

C. If FDA considers reduced fee amounts in the proposed set of guidelines, what factors should FDA consider in establishing the amount by which fees could be reduced?

1. Should FDA consider the following:

- A waiver of all of the fees;
  - A percentage reduction of the fees;
- or
- A fixed dollar reduction of the fees?

2. Are there circumstances that justify one approach over another? Please explain.

3. Are there other approaches that should be considered? Please explain.

### III. Comments

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.

### IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Scallan E., R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M-A. Widdowson, S.L. Roy, *et al.*, "Foodborne Illness Acquired in the United States—Major Pathogens," *Emerging Infectious Diseases*, 17(1):7–15, 2011. Available at <http://www.cdc.gov/EID/content/17/1/7.htm>.
2. Scallan E., P.M. Griffin, F.J. Angulo, R.V. Tauxe, R.M. Hoekstra, "Foodborne Illness Acquired in the United States—Unspecified Agents," *Emerging Infectious Diseases*, 17(1):16–22, 2011. Available at <http://www.cdc.gov/EID/content/17/1/16.htm>.

Dated: July 26, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0528]

#### Food Safety Modernization Act Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates for Fiscal Year 2012

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2012 fee rates for certain domestic and foreign facility reinspections, failure to comply with a recall order, and importer reinspections that are mandated in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2011, and will remain in effect through September 30, 2012. Invoices for these fees for FY 2012 will be issued using the fee schedule established in this document. FDA is accepting comments to this document and intends to consider such comments in implementing these user fees in FY 2013.

**DATES:** Submit either electronic or written comments by October 31, 2011.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Amy Waltrip, 12420 Parklawn Dr., Rm. 2012, Rockville, MD 20857, 301–796–8811, email: [Amy.Waltrip@fda.hhs.gov](mailto:Amy.Waltrip@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FSMA (Pub. L. 111–353), section 743 of the FD&C Act (21 U.S.C. 379j–31), establishes three different kinds of fees. The fees are assessed for the costs of the following activities: (1) Certain domestic and foreign facility reinspections (section 743(a)(1)(A)), (2) failure to comply with a recall order under section 423 or 412(f) of the FD&C Act (section 743(a)(1)(B)), and (3) certain importer reinspections (section 743(a)(1)(D)).

Fees for each of these activities are to be established to capture 100 percent of the costs of each activity for each year (sections 743(b)(2)(A), (B), and (D) of the FD&C Act), and must be made available

solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3) of the FD&C Act).

These fees are effective on October 1, 2011, and will remain in effect through September 30, 2012. FDA is accepting comments to this document and intends to consider such comments, as well as experience and additional data gained in implementing these user fees in FY 2012, in implementing these user fees in FY 2013.

##### II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2012

FDA is required to estimate 100 percent of its cost for each activity and assess fees for FY 2012. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (or the operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

###### A. Estimating the Full Cost Per Direct Work Hour in FY 2010

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of a full-time-equivalent (FTE) or paid staff year for the relevant activity. This is most reasonably done by dividing the total funds allocated to the elements of FDA primarily responsible for carrying out the activities for which fees are being collected by the total FTEs allocated to those activities, using information from the most recent FY for which data are available. For the purposes of the FSMA fee provisions, primary responsibility for the activities for which fees will be collected rests with FDA's Office of Regulatory Affairs (ORA), which carries out inspection and other field-based activities on behalf of FDA's product centers, including the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), which have FSMA implementation responsibilities. Thus, as the starting point for estimating the full cost per direct work hour, FDA will use the total funds allocated to ORA for CFSAN and CVM related field activities. The most recent FY with available data is FY 2010. In that year, FDA obligated a total of \$626,095,116 for the Office of Regulatory Affairs (ORA) in carrying out work related to programs of the CFSAN and CVM, excluding the costs of foreign inspection travel. These are the staff primarily conducting the work related to the reinspection and recall activities

for which fees would be charged. The obligated total amount paid for salary, benefits, and operating costs of 2,701 FTEs or paid staff years utilized by ORA in FY 2010, but exclude the cost of foreign inspection travel. Dividing \$626,095,116 by 2,701 FTEs, results in an average cost of \$231,801 per paid staff year, excluding the costs of foreign inspection travel.

Not all of the FTEs required to support the activities for which fees will be collected are conducting direct work such as inspecting or reinspecting facilities, examining imports, or monitoring recalls. Data collected over a number of years and used consistently in other FDA user fee programs (e.g., under the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA)) show that every seven FTEs who perform direct FDA work require three indirect and supporting FTEs. These indirect and supporting FTEs function in budget, facility, human resource, information technology, planning, security, administrative support, legislative liaison, legal counsel, program management, and other essential program areas. On average, two of these indirect and supporting FTEs are located in ORA or the FDA center where the direct work is being conducted, and one of them is located in the Office of the Commissioner. To get the fully supported cost of an FTE, FDA needs to multiply the average cost of an FTE by 1.43, to take into account the indirect and supporting functions. The 1.43 factor is derived by dividing the 10 fully supported FTEs by 7 direct FTEs. In FY 2010, the average cost of an FTE was \$231,801. Multiplying this amount by 1.43 results in an average fully supported cost of \$331,476 per FTE, excluding the cost of foreign inspection travel.

To calculate an hourly rate, FDA must divide the average fully supported cost of \$331,476 per FTE by the average number of supported direct FDA work hours. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR

Total number of hours in a paid staff year .....	2,080
Less:	
10 paid holidays .....	80
20 days of annual leave ...	160
10 days of sick leave .....	80
10 days of training .....	80
2 hours of meetings per week .....	80
Net Supported Direct FDA Work Hours Available for Assignments .....	1,600

Dividing the average fully supported cost of an FTE in FY 2010 (\$331,476) by the total number of supported direct work hours available for assignment (1,600) results in an average fully supported cost of \$207 (rounded to the nearest dollar), excluding foreign inspection travel costs, per supported direct work hour in FY 2010—the last FY for which data are available.

*B. Adjusting FY 2010 Costs for Inflation to Estimate FY 2012 Costs*

To adjust the hourly rate for FY 2012, FDA must estimate cost of inflation in each year for FY 2011 and FY 2012. FDA uses the method prescribed for estimating inflationary costs under the PDUFA provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the only provision the FD&C Act that provides a method for estimating future inflationary costs. The inflationary adjustment specified in these provisions, since FY 2008, is the greater of the following amounts: (1) The total percentage change that occurred in the Consumer Price Index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the FY for which fees are being set; (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area; or (3) the average annual change in cost, per FDA FTE, of all personnel compensation and benefits paid per FTE over the previous five of the most recent six FYs. PDUFA IV provides for this adjustment to be

cumulative and compounded annually after FY 2008 (see section 736(c)(1)).

For FY 2012, the first factor is the CPI increase for the 12-month period ending in June 2011. The CPI for June 2011 was 225.722 and the CPI for June 2010 was 217.965. (These CPI figures are available on the Bureau of Labor Statistics Web site at <http://data.bls.gov/cgi-bin/surveymost?bls> by checking the first box under “Price Indexes” and then clicking “Retrieve Data” at the bottom of the page. FDA has verified the Web site addresses throughout this document, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) The CPI for June 2011 is 3.559 percent higher than the CPI for the previous 12-month period.

The second factor for the FY 2012 inflationary increase is the increase in pay for the previous FY (FY 2011 in this case) for Federal employees stationed in the Washington, DC metropolitan area. (This figure is published by the Office of Personnel Management, and can be found on the Web site at <http://www.opm.gov/oca/11tables/html/dcb.asp> above the salary table. For FY 2011, the inflationary increase was 0.00 percent.

For FY 2012, the third factor is the average change in FDA’s cost for compensation and benefits per FTE over the previous five of the most recent six FYs (FY 2006 through FY 2010). The data on total compensation and benefits paid and numbers of FTEs paid, from which the average cost per FTE can be derived, are published in FDA’s Justification of Estimates for Appropriations Committees. Table 2 of this document summarizes the actual costs and FTE data for the specified FYs, and provides the percent changes from the previous FYs and the average percent change over the previous five of the most recent six FYs, which is 3.72 percent.

TABLE 2—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	Average for latest 5 years
Total PC&B .....	\$1,077,604,000	\$1,114,704,000	\$1,144,369,000	\$1,215,627,000	\$1,464,445,000	\$1,634,108,000	.....
Total FTE .....	9,910	9,698	9,569	9,811	11,413	12,526	.....
PC&B per FTE .....	\$108,739	\$114,942	\$119,591	\$123,905	\$128,314	\$130,457	.....
% Change from Previous Year .....	5.75%	5.70%	4.05%	3.61%	3.56%	1.67%	3.72%

Taking all three factors into consideration, the inflationary increase

for FY 2012 is 3.72 percent. The average percent change over the previous five of

the most recent six FYs is 3.72 percent which is greater than the CPI change

during the 12-month period ending June 30 preceding the FY for which fees are being set (3.559 percent), and the increase in pay for the previous FY (FY 2011 in this case) for Federal employees stationed in the Washington, DC metropolitan area (0.00 percent). Therefore, the average percent change in PC&B cost per FTE (3.72 percent) becomes the inflation adjustment for the fee revenue for FY 2012.

The inflationary adjustment for FY 2011 under the same provisions in section 736(c)(1) of the FD&C Act was 4.53 percent—the average percent change over the previous five of the most recent six FYs (FY 2005 through FY 2009). This 4.53 percent is greater than the CPI increase during the 12-month period ending June 30 preceding the FY for which fees were being set on June 30, 2010 (1.053 percent), and the increase in pay for FY 2010 for Federal employees stationed in Washington, DC (2.42 percent).

Section 736(c)(1) of the FD&C Act requires the inflationary adjustment to be cumulative and compounded. This factor for FY 2012 (3.72 percent) is compounded by adding 1 and then multiplying by 1 plus the inflationary adjustment factor for FY 2011 (4.53 percent), to account for the 2 years of inflationary adjustments since FY 2010. The result of this multiplication (1.0372 times 1.0453) becomes the inflationary adjustment for FY 2012, which is 1.0842, or an increase of 8.42 percent over FY 2010 costs.

Increasing FY 2010 average fully supported cost per supported direct FDA work hour of \$207 (excluding foreign inspection travel costs) by 8.42 percent yields an inflationary adjusted cost of \$224 per a supported direct work hour in FY 2012, excluding foreign inspection travel costs. This is the unit cost that FDA will use in billing the reinspection and the recall activities for FY 2012 if no foreign travel is required for the activity.

In FY 2010, ORA spent a total of \$1,010,900 on a total of 91 foreign inspection trips related to FDA's food and veterinary medicine programs, which averaged a total of \$11,109 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$11,109 per trip by 120 hours per trip results in a total and an additional cost of \$93 per paid hour spent for foreign inspection travel costs in FY 2010. To adjust \$93 for inflationary increases in FY 2011 and FY 2012, FDA must multiply it by the same inflation factor mentioned previously in this document (1.0842) which results in an estimated cost of \$101 dollars per paid hour in addition

to \$224 for a total of \$335 per paid hour (\$224 plus \$101) for each direct hour of work requiring foreign inspection travel. These are the rates that FDA will use in charging fees in FY 2012 when foreign travel is required.

TABLE 3—FSMA FEE SCHEDULE FOR FY 2012

Fee category	Fee rates for FY 2012
Hourly rate if no foreign travel is required .....	\$224
Hourly rate if foreign travel is required .....	335

Congress directed FDA to publish, within 180 days of enactment of FSMA, a proposed set of guidelines in consideration of the burden of fee amounts on small business (section 743(b)(2)(B)(iii) of the FD&C Act). Such consideration may include reduced fee amounts for small businesses. FDA believes it is important to gather additional information before publishing such guidelines. Therefore, the Agency is publishing a separate document in this issue of the **Federal Register** requesting public input to help the Agency understand what factors should be taken into account when drafting the proposed guidelines. The Agency intends to consider the comments received and then publish for comment a proposed set of guidelines on the considerations of the burden of fee amounts on small business. Any adjustment to the fee schedule for small business must be done through notice and comment rulemaking (see section 743(b)(2)(B)(iii)). Thus, there will be no separate small business fees published for FY 2012 (table 3 of this document) and the published fees in this document will apply to all businesses in FY 2012.

FDA recognizes, however, that for some small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, and there may be unique circumstances in which some relief would be appropriate. Thus, during FY 2012, FDA will consider waiving in limited cases some or all of an invoiced fee based on a severe economic hardship, the nature and extent of the underlying violation, and other relevant factors.

**III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)**

*A. What will cause this fee to be assessed?*

The fee will be assessed for a reinspection conducted under section

704 of the FD&C Act to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs or holds food<sup>1</sup> for consumption necessitated as a result of a previous inspection (also conducted under section 704) of this facility which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FD&C Act. FDA considers such non-compliance to include non-compliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider non-compliance that is materially related to a food safety requirement to include circumstances where the non-compliance is of a technical nature and not food safety related (e.g., failure to comply with a food standard or incorrect font size on a food label). Determining when non-compliance, other than under section 402 and 403(w) of the FD&C Act, is materially related to food safety may depend on the facts of a particular situation. FDA may consider issuing guidance to provide additional information about the circumstances under which FDA would consider when non-compliance is materially related to a food safety requirement.

Under section 743(a)(1)(A) of the FD&C Act, FDA shall assess and collect fees from "the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d)) and the United States agent for each foreign facility subject to a reinspection" to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term "reinspection" with respect to domestic facilities as "1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction."

The FD&C Act does not contain a definition of "reinspection" specific to foreign facilities. In order to give meaning to the language in section

<sup>1</sup> The term "food" for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

743(a)(1)(A) of the FD&C Act to collect fees from the United States agent of a foreign facility subject to a reinspection, the Agency is using the following definition, of "reinspection," for purposes of assessing and collecting fees under section 743(a)(1)(A) of the FD&C Act, with respect to a foreign facility: "1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction."

This definition allows FDA to fulfill the mandate to assess and collect fees from the United States agent of a foreign facility in the event that an inspection reveals non-compliance materially-related to a food safety requirement causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of non-compliance materially related to a food-safety requirement of the FD&C Act. The definition of "reinspection-related costs," as defined in section 743(a)(2)(B) of the FD&C Act, relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A) of the FD&C Act.

*B. Who will be responsible for paying this fee?*

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the United States agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

*C. How much will this fee be?*

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility,

preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 3 of this document.

**IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)**

*A. What will cause this fee to be assessed?*

The fee will be assessed for not complying with a recall order under section 423(d) or 412(f) of the FD&C Act to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Noncompliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

*B. Who will be responsible for paying this fee?*

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

*C. How much will this fee be?*

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 3 of this document.

**V. Fees for Import Reinspection/ Reexamination Under Section 743(a)(1)(D)**

*A. What will cause this fee to be assessed?*

Under section 743(a)(2)(A)(ii) of the FD&C Act, for a fee to be assessed, there must be two sets of examinations. First, there must be an examination conducted under section 801 of the

FD&C Act (21 U.S.C. 381), which must identify noncompliance materially related to a food safety requirement of the FD&C Act.

Second, subsequent to the first examination, there must be 1 or more additional examinations conducted under section 801. These additional examinations must be conducted specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. Moreover, per section 743(a)(1)(D) of the FD&C Act, an importer subject to a reinspection will be assessed a fee to cover reinspection-related costs.

FDA has determined that at least the following four specific situations will cause a fee to be assessed:

1. Reconditioning of Imported Food

FDA reviews food that is imported or offered for import to determine admissibility into the United States (see, e.g., section 801(a) of the FD&C Act). Food is subject to refusal of admission if, among other reasons, (a) it appears to be adulterated or misbranded, or (b) if it is a dietary supplement subject to section 761 of the FD&C Act (21 U.S.C. 379aa-1), FDA has credible evidence or information indicating that the responsible person has not complied with a requirement of that section or has not allowed access to records described in that section. When FDA initiates a refusal of admission, often referred to as detaining the product, notice is given to the owner or consignee. If the detention is based on one of the reasons just described, the owner or consignee of the food may request permission to recondition the food under section 801(b) of the FD&C Act. When the basis is that the food appears to be adulterated or misbranded, the request can be to bring the food into compliance by relabeling or other action, such as heat treatment, or to render it other than a food, drug, device, or cosmetic. When the basis relates to section 761 (serious adverse event reporting for dietary supplements), the request can be for the responsible person, as defined in section 761, to take action to ensure that the responsible person is in compliance with section 761.

A request for reconditioning is made after FDA has determined that the food is subject to refusal of admission under section 801(a) of the FD&C Act. For the purpose of section 743 of the FD&C Act, FDA considers its review of information for the purpose of determining whether an article of food is admissible to be "an examination conducted under section 801." If that review leads FDA to determine that the food is subject to

refusal of admission under section 801(a), FDA considers that to mean that its examination “identified noncompliance” for the purpose of section 743. This examination could involve, for example, a laboratory analysis of physical samples of the product or a review of the product’s label. It could also involve reviewing other information FDA obtains, such as reviewing sample results from a reliable third party, relevant epidemiological evidence, or the results from an FDA or third party inspection of a facility where the food was processed. A detention without physical examination could also be based on information contained in an import alert.

When food is on an import alert, it typically means that FDA has concluded there is sufficient evidence or other information to detain without physical examination of future shipments of the imported food (e.g., that future shipments appear to be adulterated or misbranded) and they are subject to refusal unless the owner or consignee shows the product is compliant (e.g., through third-party laboratory analysis). FDA considers situations where FDA’s review of information leads it to conclude that food should be placed on an import alert for detention without physical examination to be “an examination conducted under section 801 [that] identified noncompliance” for the purposes of section 743. FDA’s Regulatory Procedures Manual (RPM), Chap. 9, discusses the types of reviews FDA conducts, and the types of information it reviews, in determining whether to detain a product or to place a product on an import alert.

For a fee to be assessed under section 743, FDA’s determination that the food is subject to refusal of admission must be on a basis materially related to food safety requirements (see section III.A of this document for a discussion about “materially related to food safety requirements”).

If FDA authorizes a request for reconditioning, the reconditioning operations are carried out under the supervision of either FDA or U.S. Customs and Border Protection (CBP) (section 801(b) of the FD&C Act; 21 CFR 1.96(a)). FDA considers the review and approval of the request, as well as this supervision to be “1 or more examinations conducted under section 801 \* \* \* specifically to determine whether compliance has been achieved” to FDA’s satisfaction.

## 2. Importer Seeking Admission of an Article That Has Been Detained

If FDA has determined that an article of food is subject to refusal of admission

under section 801(a) of the FD&C Act, FDA gives notice of this to the owner or consignee, who then has an opportunity to introduce evidence regarding the admissibility of the food (section 801(a) of the FD&C Act; 21 CFR 1.94(a)). As discussed previously in this document, where FDA has reviewed information for the purpose of admissibility and determined that the food is subject to refusal of admission under section 801, FDA considers that it has conducted “an examination conducted under section 801 [that] identified noncompliance.” This includes situations where FDA’s review determines that food should be placed on an import alert for detention without physical examination.

If the owner or consignee chooses to submit evidence regarding admissibility, FDA reviews the information to determine whether—despite the appearance that the product is adulterated, misbranded, or otherwise subject to refusal of admission—the food is compliant and admissible into the United States. The evidence the owner or consignee submits varies. Depending on the circumstances, it could include, for example, the results of laboratory analyses of samples conducted on the owner/consignee’s behalf to show the product is not contaminated. FDA considers its review of the evidence submitted to be “1 or more examinations conducted under section 801 \* \* \* specifically to determine whether compliance has been achieved” to FDA’s satisfaction.

Not all situations where the owner/consignee provides information or evidence to demonstrate compliance will result in the assessment of a fee. An example is if a food, not subject to an Import Alert, is detained based on an appearance of adulteration or misbranding, but information is presented that demonstrates that the food is not adulterated or misbranded. FDA considers such a situation to be one in which a fee is not assessed.

A fee may or may not be assessed under certain circumstances related to food that is detained based on an import alert for detention without physical examination covering food from a particular geographic region or country. FDA may place a region or country on an import alert if there appears to be an ongoing problem or condition in that region or country such that it causes the appearance of a violation for future shipments of imported articles originating there. If food from a region or country is subject to an import alert and is subsequently detained based on the overarching import alert, the owner or consignee may seek admission by providing evidence that the problem or

conditions regarding the food it is importing have been resolved. Alternatively, the owner or consignee may provide evidence that the problems or conditions that led to the alert, even if widespread in the region or country, did not apply to its food and, thus, it did not need to resolve any compliance-related issues. FDA considers the latter situation to be one in which a fee is not assessed. A fee may be assessed, however, when FDA reviews compliance information specific to the food being imported or specific to a particular processor in determining whether to issue a region- or country-wide import alert. An example is a situation where FDA analyzed samples of food from Processor A and found it to be contaminated, the food is later placed on a region- or country-wide import alert, and the owner or consignee is now importing or offering for import food from Processor A. If the owner or consignee seeks admission of the food by providing third party laboratory analyses to show the food is not contaminated, FDA’s review of this information would be “1 or more examinations conducted under section 801 \* \* \* specifically to determine whether compliance has been achieved” to FDA’s satisfaction.

## 3. Entity Requesting Removal From an Import Alert for Detention Without Physical Examination

Once placed on import alert, food imported from a particular firm, region, or country may remain in this status until FDA has sufficient evidence or other information, such as information that removes the appearance of the violation that led to the initial placement on import alert. Depending on the situation that led to the import alert, FDA’s RPM Chapter 9 or the import alert itself may explain the types of information that should be provided.

As discussed previously in this document, where FDA has reviewed information and determined that food should be placed on an import alert for detention without physical examination, it considers that it has conducted 1 or more examinations conducted under section 801 that identified noncompliance.

Where an entity requests removal of food from an import alert and provides supporting information, FDA considers its review of this information, along with any other related examination it undertakes in considering the request, to be “1 or more examinations conducted under section 801 \* \* \* specifically to determine whether compliance has been achieved” to FDA’s satisfaction.

As discussed in section V.A.2 of this document, some requests for removal from region- or country-wide import alerts will not lead to the assessment of a fee. Fees would only be assessed in situations where, in issuing the alert, FDA reviewed compliance information specific to a particular person or entity sufficiently related to the request for removal. An example of such a situation is where FDA analyzed samples of food from Processor A and found it to be contaminated, the food is then placed on a region- or country-wide import alert, and FDA receives a request to remove food from Processor A from the import alert.

#### 4. Destruction of Food That Has Been Refused Admission

If a product is refused admission under section 801(a) of the FD&C Act, it must be exported within 90 days of the document of refusal or it is subject to destruction by CBP (section 801(a) of the FD&C Act). In practice, when a product is destroyed, destruction is often conducted by the owner or consignee under the supervision of FDA or CBP. Where FDA conducts a review and/or approves a destruction proposal and such supervision of destruction occurs, FDA considers this to be "1 or more examinations conducted under section 801 \* \* \* specifically to determine whether compliance has been achieved" to FDA's satisfaction.

#### B. Who will be responsible for paying this fee?

The importer that is subject to the additional examinations that are described in section V.A of this document is responsible for paying the fee, according to section 743(a)(1)(D) of the FD&C Act.

#### 1. Reconditioning of Imported Food

For reconditioning, the entity that is responsible for the reconditioning is responsible for paying the fee. The request for reconditioning can only be made by the owner or consignee of the food (21 CFR 1.95). If ownership changes, the new owner will be responsible for the reconditioning if that new owner executes a bond and obtains a new authorization (21 CFR 1.96(d)).

#### 2. Importer Seeking Admission of an Article That Has Been Detained

The entity that introduces evidence regarding admissibility is responsible for paying this fee. This is the owner or consignee of the food that is being imported or offered for import. (Section 801(a) of the FD&C Act; 21 CFR 1.83(b) and 1.94(a).)

#### 3. Entity Requesting Removal From an Import Alert for Detention Without Physical Examination.

FDA considers the entity that requests removal of the food from the import alert to be the importer subject to the examination and, thus, responsible for paying this fee.

#### 4. Destruction of Food That Has Been Refused Admission

FDA considers the entity that destroys the product under FDA or CBP supervision to be the importer subject to the examination and, thus, responsible for paying this fee.

#### C. How much will this fee be?

The fee is to cover all expenses incurred in connection with arranging, conducting, and evaluating the results of the one or more additional examinations that are described in section V.A of this document.

For reconditioning, section 801(c) of the FD&C Act directs the owner or consignee to pay all expenses in connection with the supervision of reconditioning with respect to food and certain other FDA-regulated products. Those parties have been paying these expenses, but FDA did not have authority to retain those fees. FDA considers the enactment of section 743 of the FD&C Act to mean that, for food, FDA is now authorized to assess and retain these fees, but only with respect to the reconditioning of food and only if the other conditions of section 743 are met. If a fee is authorized under section 743 for a particular article of food, FDA considers this to mean it cannot collect a fee related to reconditioning that article under section 801(c).

For destruction, section 801(c) of the FD&C Act also directs the owner or consignee to pay all expenses in connection with the destruction of food and certain other FDA-regulated products under section 801(a). However, neither FDA nor CBP have had the authority to retain those fees. FDA considers the enactment of section 743 of the FD&C Act to mean that, for food, FDA is now authorized to assess and retain these fees, but only with respect to the destruction of food and only if the other conditions of section 743 are met. If a fee is authorized under section 743 for a particular article of food, FDA considers this to mean it cannot collect a fee related to destruction of that article under section 801(c) of the FD&C Act.

The direct hours spent on each such import reinspections will be billed at the appropriate hourly rate shown in table 3 of this document.

#### VI. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 30 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

#### VII. What are the consequences of not paying these user fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

#### VIII. Comments

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.

Dated: July 26, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2011-N-0556]

#### Center for Devices and Radiological Health 510(k) Clearance Process; Institute of Medicine Report: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years;" Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments on the Institute of Medicine (IOM) report entitled: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years." The establishment of this public docket does