B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2011, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2012 using this fee schedule. Fees will be due and payable 30 days after the issuance of the invoices. FDA will issue invoices in November 2012 for any products and sponsors subject to fees for FY 2012 that qualify for fees after the December 2011 billing.

Dated: July 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19334 Filed 7–29–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0529]

Burden of Food and Drug Administration Food Safety Modernization Act Fee Amounts on Small Business; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Request for comments and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain information that will be used to formulate a proposed set of guidelines in consideration of the burden of fee amounts on small business, as set forth in the FDA Food Safety Modernization Act (FSMA). FSMA provides the Agency with authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to assess and collect user fees, including those for costs associated with certain domestic and foreign facility reinspections, failure to comply with a recall order, and importer reinspections. The Agency is seeking public comment on what burdens these fees impose on small business, and whether and how the Agency should alleviate such burdens. In particular, the Agency is seeking public comments on whether a reduction of fees or other consideration for small business is appropriate, and if so, what factors the Agency should consider for each. In addition, the Agency is seeking public comment on how small business should be defined or recognized. FDA is establishing this docket in order to provide an opportunity for interested parties to provide data and share views that will inform future Agency actions with respect to these matters.

DATES: Submit either electronic or written comments by October 17, 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: Alexis Nazario-Negron, Office of Financial Management, Food and Drug Administration, 1350 Piccard Dr., rm. 210E,Rockville, MD 20850, 301–796–7223, *Alexis.Nazario-Negron@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. 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 (Refs. 1 and 2). 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 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 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.

Among the new authorities Congress provided in FSMA, the Secretary of Health and Human Services (and by delegation, FDA) is to assess and collect fees from industry for FDA's costs associated with certain activities. Section 107(a) of FSMA (which amends the FD&C Act by adding section 743 (21 U.S.C. 379j-31)) mandates that FDA assess and collect fees for costs associated with certain domestic and foreign facility reinspections, failure to comply with a recall order under sections 423 and 412(f) of the FD&C Act (21 U.S.C. 350l and 350a(f)), and certain importer reinspections (section 743(a)(1) of the FD&C Act).[1]

Section 743(b)(2)(A) of the FD&C Act specifies that the Agency must base these fees on an estimation of 100 percent of the costs of the various activities which are described in section 743(a)(1), for the fiscal year. These fees must be published in the **Federal Register** not later than 60 days before the start of each fiscal year. Elsewhere in this issue of the **Federal Register**, FDA is publishing notice of these fees.

Congress directed FDA to publish, within 180 days of enactment of FSMA, a proposed set of guidelines in consideration of the burden of fee

[1] FDA is not soliciting comments, in this **Federal Register** notice, on the burdens to small businesses that participate in the voluntary qualified importer program (VQIP) under section 743(a)(1)(C) of the FD&C Act. FDA intends to consider such burdens at the time the VQIP is established.

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. However, FDA would like to gather additional information before publishing such guidelines. Therefore, the Agency is publishing this notice to request 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 (section 743(b)(2)(B)(iii) of the FD&C Act). Thus, the Agency would consider the proposed set of guidelines, and comments on such guidelines, in any future rulemaking should it decide to propose to adjust the fee schedule for small business.

II. Request for Comments and Information

In order to better inform the Agency, the Agency seeks comment on the following questions, although any additional comments that can inform the guidelines are welcome.

A. Is a fee reduction or other consideration for small business appropriate? Please explain

Section 743(b)(2)(B)(iii) of the FD&C Act states that the proposed set of guidelines may include consideration of reduced fee amounts for small business, but consideration of reduced fee amounts is not required.

1. What is the impact, if any, of fee amounts on small business, in general, or to specific types of small businesses, that FDA should consider in the proposed set of guidelines? Please explain.

2. Should the Agency consider the type of fee collected when considering the burdens to small business? For example, do the types of activities for which a fee is collected for reinspection have a different impact to a small business than those collected based on a failure to comply with a recall order? Please explain.

3. Assuming there is an impact of fee amounts to small business, or certain types of small businesses, should the Agency consider a reduction in the fees for such small businesses in the proposed set of guidelines? If so, should the Agency consider the reduction in fees to all small businesses, or for only those small businesses that have a demonstrated need for reduced fees? Please explain. If the Agency should not consider a reduction in the fees for small business, why not? Please explain.

4. Are there ways to alleviate any burden on small business other than a fee reduction? Please explain.

B. How should small business be defined or recognized for the purpose of the proposed guidelines?

Several provisions in FSMA require FDA to define small and very small business. For example, section 103(a) of FSMA amends the FD&C Act by adding section 418 (21 U.S.C. 350g) regarding ''Hazard Analysis and Risk-Based Preventive Controls.'' Section 418(n)(1)(B) of the FD&C Act requires FDA to define ''small business'' and ''very small business'' for the purpose of the preventive control regulations for facilities. Similarly, FSMA section 105(a) amends the FD&C Act by adding section 419 (21 U.S.C. 350h) regarding standards for produce safety. Section 419(a)(3)(F) of the FD&C Act requires FDA to define ''small business'' and ''very small business'' for the purpose of the produce safety regulations.

In addition, the Agency has issued a number of final rules where the Agency considered business size when considering the regulatory impact of the rule to industry, including the following final rules:

- ''Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products'' (60 FR 65096, December 18, 1995) (Docket No. FDA–1993–N–0065 (formerly Docket No. 1993N–0195));
- ''Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice'' (66 FR 6138, January 19, 2001) (Docket No. FDA–1997–N–0505 (formerly Docket No. 1997N–0511));
- ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' (72 FR 34752, June 25, 2007) (Docket No. FDA–1996–N–0028 (formerly Docket No. 1996N–0417 or 97N–0417));
- ''Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution'' (65 FR 76092, December 5, 2000) (Docket No. FDA–1998–N–0087 (formerly Docket No. 1998N–1230); Docket No. FDA–1996–P–0025 (formerly Docket No. 96P–0418); and Docket No. FDA–1997–P–0017 (formerly Docket No. 1997P–0197));
- ''Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation'' (74 FR 33030, July 9, 2009) (Docket No. FDA–2000–N–0190 (formerly Docket No. 2000N–0504)).

FDA seeks comment on how a small business should be defined or recognized for purposes of the proposed set of guidelines in consideration of the burden of fee amounts on small business. More specifically, the Agency requests comment on the following questions.

1. If FDA has defined, by regulation under other FSMA or non-FSMA authorities, an entity as a small or a very small business, should such a definition be considered in the proposed set of guidelines to identify the businesses that may be burdened by the fee amounts under section 743 of the FD&C Act or should the Agency consider a separate definition of small business for purposes of considering the burden of fee amounts? Please explain.

2. If the Agency relies on an existing regulatory definition of small or very small business that the Agency established under other FSMA or non-FSMA authorities, should any such definition apply in any circumstance where a fee is imposed or only where the fee derives from the rule where such business is defined as a small business? For example, if a facility is reinspected for a violation of the preventive controls regulations, should the Agency consider adjustments to the fee only if the facility meets the definition of small business under the preventive controls regulations, or should the Agency consider such adjustments if the facility meets any definition of small business under any FDA regulation? Please explain.

3. There may be circumstances where no regulatory definition of small business exists for a given facility. Under these circumstances, what factors or characteristics should FDA use to identify small businesses for which FDA may consider the burden of fee amounts? Please explain. Factors to consider could include, but are not limited to, the segment of the food supply chain to which the entity belongs (*e.g.,* growers, processors, importers and distributors, retailers, *etc.*); the sector to which the entity belongs (*e.g.,* seafood, produce, dairy, eggs, juice, dietary supplements, *etc.*); the number of employees; the gross revenue, net income, net assets, market liquidity, or other financial measures or ratios; and whether the entity has a subsidiary or is a subsidiary of a parent company.

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.

[FR Doc. 2011–19333 Filed 7–29–11; 8:45 am]

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.*

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