

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N-0278]

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**Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002; Reopening of
Comment Period**

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) are reopening for 30 days the comment period for FDA's prior notice interim final rule (IFR) that published in the **Federal Register** of October 10, 2003 (68 FR 58974). The prior notice interim final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. FDA is taking this action consistent with its statement in the preamble of the prior notice IFR (68 FR 58974 at 59023) that it would reopen the comment period for an additional 30 days in March 2004, to ensure that those who comment on this interim final rule would have had the benefit of our outreach and education efforts and would have had some experience with the systems, timeframes, and data elements of the prior notice system.

DATES: Submit written or electronic comments by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: May D. Nelson, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1722.

SUPPLEMENTARY INFORMATION:

I. Background

On October 10, 2003, FDA and CBP issued an IFR to implement new section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which required prior notification of imported food to begin on December 12, 2003. The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States (68 FR 58974). The interim final rule requires that the prior notice be submitted to FDA electronically via either CBP's Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or FDA's Prior Notice System Interface (FDA PN System Interface) (21 CFR 1.280). Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held (21 CFR 1.283).

Under section 801(m)(2)(A) of the FD&C Act, FDA is to choose timeframes that "shall be no less than the minimum amount of time necessary for the Secretary [of Health and Human Services] to receive, review, and appropriately respond to such notification* * *" Using this standard, the prior notice IFR

requires that the information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival (21 CFR 1.279). However, when we issued the interim final rule, FDA committed to exploring ways to increase integration of advance electronic notification processes with CBP and to reduce prior notice timeframes. Indeed, we stated in the preamble to the interim final rule (68 FR 58974 at 58995) that, by March 12, 2004, FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize their rule entitled "Required Advance Electronic Presentation of Cargo Information," (68 FR 43574, July 23, 2003).

For this reason, as well as to obtain comments on other aspects of the rule, we issued this rule as an interim final rule, with an opportunity for public comment for 75 days. Moreover, to ensure that those who comment on this interim final rule would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days in March 2004, coinciding with the issuance of the plan by FDA and CBP relating to timeframes.

In light of the significance of the prior notice IFR, in December 2003 FDA and CBP issued a compliance policy guide (CPG) that describes our strategy for maintaining an uninterrupted flow of food imports while implementing the prior notice requirements of the Bioterrorism Act. (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;” Availability (68 FR 69708, December 15, 2003), <http://www.cfsan.fda.gov/guidance.html>). The prior notice CPG states that until August 12, 2004, FDA and CBP intend to primarily emphasize educating the affected firms and individuals. During this period, the agencies intend to utilize communication and education initiatives, escalating imposition of civil monetary penalties, and ultimately refusal of imported food shipments. Upon issuance of the CPG, both agencies stated that they expected affected firms and individuals to demonstrate a good faith effort at compliance while the transitional policy was in place.

II. Comments

We previously issued this rule as an interim final rule, with an opportunity for public comment for 75 days. Moreover, to ensure that those that comment on this interim final rule would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days in March 2004. Accordingly, we are seeking comments on all aspects of the prior notice IFR.

In the prior notice IFR, we expressed interest in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as CBP’s Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) program, or food imported by other government agencies (68 FR 58995).

C-TPAT is a government/business initiative to increase cargo security while improving the flow of trade. Under this program, businesses must

conduct comprehensive self-assessments of their supply chain using the security guidelines developed jointly with CBP, and they must familiarize companies in their supply chain with the guidelines and the program. These businesses must provide CBP with specific and relevant information about their trucks, drivers, cargo, suppliers, and routes. As C-TPAT members, companies may become eligible for expedited processing and reduced inspections, but are not exempt from advance electronic information requirements. (See CBP's Required Advance Electronic Presentation of Cargo Information Final Rule (the Advance Electronic Information Rule) (68 FR 68140)).

FAST, an acronym for Free and Secure Trade between the United States and Canada, and the United States and Mexico, is an expedited-clearance system designed to improve border security without slowing the flow of legitimate trade across the northern and southern U.S. borders. FAST processing is available to importers, carriers and foreign manufacturers (southern border) who participate in C-TPAT and who use a FAST-registered driver. The initiative builds on the same concepts that drove the rapid, post-9/11 construction and implementation of C-TPAT.

FDA and CBP plan to assess the feasibility of including the FAST timeframes in FDA's prior notice final rule, as well as other flexible alternatives raised by comments. To assist in this assessment, FDA and CBP request comment on the following questions:

C-TPAT/FAST Questions:

1. Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

2. If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

3. Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

Any membership in C-TPAT or FAST, or any benefit received as a result of membership will not be affected by commenting in this rulemaking.

Flexible Alternative Questions:

1. If timeframes are reduced in FDA's prior notice rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

2. In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

3. In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?

4. Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

5. Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

6. If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

7. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

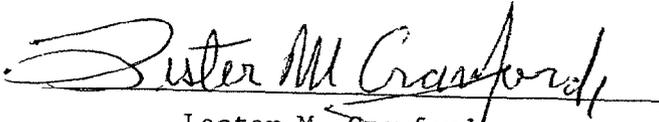
Interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the prior notice IFR as indicated in the **DATES** section of this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation was effective on December 12, 2003. We will address comments received during this reopened comment period and the previous comment period that closed on December 24, 2003, and will confirm or amend the interim final rule in a final rule. We, however, will not address any comments that have been previously considered during this rulemaking.

Dated: Mar. 24, 2004

March 24, 2004.

cf0417

A handwritten signature in cursive script that reads "Lester M. Crawford". The signature is written in dark ink and is positioned above a horizontal line.

Lester M. Crawford,
Acting Commissioner for Food and Drugs.

Dated: April 6, 2004.

Robert C. Bonner

Robert C. Bonner,
Commissioner, Customs and Border Protection.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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