article of food is adulterated or misbranded.

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Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10953 Filed 5–4–11; 8:45 am]

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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: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on prior notice of imported food. As required by the FDA Food Safety Modernization Act, FDA is issuing this interim final rule to require an additional element of information in a prior notice of imported food. This change 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 new information can help FDA make better informed decisions in managing the potential risks of imported food into the United States.

DATES: This interim final rule is effective July 3, 2011. Interested persons may submit either electronic or written comments on this interim final rule by August 3, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by June 6, 2011 (see the "Paperwork Reduction Act of 1995" section of this document (section IV of this document).

FOR FURTHER INFORMATION CONTACT: Anthony C. Taube, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 12420 Parklawn Dr., ELEM–4051, Rockville, MD 20857, 866–521–2297.

ADDRESSES: You may submit comments on this interim final rule, identified by Docket No. FDA–2011–N–0179 and/or RIN number 0910–AG65 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Background

Each year about 48 million people (1 in 6 Americans) are sickened, 128,000 are hospitalized, and 3,000 die from food borne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 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 amends section 801(m) of the Federal Food, Drug, and Cosmetic Act (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 of FSMA also requires the Secretary of Health and Human Services to issue an interim final rule implementing this statutory change no later than 120 days following the date of enactment of the legislation and provides that the amendment made by section 304 of FSMA takes effect 180 days after the date of enactment, which is July 3, 2011.

B. 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. Among other things, the Bioterrorism Act 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 interim

[1] On May 15, 2003, the Treasury Department issued Treasury Department Order Number No. 100–16 delegating to the DHS its authority related to the customs revenue functions, with certain

final rule (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 (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (PNSI). 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 2010, 10,116,018 prior notices were submitted, 8,570,497 of which were submitted through the CBP system with the remaining 1,545,521 being submitted through the FDA system.

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 describes the information that must be submitted in a prior notice. This interim final rule amends those regulations as required by section 304 of FSMA. Specifically, the interim final rule is amending 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.

II. Executive Orders 12866 and 13563: Cost Benefit Analysis

FDA has examined the impacts of this interim 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 (Pub. L. 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. OMB has determined that this is a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. 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 (Pub. L. 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 $135 million, using the most current (2009) 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.

The Economic Impact Analysis of the 2008 Final Rule: (1) Responded to comments received on the economic analysis of the 2003 IFR, (2) revised the analysis set forth in the 2003 IFR using new data, (3) presented an economic analysis of the leading alternative to the 2003 IFR using new data, and (4) explained the marginal benefits and costs of the final rule itself, relative to the 2003 IFR.

This Economic Impact Analysis further revises the analysis set forth in the 2008 final rule by addressing the economic impact of the new statutory requirement in FSMA.

A. Need for Regulation

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. Requiring notice of prior refusals allows FDA to better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. This interim final rule implements section 304 of FSMA by amending the rule that is already in effect.

B. Costs

In the 2003 IFR (68 FR 58974 at 59027), FDA estimated that it takes 1 hour on average to submit the prior notices for each import entry, and this estimate was not revised for the 2008 final rule. In the final rule (73 FR 66294 at 66386), FDA estimated that, on average, one import entry includes 3.6 distinct food articles or lines and thus requires 3.6 prior notices per import entry. For the final rule the estimated cost of submitting prior notice was $75 per entry assuming 3.6 lines per entry. This estimate includes 45 minutes of an administrative worker's time to gather information to initially complete the prior notice, and then 15 minutes of a manager's time to verify that the information is correct.

Additional costs associated with implementing changes in this interim final rule will be borne by all persons who submit prior notice for an article of food that is imported or offered for import into the United States. These costs are estimated as the additional time it will take for a person to gather and verify the information about whether the article was refused entry and to enter the information into an electronic system. To the extent that the information is readily available and verifiable, we reason that it could take as few as 7 seconds to as many as 108 seconds per entry to do this. In 2010, FDA received 10,116,018 prior notices. In the 2008 economic analysis, FDA estimated an average of 3.6 prior notices (lines) per entry. For purposes of this analysis we consider 3.6 to be a likely approximation of the current number of lines per entry. By dividing the number of prior notices by the 3.6 lines per entry we estimate that there are currently 2.8 million imported food entries (10,116,018 divided by 3.6). By multiplying the number of entries by the additional seconds, we estimate the additional number of hours to provide the additional information for all prior notice submitters to be an average of about 45,000 hours per year. Table 1 of this document shows the possible additional time ranges that submitters may need in order to comply with this interim final rule. The economic impact analysis of the 2008 final rule estimated that the prior notice submissions for some entries (3.6 prior notices per entry) can take more than 1 hour to complete and others may take less than 1 hour. The amount of time needed to complete the submission for an entry can reasonably vary by several minutes. As seen in table 1 of this document, the

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 interim final rule is being issued jointly with the Secretary of Homeland Security.

additional average time of 58 seconds required to provide this information is estimated as the average of 7 and 108 seconds 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.

TABLE 1—ESTIMATED RANGE OF TIME NEEDED FOR READING AND/OR ENTERING NEW INFORMATION

	Calculation			
(A) Number of prior notices (lines) in 2010 *	A	10,116,018	10,116,018	10,116,018
(B) Lines per entry **	B	3.6	3.6	3.6
(C) Food entries per year	C = A/B	2,810,005	2,810,005	2,810,005
(D) Number of submitters ***	D	129,757	129,757	129,757
(E) Entries per submitter	E = C/D	22	22	22
		Lower bound	Average	Upper bound
(F) Additional time per line (seconds)	F	2	16	30
(G) Additional time per entry (seconds)	G = B × F	7	58	108
(H) Additional hours per entry	H = G/3,600	0.002	0.016	0.030
(I) Additional hours per submitter per year	I = H × E	0.04	0.35	0.65
(J) Additional hours per year for all submitters	J = C × H	5,620	44,960	84,300

* Data from FDA Prior Notice Center.
** Based on estimate in the **Federal Register** of November 7, 2008 (73 FR 66294 at 66386).
*** OASIS 2010 data.

C. Benefits

FDA's prior notice system provides us with enhanced knowledge of what articles of food are being imported or offered for import into the United States. Requiring prior notice of imported food shipments and defining the required data improves our ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Before prior notice was required, FDA received almost no advance notice information about food products entering the United States from foreign sources, or the location of the food's anticipated port of arrival. With the information required by prior notice, FDA does know what articles of food are being imported or offered for import before they arrive at the port. In the event of a credible threat for a specific product or a specific manufacturer or processor, for example, FDA will be able to mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals.

FDA's Prior Notice Center reviews prior notices and assesses the risk related to imported food shipments. FDA will be able to use the additional information from this interim final rule to better identify imported food shipments that may pose a safety or security risk to U.S. consumers. Personnel at 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.

III. Small Entity Analysis

FDA examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities.

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. Because the compliance costs are negligible, FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act this interim final rule will not have a significant impact on a substantial number of small businesses.

IV. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of these requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Information Required in Prior Notice of Imported Food.

Description: FDA is issuing regulations to require 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." Persons submitting prior notice will gather and verify information about whether the article was refused entry to any country and enter the information into an electronic system.

Description of Respondents: All persons who submit prior notice for an article of food that is imported or offered for import into the United States. FDA estimated that in 2010 there were about 129,757 prior notice submitters.

Burden: FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
1.281	129,757	22	2.8 million	0.016	44,960

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of annual responses is equivalent to the annual number of entries that are submitted. In 2010, FDA received 10,116,018 prior notices. By dividing the number of prior notices by the average number of lines per entry, we estimate 2.8 million entries. By further dividing the number of entries by the number of respondents, we estimate the average annual frequency per response to be 22. We estimate that it would take on average about 58 seconds (0.016 hours) for each respondent to submit the additional information as part of prior notice. By multiplying the number of entries by the additional 58 seconds, we estimate the total number of hours to provide the additional information to be an average of approximately 45,000 hours per year which also translates to about 20 minutes (0.35 hours) per year per respondent.

The information collection provisions for this interim final rule 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.

Interested persons are requested to fax comments regarding information collection by June 6, 2011, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title, Information Required in Prior Notice of Imported Food.

V. 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.

VI. 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.

VII. Comments

The requirements in this interim final rule will be in effect on July 3, 2011. FDA invites public comment on this interim final rule, and will consider modifications to it based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.281 is amended by adding paragraphs (a)(18), (b)(12), and (c)(19) to read as follows:

§ 1.281 What information must be in a prior notice?

(a) * * *

(18) Any country to which the article has been refused entry.

(b) * * *

(12) Any country to which the article has been refused entry.

(c) * * *

(19) Any country to which the article has been refused entry.

Dated: April 29, 2011.

Janet Napolitano,

Secretary of Homeland Security.

Dated: April 29, 2011.

Kathleen Sebelius,

Secretary of Health and Human Services.

[FR Doc. 2011–10955 Filed 5–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0097]

RIN 1625–AA00

Safety Zone; Blue Crab Festival Fireworks Display, Little River, Little River, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Little River in Little River, South Carolina during the Blue Crab Festival Fireworks Display on Friday,