4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-N-0179]

RIN 0910-AG65

Information Required in Prior Notice of Imported Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that adopts, without change, the interim final rule (IFR) entitled "Information Required in Prior Notice of Imported Food" that published in the Federal Register (76 FR 25542; May 5, 2011) (2011 IFR). This final rule adopts the IFR's requirement of an additional element of information in a prior notice of imported food, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country to which the article has been refused entry.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Each year about 48 million people (1 in 6 Americans) get sick; 128,000 are hospitalized; and 3,000 die from food borne diseases, according to 2011 data from the Centers for Disease Control and Prevention (http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html). This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) (Public Law 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 304 of FSMA amended section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)) to require that additional information be provided in a

prior notice of imported food submitted to FDA. This change requires a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, "any country to which the article has been refused entry." Section 304 also required the Secretary of Health and Human Services to issue an IFR implementing this statutory change no later than 120 days following the date of enactment of FSMA and further specified that the amendment made by section 304 take effect 180 days after the date of FSMA's January 4, 2011, enactment, which was July 3, 2011. On May 5, 2011, FDA issued an IFR that implemented section 304 and contained a request for comments. The IFR became effective on July 3, 2011. This final rule adopts, without making any changes, the regulatory requirements established in the IFR.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action with an immediate effective date comes within the good cause exception in 5 U.S.C. 553(d)(3) (21 CFR 10.40(c)(4)(ii)). As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

II. Brief History of Prior Notice

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was signed into law on June 12, 2002, and among other things, it amended the FD&C Act by adding section 801(m). This provision created the requirement that FDA receive certain information about imported foods before arrival in the United States. It also provided that an article of food imported or offered for import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA. The Secretary of Health and Human Services was directed to issue implementing regulations, after consultation

with the Secretary of the Treasury, by December 12, 2003, requiring prior notice of imported food.

In accordance with the Bioterrorism Act, the Department of Health and Human Services (HHS) and the Department of the Treasury jointly published a notice of proposed rulemaking (proposed rule) in the Federal Register of February 3, 2003 (68 FR 5428), proposing requirements for submission of prior notice for human and animal food that is imported or offered for import into the United States. On October 10, 2003, HHS and the Department of Homeland Security (DHS)[1] issued the prior notice IFR (2003 IFR) (68 FR 58974) (corrected by a technical amendment on February 2, 2004; 69 FR 4851). The 2003 IFR required that prior notice be submitted to FDA electronically using either the U.S. Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System or the FDA Prior Notice System Interface. The 2003 IFR also set forth the timeframes within which prior notice must be submitted.

In the Federal Register of November 7, 2008 (73 FR 66294), HHS and DHS published a final rule that made a number of changes to the 2003 IFR, including changes to certain provisions containing definitions, submission timeframes, and the information that must be submitted in a prior notice. The final rule went into effect on May 6, 2009. In calendar year 2011, 10,537,372 prior notices were submitted, 9,054,230 of which were submitted through the CBP system with the remaining 1,483,142 being submitted through the FDA system.

[1] On May 15, 2003, the Treasury Department issued Treasury Department Order Number No. 100-16 delegating to DHS its authority related to the customs revenue functions, with certain delineated exceptions in which the Treasury Department retained its authority. See Appendix to 19 CFR Part 0. The Treasury Department transferred to DHS its regulatory authority relating to the requirements for prior notices. Thus the Secretary of HHS issued the regulations implementing section 801(m) of the FD&C Act (21 U.S.C. 381(m)) jointly with the Secretary of Homeland Security. Similarly, this final rule is being issued jointly with the Secretary of Homeland Security.

The prior notice regulations are codified at Title 21, Code of Federal Regulations (CFR) part 1, subpart I (21 CFR 1.276 to 1.285). Section 1.281 of the regulations (21 CFR 1.281) describes the information that must be submitted in a prior notice. The 2011 IFR amended those regulations as required by section 304 of FSMA. Specifically, the 2011 IFR amended paragraphs (a), (b), and (c) of § 1.281 to require that the prior notice include the identity of any country to which an article of food has been refused entry. This final rule adopts these changes to § 1.281.

III. Comments on the Interim Final Rule

FDA received 15 comments in response to the IFR. After considering these comments, the Agency is not making any changes to the regulatory language included in the IFR. Relevant portions of these comments are summarized and responded to in this document. To make it easier to identify comments and FDA's responses, the word "Comment," in parentheses, appears before the comment's description, and the word "Response," in parentheses, appears before FDA's response. Each comment is numbered to help distinguish among different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

(Comment 1) Several comments requested that FDA clarify the scope of the term "refused entry" in the requirement to report in a prior notice the name of "any country to which an article of food has been refused entry". Many comments stated that refusals can occur for various reasons (e.g., labeling, noncompliance with wood packing materials/pallets or food safety reasons) and suggested limiting the reporting requirement to refusals due to food safety-related reasons. One comment noted that only requiring reporting of refusals associated with safety risks will avoid an influx of nonmission-critical data and enable FDA's Division of Food

Defense Targeting (formerly known as the Prior Notice Center) to allocate its resources in a manner that is effective and consistent with FDA's goal to ensure the safety and security of the U.S. food supply.

(Response) For purposes of this regulation, FDA considers "refused entry" to mean a refusal of entry or admission of human or animal food based on food safety reasons, such as intentional or unintentional contamination of an article of food. FDA agrees that only refusals for food safety reasons should be reported. This is consistent with the intent of the provision, which is to provide FDA with additional information to better identify imported food shipments that may pose a safety or security risk to U.S. consumers. FDA plans to explain the meaning of refused entry in its guidance on the prior notice rule and this should prevent confusion regarding the term.

(Comment 2) Several comments suggested including information regarding the reason for refusal in the prior notice to facilitate and better inform FDA's decisionmaking process. One comment recommended the use of affirmation of compliance codes for various types of refusals, using the country identifier as the affirmation of compliance qualifier.

(Response) At this time, FDA is not requiring the reason for refusal to be submitted along with the identity of the country. As FDA reviews the prior notice submission information, it may contact the submitter or other parties to obtain further information to assist with its review.

(Comment 3) Several comments requested that FDA clarify the scope of the term "article of food" in the requirement to report in a prior notice the name of any country to which an "article of food" has been refused entry. In particular, comments suggested clarifying whether "article of food" refers to a specific shipment of food that is the subject of a specific prior notice, or to food within the same lot or batch numbers that may be sent to other countries. Two

comments recommended limiting the scope of the term "article of food" to a specific article of food that is the subject of a specific prior notice so that compliance with the rule does not create a burden on industry.

(Response) For purposes of this regulation, FDA considers the term "article of food" to refer only to the specific food item for which prior notice is being submitted. As such, FDA does not consider "article of food" to refer to food from the same batch or lot that is not being imported or offered for import into the United States and for which prior notice will not be submitted, or to refer to food of a similar type that was previously refused entry by a country. As an example, consider a situation where some of the food from a batch or lot is shipped to the United States and at the same time the rest of the food is shipped to Country A. If Country A refuses entry, this fact is not submitted as part of prior notice for the portion that had been shipped to the United States. However, if the food that was originally shipped to Country A is subsequently shipped to the United States, then the prior notice for this shipment must include Country A as the country to which the article has been refused entry.

(Comment 4) One comment suggested that FDA clearly define the term "any country" as that term is used in the requirement to report in a prior notice the name of "any country" to which an article of food has been refused entry.

(Response) FDA considers this term sufficiently clear and thus is not defining it in the regulation. For the purpose of the prior notice requirements and reporting the name of "any country" to which an article of food has been refused as required by 21 CFR 1.281(a)(18), (b)(12), and (c)(19), "any country" refers to the country or countries, including the United States, where an Agency or representative of the government of the country has refused entry to the article of food.

(Comment 5) A few comments suggested that FDA clarify what documentation or verification is required to support the declaration or nondeclaration in a prior notice of imported food the name of any country to which the article of food has been refused entry.

(Response) The prior notice regulation does not contain any specific requirements regarding documentation of the information submitted as part of prior notice. However, in some circumstances FDA may request documents or other information pertaining to the refusal to facilitate FDA's review of the prior notice. In addition, FDA may request such information to help inform its admissibility decisions.

(Comment 6) One comment suggested that FDA provide clear guidance on the criteria being used when admissibility decisions are made about an article of food that has been refused entry by another country.

(Response) FDA uses prior notice information to make decisions about which imported food shipments to inspect at the time of arrival. Currently, we target foods which, based on the information submitted and our further review, may pose a significant risk to public health. In addition, the fact that another country has refused admission can help inform FDA's admissibility decisions. When the article of food has been refused entry by another country, it may have been for a reason that would also constitute a violation of U.S. law. Even if it is not, this fact will be considered with other information in determining whether a product is subject to refusal of admission in the United States.

(Comment 7) Two comments expressed the importance of ensuring that the new regulations do not become a barrier to trade.

(Response) The comments did not assert that the new requirement is a barrier to trade, and FDA believes it is consistent with the obligations of the United States under applicable trade agreements.

(Comment 8) One comment stated that it is unreasonable to hold importers liable for what could later be found to be a false declaration because importers or their agents, through no fault of their own, may be unaware the article of food had been refused entry by a country.

(Response) Per § 1.278, prior notice must be submitted by a person with knowledge of the required information. When there is a violation of the prior notice regulations, FDA will look at the totality of the circumstances in determining whether and how to enforce the violation. FDA has guidance on enforcing the requirements for submitting prior notice, contained in a compliance policy guide entitled "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm). It explains, for example, that "FDA and CBP's strategy for enforcing violations of [prior notice] is to take into account the severity of the violations, whether they are flagrant, and whether the person has had previous violations, particularly if they were similar types of violations".

IV. Executive Orders 12866 and 13563: Cost Benefit Analysis

FDA has examined the impacts of this final rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Office of Management and Budget (OMB) has determined that this is not a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule "after being required… to publish a general notice of proposed rulemaking." Although we are not required to perform a regulatory flexibility analysis because we were not required to publish a proposed rule prior to this final rule, we have nonetheless conducted a regulatory flexibility analysis for this final rule. Because the costs per entity of this rule are small, the Agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Section 304 of FSMA requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The 2011 IFR implemented section 304 of FSMA by amending the prior notice

regulation that had been in effect. This final rule adopts, without making any changes, the regulatory requirements established in the IFR.

In the 2003 IFR, FDA analyzed the economic impact of the requirements for submitting prior notice for human and animal food that is imported or offered for import into the United States. The Economic Impact Analysis of the 2008 final rule (73 FR 66294 at 66386) revised the analysis set forth in the 2003 IFR using new data and explained the marginal benefits and costs of the final rule itself, relative to the 2003 IFR.

Based on the analysis set forth in the 2008 final rule, the Economic Impact Analysis of the 2011 IFR estimated the marginal benefits and costs of the new statutory requirement in section 304 of FSMA. The 2011 analysis explained that any additional costs are from the additional time it will take submitters to read and enter the new information. The time needed for reading or entering new information was estimated as the average between 7 and 108 seconds per entry or 58 seconds (on average) per entry. Since the additional time required to provide the new information is a small fraction of the variation in time it can take to complete the prior notice for an entry, the marginal cost for the additional 58 seconds (on average) that it would take to provide the additional information would be negligible.

The 2011 analysis did not quantify potential benefits from the 2011 IFR. However, potential benefits can result from FDA's ability to use the additional information to better identify imported food shipments that may pose a safety or security risk to U.S. consumers. Personnel at the Division of Food Defense Targeting (formerly known as the Prior Notice Center) decide on a case-by-case basis whether the article of food needs to be held for examination upon arrival at the port. Having notice of an article of food imported or offered for import into the United States before it reaches a U.S. port allows FDA personnel to be ready at

any time to respond to shipments that appear to pose a significant health risk to humans or animals.

FDA did not receive any comments that would warrant further revising the economic analysis of the 2011 IFR. Thus, this economic analysis confirms the economic impact analysis of the 2011 IFR. For a full explanation of the economic impact analysis of this final rule, interested persons are directed to the text of the 2011 (76 FR 25542 at 25543) and the 2008 (73 FR 66294 at 66386) economic impact analyses.

V. Small Entity Analysis

A regulatory flexibility analysis is required only when the Agency must publish a notice of proposed rulemaking (5 U.S.C. 603, 604). Section 304 of FSMA directed us to issue an IFR implementing that statutory provision, and FDA published the 2011 IFR and this final rule without a notice of proposed rulemaking. Although FDA was not required to publish a notice of proposed rulemaking and, therefore, no regulatory flexibility analysis is required, FDA has nonetheless conducted such an analysis and examined the economic implications of this final rule on small entities. FDA concludes that this final rule will not have a significant impact on a substantial number of small businesses.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 1.281 have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. The requirements were approved and assigned OMB control number 0910-0683. This approval expires April 30, 2014. An Agency may not conduct

or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FDA did not receive comments that would affect the Paperwork Reduction Act burden estimates made in the 2011 IFR (76 FR 25542 at 25544). Therefore the estimated Paperwork Reduction Act burden for this final rule is the same as the estimated burden in the 2011 IFR.

VII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

PART 1--GENERAL ENFORCEMENT REGULATIONS

Accordingly, the interim rule amending 21 CFR part 1, which was published at 76 FR 25542 on May 5, 2011, is adopted as a final rule without change.

Dated:_May 22, 2013_____.

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Kathleen Sebelius,

Secretary of Health and Human Services.

Dated:_May 22, 2013_____.

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Janet Napolitano,

Secretary of Homeland Security.

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