

rate for the backlog fee related to generic drug user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), authorizes FDA to assess and collect user fees for certain applications and supplements associated with human generic drug products, on applications in the backlog as of October 1, 2012, on finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities, and on type II API drug master files (DMFs) to be made available for reference. GDUFA directs FDA to establish each year the Generic Drug User Fee rates for the upcoming year. In the first year of GDUFA (FY 2013), some rates will be published in separate **Federal Register** notices because of the timing specified in the statute. Each year thereafter the GDUFA fee rates will be published 60 days before the start of the FY. This document establishes the FY 2013 rate for the backlog fee (\$17,434). This fee is effective on October 1, 2012.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., PI50, rm. 210J, Rockville, MD 20850, 301-796-7103.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42), as added by GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), which was signed by the President on July 9, 2012), establish user fees associated with human generic drug products. Fees are assessed on the following: (1) Applications in the backlog as of October 1, 2012; (2) certain types of applications and supplements associated with human generic drug products; (3) certain facilities where APIs and FDFs are produced; (4) certain type II API DMFs associated with human generic drug products. This notice focuses solely on the backlog fee.

II. Fee Revenue Amount for FY 2013

The total fee revenue amount for FY 2013 is \$299,000,000, as set in the statute (section 744B(b)(1)(A) of the FD&C Act). Under that provision, FDA uses the yearly revenue amount as a starting point to set the fees. The GDUFA statute states that the backlog fee will make up \$50,000,000 of the total revenue collected for FY 2013 (section 744B(b)(1)(A)(i) of the FD&C Act). For more information about

GDUFA, please refer to the FDA Web site (<http://www.fda.gov/gdufa>). The backlog fee calculation for FY 2013 is described in this document.

III. Backlog Fee

Under GDUFA, each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a backlog fee for each such application (section 744B(a)(1)(A) of the FD&C Act). The backlog fee is due no later than 30 days after publication of this notice (section 744B(a)(1)(D) of the FD&C Act). The backlog fee is assessed one time only, for FY 2013, and no backlog fee will be assessed in subsequent years. Once incurred, the backlog fee obligation can only be discharged by payment in full.

Under section 744B(a)(1)(B) of the FD&C Act, FDA calculates the backlog fee by taking the exact number of pending abbreviated new drug applications in the backlog that have not received tentative approval as of October 1, 2012, and dividing \$50,000,000 by that number. Since there are 2,868 applicable applications in the backlog, the backlog fee is calculated to be \$17,434 (\$50,000,000 divided by 2,868 rounded to the nearest dollar).

IV. Fee Payment Options and Procedures

To make a payment of the backlog fee, you must complete a generic drug user fee cover sheet, available on the FDA Web site (<http://www.fda.gov/gdufa>) and generate a user fee payment identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after completing the generic drug user fee cover sheet and generating the user fee payment ID number.

Please include the user fee payment ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101.

(**Note:** This U.S. Bank address is for courier delivery only.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference the user fee payment ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your backlog fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD, 20850. The tax identification number of the Food and Drug Administration is 53-0196965.

Dated: October 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R3-ES-2012-N247;
FX3ES11130300000D2-123-FF03E00000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Bald Eagle Post-delisting Monitoring

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on November 30, 2012. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before November 26, 2012.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the

Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 2042–PDM, 4401 North Fairfax Drive, Arlington, VA 22203 (mail), or *INFOCOL@fws.gov* (email). Please include “1018–0143” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *INFOCOL@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at <http://www.reginfo.gov>. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1018–0143.

Title: Bald Eagle Post-delisting Monitoring.

Type of Request: Extension of a currently approved collection.

Description of Respondents: States, tribes, and local governments; Federal land managers; and nongovernmental partners.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once every 5 years.

Note: For each 5-year survey, we estimate a total of 48 respondents will provide 48 responses totaling 1,478 burden hours. The burden estimates below are annualized over the 3-year period of OMB approval.

Estimated Annual Number of Respondents: 16.

Estimated Total Annual Responses: 16.

Estimated Time per Response: 30.8 hours.

Estimated Total Annual Burden Hours: 493.

Abstract: This information collection implements the requirements of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) (ESA). There are no corresponding Service regulations for the ESA's post-delisting monitoring requirement.

The bald eagle (*Haliaeetus leucocephalus*) in the lower 48 States was removed from the List of Endangered and Threatened Wildlife (delisted) on August 8, 2007 (72 FR 37346, July 9, 2007). Section 4(g) of the ESA requires that all species that are recovered and removed from the List of Endangered and Threatened Wildlife be monitored in cooperation with the States for a period of not less than 5 years. The purpose of this requirement is to detect any failure of a recovered species to sustain itself without the protections of the ESA. We work with

relevant Federal, State, and tribal entities, and other species experts to develop plans and procedures for systematically monitoring recovered wildlife and plants after a species is delisted. The bald eagle has a large geographic distribution that includes a substantial amount of non-Federal land. Although the ESA requires that monitoring of recovered species be conducted for not less than 5 years, the life history of bald eagles is such that it is appropriate to monitor this species for a longer period of time in order to meaningfully evaluate whether or not the bald eagle continues to maintain its recovered status.

We plan to monitor the status of the bald eagle in the 48 contiguous States by collecting data on nests over a 20-year period with sampling events held once every 5 years. The Post-delisting Monitoring Plan for the Bald Eagle (Plan) describes monitoring procedures and methods. The Plan is available at http://www.fws.gov/midwest/eagle/protect/FINAL_BEPDM11May2010.pdf. We will use the monitoring data to review the status of the bald eagle in the United States and determine if it remains recovered and, therefore, does not require the protections of the ESA.

Comments: On June 7, 2012, we published in the **Federal Register** (77 FR 33765) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on August 6, 2012. We received one comment. The commenter objected to the removal of the bald eagle from the endangered species list, but did not address the information collection requirements. We did not make any changes to our requirements based on this comment.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal

identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: October 19, 2012.

Tina A. Campbell,

Chief, Division of Policy and Directives Management, U.S. Fish and Wildlife Service.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–MB–2012–N246; FF09M21200–123–FXMB1231099BPP0L2]

Proposed Information Collection; Alaska Migratory Bird Subsidence Harvest Household Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to renew approval for the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on April 30, 2013. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by December 24, 2012.

ADDRESSES: Send your comments on the IC to the Service Information Collection Clearance Officer, Fish and Wildlife Service, MS 2042–PDM, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); or *INFOCOL@fws.gov* (email). Please include “1018–0124” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey at *INFOCOL@fws.gov* (email) or 703–358–2482 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–712) and the Fish and