Bureau's supervisory authority under 12 U.S.C. 5514, including for the reasons set forth in 12 U.S.C. 5514(a)(1)(C).

Subpart C—Post-Determination Procedures

§ 1091.113 Petition for termination of order.

(a) Any person subject to an order issued pursuant to § 1091.109(a)(1) may, no sooner than two years after issuance of such an order and no more frequently than annually thereafter, petition the Director for termination of the order.

(b) A petition for termination submitted pursuant to paragraph (a) of this section shall set forth the reasons supporting termination of the order, including any actions taken by a respondent since issuance of the order to address the conduct that led to issuance of the order, and may include any supporting information or evidence that the petitioner believes is relevant to the Director's determination of the matter.

(c) A petition for termination shall be filed by the petitioner with the Executive Secretary at the mailing or electronic address provided by the Bureau.

(d) The Director shall, promptly upon receipt of a petition for termination, send a copy of the same to the initiating official.

(1) The initiating official may, within 30 days of his or her receipt of a copy of a petition for termination, file with the Director a response to the petition stating whether the initiating official recommends that the order be terminated, or modified, or that the petition for termination be denied and the basis for such recommendation.

(2) The initiating official shall serve a copy of the response to a petition for termination on the petitioner pursuant to § 1091.107 at the time of filing it with the Director.

(e) Not later than 90 days after submission of a petition under paragraph (a) of this section, the Director shall issue a written decision either terminating or modifying the order, or denying the petition. If the Director modifies the order or denies the petition, the Director shall explain the basis for his or her decision with respect to the petition and send the written decision to the petitioner and the initiating official.

(1) The Director shall serve the written decision on a petition for termination of order on a respondent pursuant to § 1091.107.

(2) The Director shall send a copy of the written decision on a petition for termination of order to the recommending official and initiating official promptly upon issuing the written decision.

(3) The decision of the Director made pursuant to this paragraph (e) shall constitute final agency action under 5 U.S.C. 704.

Subpart D—Time Limits and Deadlines

§ 1091.114 Construction of time limits.

(a) *General rule.* In computing any period of time prescribed by this part, or by order of the recommending official or Director, the date of the act or event that commences the designated period of time is not included. The last day so computed is included unless it is a Saturday, Sunday, or Federal holiday as set forth in 5 U.S.C. 6103(a). When the last day is a Saturday, Sunday, or Federal holiday, the period runs until the end of the next day that is not a Saturday, Sunday, or Federal holiday. Intermediate Saturdays, Sundays, and Federal holidays are included in the computation of time, except when the time period within which an act is to be performed is ten days or less, not including any additional time allowed for in paragraph (c) of this section.

(b) *Filing or service of papers.* Filing and service are deemed to be effective:

(1) In the case of personal service or same day commercial courier delivery, upon actual receipt by the person served;

(2) In the case of overnight commercial delivery service, U.S. Postal Service Express Mail delivery, or First Class, Registered, or Certified Mail, upon deposit in or delivery to an appropriate point of collection; or

(3) In the case of electronic transmission, including email, upon transmission.

(c) *Calculation of time for service and filing of responsive papers.* Whenever a time limit is measured by a prescribed period from the service of any notice or paper, the applicable time limits are calculated as follows:

(1) If service is made by U.S. Postal Service First Class, Registered, or Certified Mail, add three calendar days to the prescribed period;

(2) If service is made by Express Mail or overnight delivery service, add one calendar day to the prescribed period; or

(3) If service is made by electronic transmission, add one calendar day to the prescribed period.

§ 1091.115 Change of time limits and confidentiality of proceedings.

(a) Except as otherwise provided by law, the recommending official until the issuance of a recommended determination, or the Director at any time thereafter, at their respective discretion, may extend the time limits prescribed by this part or by any notice or order issued pursuant to this part. Any request for an extension of a time limit by a respondent must be for good cause shown, in writing, and filed with the recommending official or Director, as appropriate. The mere filing of a written request for an extension does not alleviate a respondent of the obligation to meet an applicable time limit absent written confirmation that an extension has been granted.

(b) Deadlines for action by the initiating official, recommending official, or the Director established in this part confer no substantive rights on respondents.

(c) In connection with a proceeding under this part, including a petition for termination under § 1091.113, all documents, records or other items submitted by a respondent to the Bureau, all documents prepared by, or on behalf of, or for the use of the Bureau, and any communications between the Bureau and a person, shall be deemed confidential supervisory information under 12 CFR 1070.2(i).

Russell Vought,

Acting Director, Consumer Financial Protection Bureau.

[FR Doc. 2025–18622 Filed 9–24–25; 8:45 am]

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its prior notice regulation to 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) or responses to

requests for FDA review have been issued and beginning October 1, 2026, 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. The rule will also finalize 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 will improve program efficiency and better enable FDA to protect the U.S. food supply and public health.

DATES: This rule is effective October 27, 2025.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Christopher Henderson, Office of Inspections and Investigations, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 240–402–8186, *Christopher.Henderson@fda.hhs.gov.*

Regarding the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing a final rule to amend the prior notice regulation as follows: (1) amend § 1.281(b)(10) (21 CFR 1.281(b)(10)) to add a requirement, beginning October 1, 2026, 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 (21 CFR 1.283) to add a requirement that prior notice be submitted within 10 calendar days from the date a notice of refusal or hold was issued or 10 calendar days from the date the response to a request for FDA review under § 1.283(d) was issued; (3) amend § 1.285 (21 CFR 1.285) to add a requirement that Food Facility Registration (FFR) be submitted within 30 calendar days from the date a notice of refusal or hold was issued or 30 calendar days from the date the response to a request for FDA review under § 1.285(j) was issued; and (4) 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 will 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 will help FDA better plan its operations and stop such articles from being delivered.

Many foods are regularly imported by international mail, and in FDA's experience, these foods can present similar risks to the U.S. food supply as other imported foods. Further, based on FDA's experience at international mail facilities, 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 foods highlights the need for FDA to have the name of the mail service and tracking number to adequately monitor, inspect, and refuse or hold specific food shipments.

Additionally, requiring a reasonable timeframe for post-refusal and post-hold submissions of prior notice and FFR may reduce the amount of time articles subject to refusal or holds are held at ports of entry, thus reducing associated monetary charges. It will 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 long periods of time (*e.g.,* weeks and months) reviewing multiple replacement non-compliant prior notice or registration submissions.

In addition, the final rule amends § 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 exclusively through FDA PNSI. This amendment enables prior notice for food arriving by international mail to be submitted through the PNSI or through the U.S. CBP ABI/ACE/ITDS. Further, § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) are amended 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, § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) are amended to refer to § 106.80 instead of § 106.90.

[1] Note that FDA generally intends to exercise 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. Summary of the Major Provisions of the Final Rule

This final rule amends §§ 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. This rule amends § 1.281(b)(10) to include an additional requirement, beginning October 1, 2026, 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 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)) (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, prior notice is not adequate, or no registration is provided. However, these sections do not provide a timeframe within which such submissions must be made. This final rule amends § 1.283(c)(1) and (2) to require submission or resubmission of prior notice within 10 calendar days from the date the notice of refusal was issued or 10 calendar days from the date the response to a request for FDA review under § 1.283(d) was issued. We believe that 10 days is an appropriate timeframe because it allows sufficient time to submit or resubmit prior notice if necessary.

In addition, the final rule amends § 1.285(i)(1) to require submission of a valid FFR within 30 calendar days from the date a notice of hold was issued or 30 calendar days from the date the response to a request for FDA review under § 1.285(j) was issued. We believe that 30 days is an appropriate timeframe because it allows time to obtain the information needed to submit a valid registration. If a prior notice is not submitted or resubmitted, or a registration is not provided within the required 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.

This final rule removes the requirement that only the FDA PNSI be used for the submission of prior notice for articles of food arriving by international mail and amends § 1.280(a)(2) to allow prior notice of articles of food imported or offered for import by international mail to be submitted through the FDA PNSI or the ABI/ACE/ITDS.

Finally, this final rule amends § 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 final 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. Therefore, this final rule will not significantly increase costs to small entities. See the Economic Analysis of Impacts for a detailed cost and benefit analysis.

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

Abbreviation	What it means
ABI	Automated Broker Interface.
ACE	Automated Commercial Environment.
CBP	U.S. Customs and Border Protection.
CDC	Centers for Disease Control and Prevention.
CPG	Compliance Policy Guide.
DUNS	Dun & Bradstreet Data Universal Numbering System.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FFR Number	Food Facility Registration Number.
FSMA	FDA Food Safety Modernization Act.
ITDS	International Trade Data System.
OMB	Office of Management and Budget.
PNSI	Prior Notice System Interface.
UFI	Unique Facility Identifier.
USPS	U.S. Postal Service.

III. Background

A. Introduction

FDA is issuing a final rule to amend the prior notice regulation in 21 CFR part 1, subpart I, as follows: (1) amend § 1.281(b)(10) to add a requirement, beginning October 1, 2026, 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

[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)).

of refusal under section 801(m) of the FD&C Act was issued or 10 calendar days from the date the response to a request for FDA review under § 1.283(d) was issued; (3) amend § 1.285(i) to require submission of FFR within 30 calendar days from the date the notice of hold under section 801(l) of the FD&C Act was issued or 30 calendar days from the date the response to a request for FDA review under § 1.285(j) was issued; (4) 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 (5) 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.

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 articles of food 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 service and the mail tracking number for food articles imported by international mail will 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 will also enable FDA to act quickly to identify the affected food articles and prevent contamination of the food supply. It will also help to improve emergency response time, as FDA and other agencies will 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 will bolster FDA's efforts to prevent violative and potentially dangerous food shipments from entering the United States at international mail facilities, and will also help FDA to track, identify, inspect, and contain such shipments. With this information available, FDA will be able to 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 emergency, 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 will help FDA, CBP, and USPS to track the origin and location of the international mail. The mail package can 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 will enable FDA to more swiftly prevent the article of food from entering the U.S. food supply chain.

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 five 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 FFR requirements (§§ 1.283(d) and 1.285(j)). FDA will review and respond within five calendar days of receiving the review request (§§ 1.283(d) and 1.285(j)). Submitters or transmitters can also 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 resubmit multiple replacement non-compliant prior notice or registration submissions to be reviewed by FDA. Setting a timeline for submission or resubmission of prior notice or registration following a hold or refusal will help to reduce the amount of time and resources FDA spends on processing post-hold or post-refusal resubmissions and may reduce cost to importers by decreasing the amount of demurrage charges (*i.e.,* monetary charges due to a failure of goods to leave the 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 required 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

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

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

requirement. On November 1, 2023, FDA published a proposed rule entitled ''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'' (proposed rule) (88 FR 74939).

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 regulation, 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 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 final rule will further align the prior notice regulation 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 § 1.283(d); we made a similar change in § 1.285(g) (73 FR 66294 at 66370). These changes require requests for FDA review under §§ 1.283(d) and 1.285(j) to be submitted within five calendar days of the refusal or hold and remove 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 801(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 final rule amends these provisions by imposing a timeframe for post-refusal and post-hold submissions.

D. Summary of Comments to the Proposed Rule

Most of the comments we received on the proposed rule are generally supportive of our proposed amendments to §§ 1.280, 1.281, 1.283, and 1.285. Many comments agree that these amendments to the prior notice regulation will help FDA and other agencies improve food safety and increase consumer confidence in imported food arriving through international mail. Comments agree that requiring only the anticipated date of mailing for international mail provides limited information for effective tracking. They state that requiring submitters of prior notice for articles of food arriving by international mail to provide the name of the mail service and the mail tracking number is a positive step towards improving the safety of imported food and that these proposed amendments align with the evolving landscape of international trade and the increasing use of the mail system to import various food products. Comments further note that agencies such as FDA having the name of the mail service and tracking number allows for real-time and specific tracking ability that can be more effectively utilized to mitigate potential risks, and that the practical utility of the information is likely to enable a faster and more proactive response.

Regarding the proposal to require specific timeframes for submitting prior notice and FFR following a notice of refusal or hold, multiple comments believe that imposing the timeframes is a sensible approach. Some comments state that the proposed 10-calendar day timeframe for prior notice and the 30-calendar day timeframe for FFR strikes a balance between FDA's regulatory process and providing submitters with a reasonable timeframe. They add that this not only facilitates a quicker response to potential risks but also aligns with the need for efficient resource utilization. One comment says that the 30-calendar day timeframe for post-hold registration may not be sufficient due to several procedures needed to complete an FDA food facility registration. The comment suggests that a 45-calendar day or 60-calendar day timeframe would better accommodate the potential need to obtain the unique facility identifier (UFI) to complete the FDA FFR process. The comment bases its estimation of time on how long it could take to obtain a Dun & Bradstreet Data Universal Numbering System (DUNS) number since that number serves as the UFI. One comment asks how the proposed amendments would impact laboratory samples of tea or coffee for analysis that are sent to the United States by a courier mailing service. Another comment commends

FDA's collaboration with the USPS and CBP and recommends expanding its collaboration to include the Centers for Disease Control and Prevention (CDC) and other Federal agencies.

IV. Legal Authority

We are issuing this final 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 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 determine that imposing a timeframe on post-refusal and post-hold submissions of prior notice and FFR is necessary for the efficient enforcement of sections 801(m) and 801(l) of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received five comment submissions on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from regulatory specialists representing industry, food and consumer safety advocates, a trade association, and other individuals. After considering these comments, we are revising the proposed provisions in §§ 1.283(c) and 1.285(i) to require the clock for the 10 calendar days for submission of post-refusal prior notice and the clock for the 30 calendar days for submission of post-hold registration to start from the date FDA issues the response to a request for FDA review under §§ 1.283(d) or 1.285(j), respectively, for those that file a request for review. In addition, we are delaying the requirements to submit the name of mail service and tracking number until October 1, 2026, to allow for adequate time for the PNSI and ACE systems to become ready to receive such information.

We describe and respond to the comments in sections B through E of this document. We have numbered each comment and response to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. General Comments and FDA Response

(*Comment 1*): Multiple comments express support for the proposed rule change to § 1.281. They state that requiring the international mail prior notice submitter to provide the name of the mail service and the tracking number, in addition to the already provided anticipated date of mailing, is a commonsense action that would improve food safety and increase consumer confidence in their food deliveries. One comment supports the overarching goals of the proposed rule to enhance FDA's ability to monitor and regulate imported food effectively. The comment believes that the current requirement under § 1.281(b)(10) provides limited information for effective tracking and that the proposed amendments demonstrate a thoughtful approach to adapting regulatory frameworks to evolving trends in international trade and technological capabilities. The comment suggests, given the gravity of a bioterrorist event, that leveraging CDC and other agencies dedicated to protecting public health may help to bolster compliance with the regulation. It suggests that FDA should consider expanding its collaboration to other agencies not mentioned in the proposed rule preamble.

(*Response 1*): We agree that requiring the submitter to provide the name of the mail service and the tracking number, in addition to the already provided anticipated date of mailing, will help FDA and other agencies to improve food safety and may increase consumer confidence in food importation through international mail. We further agree that our final rule, which amends § 1.281(b), will provide additional information to help FDA to effectively track and inspect articles of food arriving by international mail and that the amendments in the rule will help to bolster efficient regulatory oversight of imported food, improve food safety, and mitigate public health risk. Regarding the prior notice and FFR requirements for articles of food imported by international mail, FDA most often collaborates with CBP and USPS. However, FDA collaborates with multiple federal and state entities, including CDC, to facilitate its regulatory oversight and enforcement obligations related to food.

(*Comment 2*): One comment asks whether samples for laboratory analysis shipped through a courier mail service from around the world would be subject to the requirement to submit an international mail tracking number.

(*Response 2*): The final rule to require prior notice submission of an international mail tracking number applies to shipments of articles of food arriving by international mail. International mail means foreign national mail services. International mail does not include express consignment operators, carriers, or other private delivery services, unless such service is operating under contract as an agent or extension of a foreign mail service (§ 1.276(b)(8) (21 CFR 1.276(b)(8))).

Regarding prior notice requirements for laboratory samples, as stated in the 2008 Prior Notice final rule, many samples of food are ''articles of food imported or offered for import,'' as stated in section 801(m) of the FD&C Act. If, however, the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5), they would not be subject to prior notice requirements. In addition, if the sample is in a form that is not an article of food, then prior notice requirements would not apply. But where a sample is food, as defined under prior notice, the sample is not excluded from the final rule even if it is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption, and not for resale (73 FR 66294 at 66315). However, as discussed in the Prior Notice final

rule compliance policy guide (CPG),[6] FDA and CBP may consider not taking any regulatory action when there is no prior notice and the food is a sample not intended for human or animal consumption.

(*Comment 3*): One comment expresses concern about placing a hold on perishable food and asks if FDA would reimburse shippers for spoiled food, given that consumers may often find it not to be worthwhile to pursue a claim in small claims court for spoiled food.

(*Response 3*): Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal or any hold (§§ 1.283(a)(4) and 1.285(e)). However, FDA has procedures in place to prioritize and expedite the review of emergency and perishable shipments (see generally FDA's Investigation Operations Manual, Chapter 6, Imports). In addition, FDA has a process for holding food arriving by international mail. If an article of food arrives by international mail with inadequate prior notice or the prior notice confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the FD&C Act and there is a return address, the parcel may be returned to sender marked ''No Prior Notice—FDA Refused.'' If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel (§ 1.283(e)).

As it pertains to this final rule, the comment does not specify any perceived effect that the rule will have on the time that articles of food are held. As we stated in the proposed rule, we believe that the rule may reduce the amount of time articles subject to refusal or holds are held at ports of entry, thus reducing associated monetary charges (88 FR 74939 at 74940). We note that any potential legal dispute between private parties arising from a hold on a food shipment is outside the scope of this rule.

(*Comment 4*): One comment believes the proposed requirements to submit the name of the mail service and tracking number would not be a concern since the information should be readily available to submitters or transmitters, but asks that the requirements not be implemented until the relevant information technology systems are updated and able to accept the newly required information.

(*Response 4*): We agree that the name of the mail service and mail tracking number should be readily available to submitters or transmitters, and we did not receive comments that indicate otherwise. Our research indicates that a tracking number is available for international mail in most major countries that export food to the United States. Therefore, we are finalizing the requirements to submit the name of the mail service and tracking number for articles arriving by international mail in § 1.281(b)(10).

In response to the comment, and to provide adequate time for PNSI and ACE to be updated to accommodate the newly required information, we are delaying the requirements to submit the name of the mail service and the tracking number for articles of food arriving by international mail until October 1, 2026. If we receive information to indicate that PNSI and/or ACE will not be ready to receive the name of the mail service and tracking number by October 1, 2026, we will consider the appropriate means to address this, including whether the temporary exercise of enforcement discretion for the requirements to submit the name of the mail service and tracking number would be appropriate until the time that PNSI and ACE can receive such information.

C. Comments on Proposal To Require Post-Refusal and Post-Hold Submissions of Registration Within 30 Calendar Days and FDA Response (Proposed § 1.285(i)(1))

FDA sought comment on whether 30 calendar days from the date the notice of hold was issued would be an appropriate timeframe to require for post-hold registration submission or if a different timeframe would be more appropriate.

(*Comment 5*): One comment opines that the 30-calendar day period strikes a balance between the regulatory process and providing submitters with a reasonable timeframe. Another comment expresses concern about the proposed amendment that requires that a valid FFR number be obtained and submitted to the Agency within 30 calendar days. The comment suggests that 30 calendar days is not enough time to obtain and submit a valid facility registration number, considering the amount of time it could take to file a request for review by FDA, receive a response of the review decision, and submit the required information, if necessary. The comment contends that FDA failed to account for the time necessary for a firm to obtain a UFI, if needed. The comment explains that, currently, a DUNS number assigned by Dun & Bradstreet serves as the UFI. The comment claims that, because a food facility cannot complete the facility registration process until the DUNS number has been assigned, it may not be possible for a firm to provide the registration information within 30 calendar days according to the Dun & Bradstreet website, which states that it may take up to 30 business days to obtain a new DUNS number.[7] The comment further contends that given the fact that the key step in the registration process is not under the firm's control, the timeframe should be extended to 45 or 60 calendar days to allow firms that do not currently have a DUNS number to be able to obtain a DUNS number and complete the FFR process.

(*Response 5*): We disagree that the required timeframe should be extended to 45 or 60 calendar days from the date a notice of hold was issued and believe that 30 calendar days is a sufficient timeframe to submit a post-hold FDA food facility registration in most cases. Additionally, we considered the timeframe between when a request for FDA review is filed and when FDA issues a review decision and have revised our proposal so that the 30-calendar day timeframe for those who file a request for FDA review will start from the time FDA issues a review decision. As the comment explains, the process of completing FFR involves obtaining a UFI. Domestic and foreign facilities are required to submit a UFI recognized as acceptable by FDA as part of FFR (21 CFR 1.232(a)(2)). The UFI currently recognized as acceptable by FDA is a DUNS number, which is a unique nine-digit number assigned and managed by Dun & Bradstreet. After a DUNS number is obtained and submitted to FDA, FDA will verify the accuracy of the UFI and that the facility-specific address associated with the UFI is the same address associated with the registration (see 21 CFR 1.231(a)(3)). If there are no discrepancies between the FFR system and the DUNS data, the FFR system will automatically accept and issue an FFR number (*i.e.,* on the same day).

Regarding comments' contention that a DUNS number may take up to 30 business days to obtain, the recent data we received from Dun & Bradstreet on the length of time it takes to process and issue a DUNS number indicates that the vast majority of DUNS applications (97.3 percent in recent months) are completed, and a DUNS number is

[6] CPG Sec.110.301 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (May 2009).

[7] See *https://www.dnb.com/duns/get-a-duns.html.*

issued, in less than 10 business days, and even more (99.69 percent) are completed in less than 20 business days. For example, from September 1, 2023, to February 29, 2024, 97.3 percent of global applications for a DUNS number were completed in less than 10 business days, and 99.69 percent of DUNS applications were completed in less than 20 business days of submitting the application. From March 2021 to March 2023, 71.31 percent of global applications were completed in less than 10 business days, and 95.70 percent were completed in less than 20 business days. This trend reflects an increase in the average amount of global applications completed in less than 10 or 20 business days. Moreover, the data show that, from September 2023 to February 2024, 99.81 percent of DUNS applications were completed in less than 30 days. Based on this information, we do not believe that extending the timeline to submit registration (such as by 15 or 30 days, as suggested by the comment) is necessary. The trend in recent years is that DUNS applications are completed in less time and the vast majority are completed in less than 30 days. For these reasons, we have determined that the 30 calendar-day timeframe for a post-hold submission of an FFR number is sufficient and we decline to extend the timeframe to submit registration beyond 30 days. Therefore, we are finalizing the rule as proposed, requiring a timeframe of 30 calendar days for a post-hold submission of an FFR number.

However, the comment also mentions that the 30-day timeframe is not enough time to obtain and submit a valid FFR number, considering the amount of time it could take to file a request for review by FDA, receive a response of the review decision, and submit the required information, if necessary. We recognize that the process for requesting FDA review of a hold under § 1.285(j) may impact the ability to meet the timeframes for submitting a post-hold submission under § 1.285(i). For example, if a submitter or transmitter requests FDA review of a hold under § 1.285(j), receives a response of the review decision, and then must obtain a DUNS number to complete the FFR process, the submitter or transmitter may not be able to meet the 30-day timeframe as proposed, which would start the clock from the date a notice of hold was issued. Therefore, we are revising the rule by adding language in § 1.285(i) to clarify that the clock for the 30-day timeframe will start from the date the response to a request for FDA review under § 1.285(j) is issued, for those that file a request for review.

D. Comments on Proposal To Require Post-Refusal and Post-Hold Submissions of Prior Notice Within 10 Calendar Days and FDA Response (Proposed § 1.283(c))

FDA sought comment on whether 10 calendar days from the date the notice of refusal or hold was issued would be an appropriate timeframe to require for post-refusal and post-hold prior notice resubmission, or if a different timeframe would be more appropriate.

(*Comment 6*): The comments we received on this proposal were supportive. Comments think that the timeframe is reasonable and strikes a balance between the regulatory process and providing the submitter with a reasonable timeframe. We did not receive comments that disagreed or raised issues with this proposed amendment.

(*Response 6*): We agree that 10 calendar days is an appropriate timeframe to require for post-refusal and post-hold resubmission of prior notice. However, similar to the process for requesting FDA review of a hold under § 1.285(j), we also recognize that the process for requesting FDA review of a hold under § 1.283(d) may impact the ability to meet the timeframe for submitting a post-refusal submission under § 1.283(c). For example, a submitter or transmitter may request review of a hold under § 1.283(d), receive a response of the review decision, and then need to obtain additional information to complete prior notice submission. Accordingly, and for consistency with § 1.285(i), we revised the language in § 1.283(c) to clarify that the clock for the 10-day timeframe will start from the date the response to a request for FDA review is issued, for those that file a request for review.

VI. Effective Date

This final rule will become effective 30 days after the date of publication in the **Federal Register**.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) if they ''have an annual effect on the economy of $100 million or more; 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, or tribal governments or communities.'' The Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is not a significant regulatory action under Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This final rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the change to prior notice requirements will not significantly increase costs to small entities, we certify that the final 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 issuing ''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 $187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits, Costs, and Transfers

This rule would amend existing prior notice regulation to require the submission of the name of the mail

service and tracking number for food articles imported using international mail. The rule would also require transmitters to resubmit prior notice within 10 calendar days from the date a notice of refusal or hold is issued or 10 calendar days from the date the response to a request for FDA review is issued, and to submit FFR within 30 calendar days from the date a notice of refusal or hold is issued or 30 days from the date the response to a request for FDA review is issued. The rule also makes other technical changes.

To estimate costs and benefits associated with the rule, we assume that the appropriate baseline is the state of the world with current prior notice regulation. We then compare the likely impacts of the rule against this baseline. The costs of the rule 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 $0.44 million at a 3 percent rate of discount. At a 7 percent rate of discount, these costs range from approximately $0.04 million to $0.43 million. Our primary annualized estimates are approximately $0.24 million at both the 3 and 7 percent rates of discount.

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 $0.03 million to $0.14 million at the 3 and 7 percent rates of discount. The primary annualized value for both discount rates is $0.07 million. These estimates are summarized in table 1. Other benefits, and resulting impacts on social welfare, are highly uncertain. These benefits may include improvements in public health from a decreased incidence in outbreaks of foodborne illness or bioterrorism events. However, because it is difficult to forecast the likelihood and magnitude of such events, we do not quantify their benefits.

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

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.07	$0.03	$0.14	2023	7	10	
	0.07	0.03	0.14	2023	3	10	
Annualized Quantified					7		
					3		
Qualitative	Unquantified improvements to public health from better surveillance						
Costs:							
Annualized Monetized millions/year	0.24	0.04	0.43	2023	7	10	
	0.24	0.04	0.44	2023	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							
Small Business: None							
Wages:							
Growth:							

In line with Executive Order 14192, in table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this rule will generate $0.16 million in annualized net costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

TABLE 2—EXECUTIVE ORDER 14192 SUMMARY TABLE

[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Present Value of Costs	$3.40	$0.40	$6.41
Present Value of Cost Savings	1.05	0.53	2.10
Present Value of Net Costs	2.35	(0.12)	4.31
Annualized Costs	0.24	0.03	0.45
Annualized Cost Savings	0.07	0.04	0.15

TABLE 2—EXECUTIVE ORDER 14192 SUMMARY TABLE—Continued

[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Annualized Net Costs	0.16	(0.01)	0.30

Note: Values in parentheses denote net negative costs (*i.e.,* net cost savings).

We have developed an Economic Analysis of Impacts that assesses the impacts of the final rule (Ref. 1). The full analysis of economic impacts is available in the docket for this final rule (FDA–2011–N–0179) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this 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 final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. 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.

Title: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (0910–0923)

Description: FDA is amending its regulation 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 3—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of respondents	Average number of responses per respondent	Total annual responses	Average burden per response	Total annual hours
1.281(b)(10)—Information Included in Prior Notice					
One-Time Burden	5,460	1	5,460	0.5 (30 minutes)	2,730
Recurring Burden		143	780,780	0.07 (4 minutes)	54,655
Total					57,385

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 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 780,780 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 totals 2,730, and the recurring burden amounts to 54,655 hours. Therefore, we estimate the total annual burden to be 57,385 hours.

Although FDA received comments on the proposed rule, none were responsive to the four collection of information topics solicited. Therefore, the estimated PRA burden for this final rule is the same as the estimated burden in the proposed rule. For clarity, we have reformatted the burden chart in this final rule. The updated format differs from the proposed rule by breaking out burden estimates by activity. These revisions do not alter the nature of the information being collected.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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 rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. Reference

The following reference is on display at 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.* Although FDA verified the website address in this document, please note that websites are subject to change over time.

1. Final Regulatory Impact Analysis, Adding Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-refusal and Post-hold Submissions; 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 amends 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), (b)(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, and beginning October 1, 2026, 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) and (c)(1) and (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 or 10 calendar days from the date the response to a request for FDA review under paragraph (d) of this section 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 or 10 calendar days from the date the response to a request for FDA review under paragraph (d) of this section 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 (19 CFR part 127). 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 or 30 calendar days from the date the response to a request for FDA review under paragraph (j) of this section was issued.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–18655 Filed 9–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Part 551

[Docket ID: BOEM–2025–0038]

RIN 1010–AE34

Rescission of Expired 1-Year Grace Period for Data Extensions; Corrections

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Correcting amendments.

SUMMARY: On August 12, 2025, the Bureau of Ocean Energy Management (BOEM) published a final rule that removed reference to an expired grace period for data extensions. Some of the language from this section was inadvertently erased. This document corrects the final regulations.

DATES: Effective on September 25, 2025.

FOR FURTHER INFORMATION CONTACT: Jennifer Jones, Office of Regulatory Affairs, BOEM, 1849 C Street NW, Washington, DC 20240, at email address *jennifer.jones@boem.gov,* or at telephone number (202) 571–8664.

SUPPLEMENTARY INFORMATION: On August 12, 2025, BOEM published a final rule in the **Federal Register** (90 FR 38705) that modified paragraph (b)(2) of § 551.14. Paragraphs (b)(2)(i) through (viii), which list the required components of the application for reprocessed data term extensions, were inadvertently and unintentionally left out of the final rule text. This document corrects the final regulations to restore those paragraphs.

List of Subjects in 30 CFR Part 551

Freedom of information, Oil and gas exploration, Reporting and recordkeeping requirements, Research.

This action by the Assistant Secretary is taken herein pursuant to an existing delegation of authority.

Jacob Tyner,

Deputy Assistant Secretary, Land and Minerals Management.

Accordingly, 30 CFR part 551 is corrected by making the following correcting amendments:

PART 551—GEOLOGICAL AND GEOPHYSICAL (G&G) EXPLORATIONS OF THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 551 continues to read as follows:

Authority: Section 104, Public Law 97–451, 96 Stat. 2451 (30 U.S.C. 1714), Public Law 109–432, Div C, Title I, 120 Stat. 3000; 30 U.S.C. 1751; 31 U.S.C. 9701; 43 U.S.C. 1334; 33 U.S.C. 2704, 2716; E.O. 12777, as amended; 43 U.S.C. 1331 *et seq.,* 43 U.S.C. 1337.

■ 2. Amend § 551.14 by revising paragraph (b)(2) to read as follows:

§ 551.14 Protecting and disclosing data and information submitted to BOEM under a permit

* * * * *

(b) * * *

(2) Permittees and third parties may apply to BOEM for an extension of the 25-year proprietary term for geophysical information reprocessed 20 or more years after BOEM issued the germane permit. You must submit the application to BOEM within 90 days after completion of the reprocessing. Filing locations are listed in § 551.5(d). Your application must include:

(i) Name and address of the permittee or third party;

(ii) Product name;

(iii) Identification of the geophysical information area;

(iv) Identification of originating permit number and date;

(v) Description of reprocessing performed;

(vi) Identification of the date of completion of reprocessing the geophysical information;

(vii) Certification that the product meets the definition of processed geophysical information and that all other information in the application is accurate; and

(viii) Signature and date.

* * * * *

[FR Doc. 2025–18561 Filed 9–24–25; 8:45 am]

BILLING CODE 4340–98–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 569

Amendment to the Syria-Related Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is changing the heading of the Syria-Related Sanctions Regulations to the Promoting Accountability for Assad and Regional Stabilization Sanctions Regulations and amending the renamed regulations to implement a January 15, 2025 Syria-related Executive order and a June 30, 2025 Syria-related Executive order.

DATES: This rule is effective September 25, 2025.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Regulatory Affairs, 202–622–4855; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On June 5, 2020, OFAC issued the Syria-Related Sanctions Regulations, 31 CFR part 569 (85 FR 34510, June 5, 2020) (the ''Regulations''), to implement Executive Order (E.O.) 13894 of October 14, 2019, ''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Syria'' (84 FR 55851, October 17, 2019), pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13894. In E.O. 13894, the President determined that the situation in and in relation to Syria, and in particular certain actions by the Government of Türkiye to conduct a military offensive in northeast Syria, undermined the campaign to defeat the Islamic State of Iraq and Syria (''ISIS''), endangered civilians, and further threatened to undermine the peace, security, and stability in the region, and thereby constituted an unusual and extraordinary threat to the national security and foreign policy of