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: March 24, 2004.

Lester M. Crawford,

Acting Commissioner for Food and Drugs.

Dated: April 6, 2004.

Robert C. Bonner,

Commissioner, Customs and Border Protection.

[FR Doc. 04–8517 Filed 4–9–04; 4:51 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–0278]

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of joint plan.

SUMMARY: The Food and Drug Administration (FDA) and Customs and Border Protection (CBP) announce the availability of a plan entitled "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes.'' The plan, which includes an assessment schedule, describes the process by which FDA and CBP intend to increase integration and examine whether we could amend the timeframe requirements in FDA's prior notice interim final rule (IFR) to have the same advanced notice timeframes for arrivals by land via road or rail, or arrival via air that are currently in CBP's advance electronic information rule.

DATES: Submit written or electronic comments by May 14, 2004.

ADDRESSES: Submit written requests for single copies of the plan to the Office of Regional Operations (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which it may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the plan. 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: Joseph McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA Prior Notice Interim Final Rule

On October 10, 2003, FDA issued an IFR (the prior notice IFR) (68 FR 58974) to implement new section 801(m) of the Federal Food, Drug, and Cosmetic Act (the 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 (the 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. The prior notice IFR requires that prior notice be submitted to FDA electronically via either CBP's Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA 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 prior notice IFR, FDA was committed to exploring ways to increase integration of advance electronic notification processes with CBP and reduce prior notice timeframes further. Indeed, we stated in the preamble of the prior notice IFR (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'' (the Advance Electronic Information Rule).

For this reason, as well as to obtain comments on other aspects of the prior notice rulemaking, we issued the IFR with an opportunity for public comment for 75 days. Moreover, to ensure that those who comment on the prior notice IFR would have had the benefit of our experience with the systems, timeframes, and data elements, FDA also stated that 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.

B. CBP Advance Electronic Information Rule

On December 5, 2003, CBP issued the Advance Electronic Information Rule (68 FR 68140), which requires CBP to receive, by way of a CBP-approved electronic data interchange system, information pertaining to cargo before the cargo is either brought into or sent from the United States by any mode of commercial transportation (sea, air, rail, or truck). The cargo information required is that which is reasonably necessary to enable high-risk shipments to be identified for purposes of ensuring cargo safety and security and preventing smuggling under the laws enforced and administered by CBP. The Advance Electronic Information Rule implements the provisions of section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002.

The relevant timeframes provided in the Advance Electronic Information Rule are as follows:

• For arrival by land via road at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 1 hour prior to the arrival of the truck at the border, or for

Free and Secure Trade/Customs-Trade Partnership Against Terrorism (FAST/C–TPAT) participants, 30 minutes;

• For arrival by land via rail at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 2 hours prior to the arrival of the train at the border;

• For arrival by air, no later than the departure time ("wheels up'') of the aircraft from any foreign port or place in North America, including locations in Mexico, Central America, South America (from north of the Equator only), the Caribbean, and Bermuda, and from other areas into ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule no later than 4 hours prior to the arrival of the aircraft in the United States.

II. Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

After consultation, FDA and CBP have developed a plan to increase integration and assess whether FDA can adopt reduced timeframes. As set out in the plan, the agencies intend to assess whether FDA can meet its statutory mandate under section 801(m)(2)(A) of the FD&C Act if prior notice is received and confirmed electronically by FDA for review with reduced timeframes, including those adopted by CBP by mode of transportation listed in the following paragraphs, no fewer than:

• 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;

• 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.

As noted previously, section 801(m)(2)(A) of the FD&C Act states that FDA shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, and any timeframe FDA adopts in the final rule must be justified under this standard.

III. Comments

Elsewhere in this issue of the **Federal Register**, we are reopening the comment period on the prior notice IFR. To be considered part of the rulemaking record, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the plan as indicated in the **DATES** section of this document. Two copies of any mailed comments are to be submitted by commenting entities; individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The plan and comments FDA has received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons who wish to submit general comments on the prior notice IFR should consult the document reopening the comment period that is published elsewhere in this issue of the **Federal Register**.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

Dated: March 24, 2004.

Lester M. Crawford,

Acting Commissioner for Food and Drugs.

Dated: April 6, 2004.

Robert C. Bonner,

Commissioner, Customs and Border Protection.

[FR Doc. 04–8515 Filed 4–9–04; 4:51 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket No. 2002N–0276]

Registration of Food Facilities 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) is reopening for 30 days, on a limited set of issues, the comment period on the registration of food facilities interim final rule (IFR) that appeared in the **Federal Register** of October 10, 2003 (68 FR 58894). The IFR requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. FDA is taking this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in March 2004 to ensure that those commenting on the IFR have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration program.

DATES: Submit written or electronic comments on the identified set of issues for the IFR by May 14, 2004.

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: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an IFR to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003. In the "Request for Comments'' section of the IFR, FDA requested comments on specific issues in order to improve the assumptions used in its economic analysis. The IFR stated that its comment period would coincide with that of the prior notice IFR, given the relatedness of the two rules. Therefore, the registration IFR was open for comments for 75 days following the publication of the IFR. The IFR also stated that "to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule,'' FDA would reopen the comment period for an additional 30 days in March 2004.

II. Comments

Consistent with the intent expressed in the preamble to the IFR, we are seeking comments on the following issues in order to improve FDA's economic analysis:

1. The cost to foreign facilities of hiring and retaining a U.S. agent.