Dated: November 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30327 Filed 11–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0841]

Agency Emergency Processing Under the Office of Management and Budget Review; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA). The proposed collection of information concerns a guidance document that outlines the criteria and the process through which firms may request a reduction of fees based on severe economic hardship of the FDA Food Safety Modernization Act (FSMA) reinspection and recall user fees that are mandated by the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Fax written comments on the collection of information by December 15, 2011. FDA is requesting OMB approval of this emergency processing by January 6, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: (202) 395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–New and title ''FDA Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). FDA requests permission to use the emergency clearance procedures to obtain OMB approval of the information collection related to the economic hardship fee reduction guidance. FDA expects to use a print-and-mail or an email form for fee reduction requests. If FDA were to use the normal clearance procedures, the approval of the information collection would not be finalized in time to issue invoices in January 2012. FDA seeks OMB approval of the information collection by January 6, 2012, so the Agency can issue such guidance no later than January 2012.

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

FDA Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance (OMB Control Number 0910–NEW)

On January 4, 2011, the President signed into law FSMA (Pub. L. 111–353). Section 743 of the FD&C Act (21 U.S.C. 379j–31) amended by FSMA, requires FDA to consider the burden of fee amounts on small businesses.

Section 743(b)(2)(B)(iii) of FD&C Act states, ''* * *the Secretary shall publish in the **Federal Register** a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses.* * *'' Before publishing such guidelines, FDA believes it is important to gather additional information related to small business burdens associated with fees to set forth criteria and a rational for such criteria for when a user fee reduction is appropriate. Therefore, FDA published a document in the **Federal Register** of August 1, 2011 (76 FR 45818) (FRN) to seek public comments and information to assist the Agency to develop such guidelines. FDA will review the comments (comment period closes on November 30, 2011) and then develop the proposed set of guidelines; these will likely be implemented in fiscal year (FY) 2013. However, FDA recognizes that, meanwhile, for some small businesses the reinspection or the recall user fees, which went into effect on October 1, 2011, could impose severe economic hardship and there may be unique circumstances in which some relief would be appropriate. During FY 2012, FDA will consider waiving some or all of an invoiced fee based on a severe economic hardship. FDA intends to protect businesses and preserve free competitive enterprise.

FDA is currently developing a guidance to outline the criteria and the process through which firms may request a reduction of fees based on economic hardship. FDA wants to consider the public comments from the small business FRN before finalizing such guidance. Also, in the recent ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act'' that published in the **Federal Register** of October 6, 2011 (76 FR 62073), FDA stated that it would ''not intend to issue invoices for reinspection or recall order fees until this guidance document has been finalized.'' Therefore, FDA needs to publish such guidance soon after November 30, 2011, in order to: (1) Issue invoices and (2) provide important information for qualified firms to apply for fee reductions, which will help them to sustain their businesses. Given such a short timeframe, use of the normal clearance process to obtain OMB approval under the PRA for the information collection related to the economic hardship fee reduction guidance is likely to cause delay of publishing such guidance and subsequently cause delay of issuing invoices. The fees, required by FSMA, are to cover 100 percent of the costs of certain reinspection and recall order activities conducted by FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of Respondents	Number of Responses per Respondent	Total annual responses	Average burden per response	Total hours
Request for reduction of fees collected under section 743 of the FD&C Act	235	1	235	2	470

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

FDA estimates that 510 facilities will be subject to the reinspection and the recall fees under section 743 of the FD&C Act. Of these facilities, we estimate that 46 percent will be small businesses with annual gross sales under $250,000. Therefore, 46 percent of 510 equals to 235 respondents. Each respondent will submit 1 request for reduction of fees. Total annual responses are 235. The average burden is 2 hours, giving a total of 470 hours annual burden.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30471 Filed 11–22–11; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention

Statement of Delegation of Authority

I hereby delegate to the Administrator, Health Resources and Services Administration (HRSA), and the Director, Centers for Disease Control and Prevention (CDC), with authority to redelegate, the authority vested in the Secretary under Title III, Part P, Section 399T (42 U.S.C. 280g–8), titled ''Support for Patients Receiving a Positive Diagnosis of Down Syndrome or Other Prenatally or Postnatally Diagnosed Conditions,'' of the Public Health Service Act, as amended, insofar as such authority pertains to the functions of HRSA and CDC, respectively. HRSA and CDC will coordinate and collaborate with each other and with the National Institutes of Health, as appropriate, in implementing this authority.

This delegation excludes the authority to issue regulations, to establish advisory committees and councils, and appoint their members, and shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines.

I hereby affirm and ratify any actions taken by the Administrator, HRSA, the Director, CDC, or other HRSA and CDC officials, which involve the exercise of these authorities prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: November 14, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–30411 Filed 11–23–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* (301) 496–7057; *fax:* (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Genetically Engineered Mouse Model for Use as an Alternative Screening Method for Evaluating P-glycoprotein (P-gp) Substrate Toxicity in Avermectin-sensitive Dogs

Description of Technology: A pitfall to avermectins is central nervous system (CNS) toxicities in herding dogs. As a result, all new avermectins must be tested in a ''Collie Safety Study'' to determine the degree of CNS toxicity. The toxicity is due to a 4 base pair mutation in the ATP-binding cassette, sub-family B member 1 (ABCB1) gene. This gene encodes for the P-glycoprotein (P-gp) that affects absorption, distribution and elimination of certain drugs. Researchers at FDA have developed an alternate animal model that includes two transgenic mouse models, one containing the mutant form of the canine ABCB1 gene (Yancy 1 line) and the other containing the canine wild-type gene (Yancy 2 line). The paired mouse system can be utilized to assess the safety of avermectins and other canine drugs by determining the toxicity to canines with the mutated form of the ABCB1 gene. Ivermectin, a derivative of the avermectin family of heartworm drugs used to treat and control parasitic infections, was used to verify this mouse model. This technology will enhance the population predictions derived from clinical safety data and serve to reduce the use of dogs in avermectin derivative safety studies that are part of the Investigational New Animal Drug (INAD) approval process.

Potential Commercial Applications: Drug screening technology to assess the toxicity of canine drugs to canines with the mutated form of the ABCB1 gene.

Competitive Advantages: Use as an alternative in vivo model to canines for assessment of drug safety in the presence of the ABCB1 mutation.

Development Stage: In vivo data available (animal).

Inventor: Haile F. Yancy (FDA).

Publication: Orzechowski K, *et al.,* in press Am J Vet Res.

Intellectual Property: HHS Reference No. E–292–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime Greene; (301) 435–5559; *greenejaime@mail.nih.gov*.

Collaborative Research Opportunity: The FDA Center for Veterinary Medicine is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or