prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at McCall Municipal Airport, McCall, ID.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM ID E5 McCall, ID [Amended]

McCall Municipal Airport, ID
(Lat. 44°53′19″ N., long. 116°06′06″ W.)

That airspace extending upward from 700 feet above the surface within 5 miles west and 7 miles east of the 169° and 349° bearings from the McCall Municipal Airport extending from 21 miles south to 6 miles north of the McCall Municipal Airport; that airspace extending upward from 1,200 feet above the surface within a line from lat. 44°12′00″ N., long. 116°06′00″ W.; to lat. 45°05′00″ N., long. 117°28′00″ W.; to lat. 45°15′00″ N., long. 117°19′00″ W.; to lat. 45°05′30″ N., long. 115°52′00″ W.; to lat. 44°16′00″ N., long. 115°40′00″ W.; thence to the point of beginning.

Issued in Seattle, Washington, on 4/27/2011.

Rob Henry,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–10924 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

RIN 0910–AG67

[Docket No. FDA–2011–N–0197]

Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption

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 administrative detention of food for human or animal consumption. As required by the FDA Food Safety Modernization Act (FSMA), FDA is issuing this interim final rule to change the criteria for ordering administrative detention of human or animal food. Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This will further help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.

DATES: *Effective date:* This interim final rule is effective July 3, 2011.

Comment date: Interested persons may submit either electronic or written comments on this interim final rule by August 3, 2011.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1611.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0197 and/or RIN number 0910–AG67, 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.

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 207 of FSMA amends the criteria for ordering administrative detention of human or animal food in section 304(h)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(h)(1)(A)). Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. Decisions regarding

whether FDA has a "reason to believe" a food is adulterated or misbranded would be made on a case by case basis because such decisions are fact specific. Section 207 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 FSMA and provides that the amendment made by section 207 takes effect 180 days after the date of enactment, which is July 3, 2011.

B. Brief History of Administrative Detention

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), was signed into law on June 12, 2002. Among other things, the Bioterrorism Act amended the FD&C Act by adding subsection (h) to section 304. This provision provided FDA the authority to order the detention of any article of food if during an inspection, examination, or investigation an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act also amended the FD&C Act by adding subsection (bb) to section 301 (21 U.S.C. 331), making it a prohibited act to move an article of food in violation of a detention order or to remove or alter any mark or label required by a detention order that identifies an article of food as detained.

In accordance with the Bioterrorism Act, FDA issued a notice of proposed rulemaking (proposed rule) in the **Federal Register** of May 9, 2003 (68 FR 25242), proposing procedures for the administrative detention of an article of food. In the **Federal Register** of June 4, 2004 (69 FR 31660), the Agency issued the final rule establishing the procedures for administrative detention, including among other provisions the criteria for ordering administrative detention. The administrative detention regulations have been codified at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart K (21 CFR part 1, subpart K). This interim final rule amends those regulations. Specifically, the interim final rule is amending §§ 1.378 and 1.393(a) by replacing the existing criteria used to order administrative detention with the new criteria required by section 207 of FSMA.

II. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

FDA has examined the impacts of this interim final rule under Executive Order 12866, Executive Order 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 additional costs per entity of this rule are negligible if any, 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 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 interim final rule to result in any 1-year expenditure that would meet or exceed this amount.

In the 2003 proposed rule, FDA analyzed the economic impact of the proposed rule to provide procedures for administrative detention of food for human or animal consumption under the Bioterrorism Act (68 FR 25242 at 25250). The Economic Impact Analysis of the June 4, 2004, final rule (69 FR 31660 at 31685) revised the analysis set forth in the 2003 proposed rule. The 2004 analysis explained that any costs and/or benefits of the rule can be generated only in those circumstances in which FDA would choose to order administrative detention instead of using other enforcement tools available to the Agency, such as requesting voluntary recall, instituting a seizure action, or referring the matter to State authorities. In the 2004 analysis, FDA noted that because administrative detention was a new enforcement tool, we were not able to directly estimate how often it would be used. FDA indirectly estimated the number of potential events that would trigger an administrative detention as a subset of other existing enforcement actions at the time. The analysis assumed that FDA would be likely to choose administrative detention only if it were the most effective enforcement tool available in a particular situation.

This Economic Impact Analysis explains and further revises the analysis set forth in the 2004 final rule by addressing the economic impact of the new requirement in section 207 of FSMA.

A. Need for Regulation

The need for this interim final rule arises from section 207 of FSMA which changed the criteria for ordering administrative detention of human or animal food. The current criteria in section 304(h)(1)(A) of the FD&C Act provide FDA the authority to order the detention of an article of food if during an inspection, examination, or investigation, an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. Section 207 of FSMA changes the criteria to allow the Agency to order detention if there is reason to believe that an article of food is adulterated or misbranded. The new criteria provide FDA enhanced authority to detain articles of food that may be adulterated or misbranded for 20 calendar days with a possible 10 calendar day extension if needed to initiate legal action under section 304 or 302 of the FD&C Act (21 U.S.C. 332). This authority will further help the Agency prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the food supply in the United States. This interim final rule implements section 207 of FSMA by amending 21 CFR part 1, subpart K, which is already in effect.

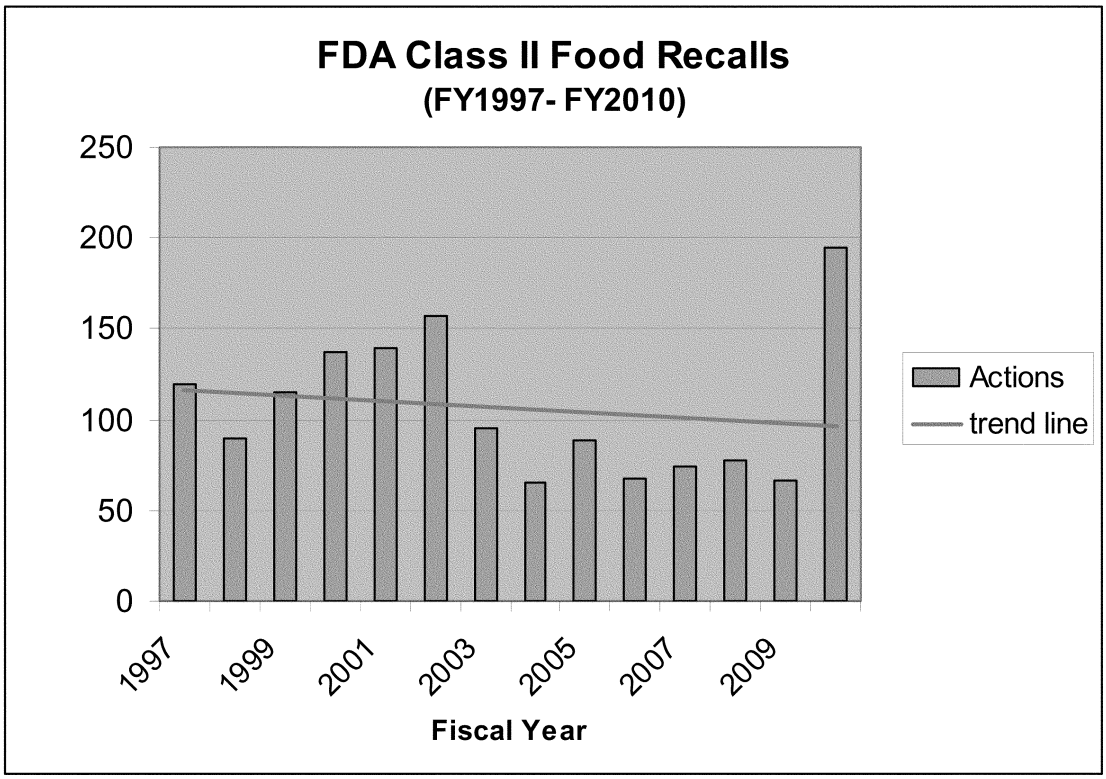
B. Costs

The economic impact analysis of the 2004 final rule estimated the costs of taking administrative detention actions relative to the costs of other

enforcement tools already available to FDA. Using these existing tools FDA could do the following: (1) Request a voluntary recall of the suspected product; (2) move directly to seize the food; or (3) refer the matter to State authorities. The 2004 analysis explained that the estimated number of potential events that would trigger an administrative detention could also trigger the existing enforcement actions. The number of actions was estimated as a range between 0 and 223 actions per year. The upper bound (223) is the sum of 184 Class I recalls, 16 direct seizures, and 23 or 10 percent of the referrals to State authorities in fiscal year 2002. This sum (223 actions) represents the upper bound number of times FDA anticipated using administrative detention, and the lower bound of 0 suggests the possibility that FDA may not order administrative detention at all in a given year. In the analysis FDA explained that the main costs of administrative detention are from the potential loss of the value of products detained that are not in fact adulterated. Although FDA did not know the fraction of detained food products that would prove not to be adulterated, FDA used 48 percent as an upper bound. This number represents the fraction of imported foods that we detain and later release. The lower bound used was 0 percent because FDA might only administratively detain adulterated food products. The total annual costs for the 2004 final rule were estimated to be between $0, if FDA never orders administrative detention, and $50 million, if FDA orders administrative detention against food products 48 percent of which are later determined not to be adulterated.

Since the Agency has had administrative detention authority, we have never administratively detained an article of food. Under the new criteria, we believe that we are more likely to use administrative detention against articles of food in situations which include, among others, where the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. These situations are analogous to the situations for ordering Class II recalls. FDA may choose to order administrative detention in a variety of situations, including Class II situations, therefore FDA has used the number of Class II recalls to estimate the costs and benefits of this interim final rule. Chart 1 below shows the number of Class II food recall actions reported in the last 14 years ranging from 65 to 195 (annual average of 160).

Chart 1. FDA Class II Food Recalls



To the extent that the changes made by this interim final rule provide FDA enhanced enforcement abilities in addition to other existing enforcement tools, the maximum number of times we can reasonably expect to order administrative detention in situations involving an article of food that meets the criteria for Class II recalls is bounded by the highest known number of times we have ordered a Class II recall. The highest number of Class II recall events in the last 14 years was 195 and the lowest number was 65. However, it is still possible that we may not use administrative detention in the event of a Class II recall situation. Therefore we estimate that the number of times we are likely to order administrative detention could range between 0 and 195 times per year. Although the 2004 cost estimates were based on the expectation that FDA would use administrative detention no more than 223 times per year, FDA has not used administrative detention as an enforcement tool. The upper bound cost

in the 2004 analysis was over estimated and given our present knowledge, we believe it is still likely to be an overestimate. By changing the criteria under which we can order administrative detention, we further reason that FDA will be more likely to order administrative detention a number of times greater than 0 but less than 195 times during any given year. We reason that any new potential costs attributable to this interim final rule are likely to be somewhat less than the upper bound costs previously estimated in the 2004 analysis, which were $50 million.

C. Benefits

The benefits of using administrative detention as a new enforcement tool were discussed in the Economic Impact Analysis of the 2004 final rule (68 FR 31660 at 31685) but were not definitively quantified because it was difficult to directly estimate how often FDA would order administrative detention of food. The primary benefits of administrative detention as described in the 2004 analysis are the value of the illnesses or deaths prevented because the Agency administratively detained food suspected of being adulterated. These benefits are generated if the following two conditions hold: (1) The food is in fact adulterated and (2) administrative detention prevents more illnesses or deaths than would have been prevented had we relied on our other enforcement tools. The more often these conditions hold, and the larger the amount of adulterated food administratively detained, the larger the estimated benefits of the final rule. The 2004 final rule analysis also discussed that additional benefits may be achieved in terms of deterrence to the extent that as the number of ordered administrative detentions increases so does the likelihood that adulterated products will not be shipped in the future. As described in the 2004 final rule, the expected benefits from new administrative detention authority depend upon FDA using administrative detention as an enforcement tool. Likewise, the expected benefits from this interim rule also depend on FDA using this authority. As mentioned in the cost analysis section, under the new criteria, FDA may choose to order administrative detention in a variety of situations, including Class II situations. We also reasoned that the expected number of future administrative detentions could increase as much as the number of Class II situations per year, which could be as many as 195. Either way, if FDA orders administrative detention 195 times in one year, the expected upper bound benefits are likely to be somewhat less than those described in the 2004 analysis as a result. At the same time, it is still possible that FDA will not use administrative detention as an enforcement tool in all of these situations, in which case the benefits would likely be 0 which is the same lower bound for benefits described in the 2004 analysis.

III. Small Entity Analysis (or Final Regulatory Flexibility 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. 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

FDA concludes that the requirements of this interim final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3220).

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 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 1.378 is revised to read as follows:

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

■ 3. Section 1.393 is amended by revising paragraph (a) to read as follows:

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has reason to believe that such

article of food is adulterated or misbranded.

* * * * *

Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

BILLING CODE 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: 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