4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0222]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 0910-0693. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@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.

User Fee Waivers, Reductions, and Refunds for Drug and Biological Products (OMB Control Number 0910-0693)--Extension

The 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 (21 U.S.C. 379g and 21 U.S.C. 379h) (the FD&C Act). The 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. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. The guidance also provides clarification on related issues such as user fee exemptions for orphan drugs.

We estimate that the total annual number of waiver requests submitted for all of these categories will be 120, submitted by 100 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 guidance. We estimate that we will receive 3 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 1 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. We have 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 the Center for Drug Evaluation and Research.

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 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 under OMB control number 3245-0101.

In the Federal Register of March 4, 2014 (79 FR 12201), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments. However, these comments did not address the information collection.

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

Table 1.--Estimated Annual Reporting Burden[1]

User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
FD&C Act sections 735 and	100	1.2	120	16	1,920

User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
736					
Reconsideration Requests	3	1	3	24	72
Appeal Requests	1	1	1	12	12
Total					2,004

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

Dated: July 11, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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