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; Guidance for Industry--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, Agency or we) 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Guidance for Industry--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 prescription drug 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 prescription drug 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.

Based on Agency records, we estimate that the total annual number of waiver requests submitted for all of these categories will be 150, submitted by 115 different applicants. 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. 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.

Previously, after receipt of a small business waiver request, FDA would request a small business size determination from the Small Business Administration (SBA). Waiver applicants would submit their supporting documentation directly to SBA for evaluation and after completing their review, SBA provided FDA with a determination whether a waiver applicant qualified as a small business for purposes of evaluating user fee waivers. The burden for submission of this information to SBA is approved under OMB control number 3245-0101.

Beginning fiscal year 2015, the SBA declined to conduct further size determinations for evaluation of small business user fee waivers and as a result, a processing change at FDA occurred. The new FDA process requires waiver applicants to submit documentation directly to FDA. In addition, fewer supporting documents than previously requested by SBA are required. As a result, we estimate that the 4 burden hours per small business waiver previously attributed to SBA and approved under OMB control number 3245-0101, should now be attributed to FDA because SBA is no longer conducting size determinations for FDA. Also, because FDA is asking that applicants submit fewer supporting documents, we estimate that these burden hours should be reduced to 2 hours instead of 4 hours. We understand that SBA plans to submit a revised burden estimate to OMB control number 3245-0101 to account for this redistribution.

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 seven requests for reconsideration annually, and that the total average burden hours for a reconsideration request will be 24 hours. In addition, 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 We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist, User Fee Appeals Officer, Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director, Division of User Fee Management, Office of Management, Center for Drug Evaluation and Research.

The burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) is not included in this analysis as the burden is included under OMB control number 0910-0297. The collections of information associated with submission of a new drug application or biologics license application are approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

In the Federal Register of May 23, 2017 (82 FR 23581), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

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

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

User Fee Waivers, Reductions, & Refunds for Drug & 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 736	115	1.3	150	16	2,400
FD&C Act section 736(d)(1)(D)(4)	25	1	25	2	50
Reconsideration requests	7	1	7	24	168
Appeal requests	1	1	1	12	12
Total					2,630

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

Dated: August 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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