,811 (163,800 + 3,124,876 ÷ 60).

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *https://www.reginfo.gov/public/do/PRAMain* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These

information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Preliminary Regulatory Impact Analysis, Requirement for Submission of Mail Tracking Number or Tracking Code for Food Articles Arriving by International Mail; available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 1 as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

■ 2. In § 1.280 revise paragraph (a)(2) to read as follows:

§ 1.280 How must you submit prior notice?

(a) * * *

(2) The FDA Prior Notice System Interface (FDA PNSI) at *https://www.access.fda.gov/.*

* * * * *

■ 3. In § 1.281 revise paragraphs (a)(5)(iv), (b)(4)(iv), (10), and (11), and (c)(5)(iv) to read as follows:

§ 1.281 What information must be in a prior notice?

(a) * * *

(5) * * *

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.,* low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.80 of this chapter;

* * * * *

(b) * * *

(4) * * *

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.,* low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.80 of this chapter;

* * * * *

(10) The anticipated date of mailing, the name of the mail service, and the mail tracking number;

(11) The name and address of the U.S. recipient; and

* * * * *

(c) * * *

(5) * * *

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.,* low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.80 of this chapter;

* * * * *

■ 4. In § 1.283 revise paragraphs (a)(6), (c)(1), and (c)(2) to read as follows:

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) * * *

(6) *No post-refusal submission or request for review.* If an article of food is refused under section 801(m)(1) of the act and no prior notice is submitted or resubmitted in accordance with paragraph (c) of this section, no request for FDA review is submitted in accordance with paragraph (d) of this section, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

* * * * *

(c) * * *

(1) If an article of food is refused under paragraph (a)(1)(i) of this section (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c) within 10 calendar days from the date the notice of refusal was issued.

(2) If an article of food is refused under paragraph (a)(1)(ii) of this section (inaccurate prior notice) and the food is not exported, the prior notice should be canceled in accordance with § 1.282 and you must resubmit prior notice in accordance with §§ 1.280 and 1.281(c) within 10 calendar days from the date the notice of refusal was issued.

* * * * *

■ 5. In § 1.285 revise paragraphs (g) and (i)(1) to read as follows:

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

* * * * *

(g) *No registration or request for review.* If an article of food is placed under hold under section 801(l) of the act and no registration number is submitted in accordance with paragraph (i) of this section, or no request for FDA review is submitted in accordance with paragraph (j) of this section, or export has not occurred in accordance with paragraph (f) of this section, the food shall be dealt with as set forth in CBP regulations relating to general order merchandise. Unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

* * * * *

(i) * * *

(1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered, and a valid registration number must be obtained and submitted to the FDA Division of Food Defense Targeting within 30 calendar days from the date the notice of hold was issued.

* * * * *

Dated: October 26, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–24086 Filed 10–31–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 425, and 495

Office of the Secretary

45 CFR Part 171

RIN 0955–AA05

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provision of the 21st Century Cures Act specifying that a health care provider determined by the HHS Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In particular, this rulemaking would establish for such health care providers a set of appropriate disincentives using authorities under applicable Federal law.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on January 2, 2024.

ADDRESSES: You may submit comments, identified by RIN 0955–AA05, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *https://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.
- *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. For example, people typically do not wish to, and generally should not, share with the general public information such as: any person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; individually identifiable health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *https://www.regulations.gov.*
- *Docket:* For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Alexander Baker, Office of Policy, Office of the National Coordinator for Health Information Technology (ONC), (202) 690–7151, for general issues.

Elizabeth Holland, Centers for Medicare & Medicaid Services (CMS), (443) 934–2532, for issues related to the Promoting Interoperability Program and the Promoting Interoperability performance category of the Merit-Based Incentive Payment System.

Aryanna Abouzari, Centers for Medicare & Medicaid Services (CMS), (415) 744–3668 or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of Regulatory Action

This proposed rule would implement the 21st Century Cures Act (Cures Act) provision for referral of a health care provider (individual or entity) determined by the HHS Office of Inspector General (OIG) to have committed information blocking ''to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking'' (42 U.S.C. 300jj–52(b)(2)(B), Public Health Service Act (PHSA) section 3022(b)(2)(B), as added by section 4004 of the Cures Act (Pub. L. 114–255, Dec. 13, 2016)). The proposals in this rule would establish disincentives for certain health care providers (as defined in 45 CFR 171.102) that are also Medicare-enrolled providers or suppliers.