

Enforcement Policy to Delay Requirements to Submit Mail Service Name and International Mail Tracking Number Until May 1, 2027: Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document and Docket No. FDA-2011-N-0179.

For questions or information regarding this guidance, contact the Office of Inspections and Investigations (OII), Office of Inspectional Performance Optimization, Division of Inspectorate Policy (DIP), Food and Drug Administration at OIIPolicyStaffs@fda.hhs.gov. For questions regarding Prior Notice, contact the FDA's Division of Targeting and Analysis (DTA) at (866) 521-2297 or prior.notice@fda.hhs.gov. For ACE inquiries, contact FDA ACE Support at ACE_Support@fda.hhs.gov

**U.S. Department of Health and Human Services
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This guidance represents the current thinking of the Food and Drug Administration (FDA, we, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The U.S. Food and Drug Administration (FDA, the Agency, or we) is issuing this guidance¹ to announce our intent not to enforce until May 1, 2027 the prior notice requirements to submit the name of the mail service and the mail tracking number for articles of food arriving by international mail. This policy provides additional time to ensure that the information technology system functionality is updated so that it can accept the mail service name and mail tracking number for food arriving by international mail as part of prior notice.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Division of Inspectorate Policy in the Office of Inspections and Investigations at the U.S. Food and Drug Administration.

II. Background

Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)) directs the FDA to issue regulations requiring prior notice to FDA of food that is imported or offered for import into the United States. The prior notice regulations specify the information about food offered for import into the United States that must be submitted to FDA. The information in prior notice enables FDA to target import inspections more effectively, thereby helping to protect our nation's food supply against bio-terrorist acts and other public health emergencies.

On September 25, 2025, FDA published a final rule titled, “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,” (90 FR 46045), to amend its prior notice regulations. Among other amendments, the rule required that, beginning October 1, 2026, prior notice submissions for food arriving by international mail must include:

- The name of the mail service; and
- The mail tracking number (21 CFR 1.281(b)(10)).

The final rule stated that receiving the name of the mail service and mail tracking number for articles of food arriving by international mail would enable the FDA to better coordinate with the U.S. Postal Service (USPS), U.S. Customs and Border Protection (CBP), and other agencies to effectively track and inspect articles that have been identified as a possible bioterrorism risk.

The final rule also allows prior notice for food arriving by international mail to be submitted through the CBP’s Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS) or the FDA’s Prior Notice Systems Interface (PNSI) (21 CFR 1.280(a)(2)).

During the public comment period for the rule, FDA received a comment (Comment 4) asking FDA not to implement requirements to submit the mail service name and mail tracking number until the relevant information technology systems were updated and able to accept the newly required information². In response to the comment, and to provide adequate time for PNSI and ACE to be updated to accommodate the newly required information, in the final rule, FDA added that the requirements to submit the mail service name and mail tracking number for articles of food arriving by international mail would begin on October 1, 2026. In the final rule preamble, FDA stated that, if we receive information to indicate that PNSI and/or ACE will not be ready to receive the name of the mail service and mail 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.

² 90 F.R. 46045, 46051 (September 25, 2025).

III. Discussion

Since publication of the final rule, FDA has become aware that the relevant information technology systems will not be ready to receive the name of the mail service for food arriving by international mail by October 1, 2026. Therefore, FDA intends not to enforce the prior notice requirements at 21 CFR 1.281(b)(10) to submit the name of the mail service and mail tracking number for food arriving by international mail until May 1, 2027.

FDA will continue to assess the status of the relevant information technology systems readiness as May 1, 2027 approaches, and update this policy, if needed.