

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

21 CFR 314.81(b)(2)(ii)(b)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) <sup>2</sup>	Total hours
Total .....	.....	.....	.....	.....	520

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60.”

Dated: July 1, 2011.  
**Leslie Kux**,  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011-17141 Filed 7-7-11; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket No. FDA-2011-D-0108]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability**

**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 (the PRA).

**DATES:** Fax written comments on the collection of information by August 8, 2011.

**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 e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-New and title “Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and

Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792,  
*Elizabeth.Berbakos@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability—(OMB Control Number 0910—New)**

*I. Background*

FDA is announcing the availability of a revised draft guidance for industry entitled “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” This revised draft guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h). This revised draft guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act, and the procedures for submitting requests for waivers or reductions and requests for reconsideration and appeal. The revised draft guidance also provides clarification on related issues such as user fee exemptions for orphan drugs. After comments are received and considered, FDA intends to promptly issue a final guidance.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on user fee waivers and reductions for drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

*II. Paperwork Reduction Act of 1995*

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain

approval from OMB for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

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

The draft guidance describes how to submit requests for waivers, reductions, and refunds of certain user fees. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. We estimate that the total annual number of waiver requests submitted for all of these categories will be 90, submitted by 75 different sponsors. We estimate that the average burden hours for preparation of a submission will total 16 hours. Because FDA may request additional information from the applicant during the review period, we have also included in this estimate time to prepare any additional information.

The reconsideration and appeal requests are not addressed in the FD&C Act but are discussed in the draft guidance. We estimate that we will receive three requests for reconsideration annually, and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive one request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. Reconsideration requests are sent to the Associate Director for Policy at the Center for Drug Evaluation and Research (CDER), and requests for appeals are sent to the User Fee Appeals Officer at FDA, with a copy to the Associate Director for Policy at CDER. We have also included in this estimate both the time needed to prepare the request for

appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at CDER.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis because that information collection is already approved by OMB under OMB control number 0910-0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses because small businesses requesting a waiver must submit

documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved by OMB under OMB control number 3245-0101.

In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section 736 of the FD&C Act .....	75	1.2	90	16	1,440
Reconsideration Requests .....	3	1	3	24	72
Appeal Requests .....	1	1	1	12	12
Total .....					1,524

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 1, 2011.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011-17142 Filed 7-7-11; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0595]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements**

**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.

**DATES:** Fax written comments on the collection of information by August 8, 2011.

**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 e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0482. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794; *Jonna.Capezzuto@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:.

**Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910-0482—Extension**

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act (21 U.S.C. 381)). In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods and cosmetics that may not be sold in the United States and maintain records demonstrating their