

**Joint FDA-CBP Plan for Increasing Integration and
Assessing the Coordination of Prior Notice Timeframes
March 2004**

On October 10, 2003, the Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) issued an interim final rule (IFR) to implement new section 801(m) of the FD&C Act (21 USC 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). In the preamble to the Prior Notice IFR (68 FR 58995), we stated 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 promulgated by CBP when it finalizes its rule entitled "Required Advance Electronic Presentation of Cargo Information." On December 5, 2003, CBP issued its Required Advance Electronic Presentation of Cargo Information Final

Rule (the Advance Electronic Information Rule) (68 FR 68140). The relevant timeframes provided in the Advance Electronic Information Rule are as follows:

- 1 hour before arrival by land by road, or 30 minutes for participants in FAST/C-TPAT;
- 2 hours before arrival by land by rail; and
- By "wheels up" for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air.

Increased Integration

FDA and CBP are currently working to increase integration in the following ways:

- Co-location of all FDA PN staff with CBP's National Targeting Center (NTC 1);

- Further refinement to FDA's targeting rule sets in CBP's Automated Targeting System (ATS), coupled with additional training in targeting techniques;
- Continued targeting support from CBP and other Federal law enforcement analysts at the NTC; and
- Enhancement of communications and cooperation with CBP to facilitate information exchange and ensure expeditious access to foods subject to prior notice holds.

Assessing Reduced Timeframes

FDA and CBP continuously are assessing the completeness of prior notice submissions received as well as the amount of time necessary to receive, review, and respond to those submissions requiring a human review. However, that process is not yet complete, as we are currently operating under the enforcement policies outlined in the Prior Notice Compliance Policy Guide (CPG). See "Notice of Availability: Compliance Policy Guide Sec. 110.310--Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (68 FR 69708 (Dec. 15, 2003)).

<http://www.cfsan.fda.gov/guidance.html>. We currently do not receive prior notice for all shipments.

FDA and CBP announce the following plan, which we intend to implement in August 2004.

- From August 12, 2004, to October 12, 2004, we plan to assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the Prior Notice IFR (i.e., 2 hours before arrival by land by road; 4 hours before arrival by air or by land by rail; and 8 hours before arrival by water).
- From October 13, 2004, to November 12, 2004, we intend to identify what changes to work practices and staffing would be necessary to determine if FDA could continue to receive, review, and respond to all prior notice submissions with reduced timeframes (e.g., 1 hour/30 minutes before arrival by land by road; 2 hours before arrival by land by rail; and by "wheels up" for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air).

- From November 13, 2004, to February 12, 2005, we plan to implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes.
- In March 2005, we intend to issue a prior notice final rule that responds to the comments we received on the Prior Notice IFR, including this plan, during the two open comment periods.

Under the statute, any timeframe must be sufficient to receive, review, and respond to prior notice submissions, as set out in section 801(m)(2)(A) of the Federal Food, Drug, and Cosmetic Act, 21 USC 801(m)(2)(A). The agencies emphasize that the evaluation of whether to reduce the timeframes for prior notice review will depend on the level of compliance industry achieves during the assessment. If we are unable to make such an assessment, our intended timeframe for issuing a prior notice final rule may be delayed.