adjustments, the Commission is adding a statement to the standard that states the adjusted $2.25 value.

This notice also makes a technical correction to change the term ''Wholesale Price Index'' to ''Producer Price Index'' and notes that the specific Producer Price Index currently applicable to cigarette lighters is the Producer Price Index for Miscellaneous Fabricated Products.

The Administrative Procedure Act

Section 553(b)(3)(B) of the Administrative Procedure Act (''APA'') authorizes an agency to dispense with notice and comment procedures when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' This amendment adds a statement to inform the public of an adjustment that has occurred automatically according to the terms of the cigarette lighter regulation. Accordingly, the Commission finds that notice and comment is unnecessary.

The APA also authorizes an agency, ''for good cause found and published with the rule,'' to dispense with the otherwise applicable requirement that a rule be published in the **Federal Register** at least 30 days before its effective date. 5 U.S.C. 553(d)(3). The Commission hereby finds that a 30 day delay of the effective date is unnecessary because this amendment informs the public of an adjustment that has occurred automatically in accordance with the requirements of the cigarette lighter standard.

List of Subjects in 16 CFR Part 1500

Cigarette lighters, Consumer protection, Fire prevention, Hazardous materials, Infants and children, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

■ Accordingly, 16 CFR part 1210 is amended as follows:

PART 1210—SAFETY STANDARD FOR CIGARETTE LIGHTERS

■ 1. The authority for part 1210 continues to read as follows:

Authority: 15 U.S.C. 2056, 2058, 2079(d).

■ 2. Revise § 1210.2(b)(2)(ii) to read as follows:

§ 1210.2 Definitions.

* * * * *

(b) * * *

(2) * * *

(ii) It has a Customs Valuation or ex-factory price under $2.00, as adjusted every 5 years, to the nearest $0.25, in accordance with the percentage changes in the appropriate monthly Producer Price Index (Producer Price Index for Miscellaneous Fabricated Products) from June 1993. The adjusted figure, based on the change in that Index since June 1993 as finalized in November 2003, is $2.25.

Dated: April 6, 2004.

Todd Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 04–8400 Filed 4–13–04; 8:45 am]

BILLING CODE 6355–01–P

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; 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 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 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: 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 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 the Customs and Border Protection (CBP) 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 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.''

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 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. 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 58974 at 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 supply chains and security practices and procedures. 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 final 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?

To be timely, 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 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. 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]

BILLING CODE 4160–01–S

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