

TABLE 1—ESTIMATED REPORTING BURDEN ¹

Additional information and/or notifications for using a different data lock point and/or a different reporting frequency	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Applicants that have a PSUR waiver for an approved application	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application	29	2.3	67	2	134
Total					321

¹ There are no capital or operating and maintenance costs associated with the information collection.

Dated: May 18, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0222]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recommendations to applicants considering whether to request a waiver or reduction in user fees.

DATES: Submit either electronic or written comments on the collection of information by July 24, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/>. Follow

the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov/> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov/>. If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–N–0222 for “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezuto, Office of Operations, Food and Drug Administration, Three White Flint

North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information 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** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

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 at the 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 collection 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.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

User fee waivers, reductions, & refunds for drug & biological products	Number of respondents	Number 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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

User fee waivers, reductions, & refunds for drug & biological products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	2,630

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

Dated: May 18, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Advisory Committee Nomination Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 (the PRA).

DATES: Fax written comments on the collection of information by June 22, 2017.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number, 0910–NEW, and title, “FDA Advisory Committee Membership Nominations.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRASStaff@fda.hhs.gov.

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

FDA Advisory Committee Membership Nominations—OMB Control Number 0910–NEW

FDA chooses to select advisory committee members through a nomination process. (Appendix A to Subpart C of 41 CFR 102–3, the Federal Advisory Committee Management Final Rule notes that the Federal Advisory Committee Act (FACA, 5 U.S.C. App. 2) does not specify the manner in which advisory committee members and staff must be appointed.) A person can self-nominate or be nominated by another individual. In order to identify and select qualified individuals to serve on its advisory committees, FDA has established an online portal, the FDA Advisory Committee Membership Application, to accept nominations of potential advisory committee members.

The FDA Advisory Committee Membership Application accepts nominations for Academician/Practitioner, Consumer Representative, and Industry Representative membership types. Nominees who are nominated as scientific members should be technically qualified experts in the field (e.g., clinical medicine, engineering, biological and physical sciences, biostatistics, food sciences) and have experience interpreting complex data. Candidates must be able to analyze detailed scientific data and understand its public health significance. The nomination process has recently been made electronic and is available at <http://accessdata.test.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. To submit a nomination, nominators or prospective nominees should upload the following documents in PDF format (see 21 CFR 14.82(c)): (1) Curriculum vitae (CV); (2) a written confirmation that the nominee(s) is (are) aware of the nomination (unless self-nominated); and (3) letters of recommendation are also suggested. For Consumer Representative nominations, a cover letter that lists consumer or community organizations for which the candidate can

demonstrate active participation is also recommended.

These documents are collected in order to determine if the nominee has the expertise in the subject matter with which the committee is concerned and has diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it (21 CFR 14.80(b)(1)(i)). In the case of Industry and Consumer Representatives, information is collected to assess the candidate's ability to represent all interested persons within the class which the member is selected to represent (21 CFR 14.86).

Each nominee should be sure to review the Agency Web site for information on:

- Vacancies, qualifications, and experience for more details concerning vacancies on each committee and the qualifications and experience common for nominees. Vacancies are updated periodically; therefore, one or more vacancies listed may be in the nomination process or a final appointment may have been made.
- Potential conflicts of interest such as financial holdings, employment, and research grants and/or contracts in order to permit evaluation of possible sources of conflict of interest.

Also, FDA asks that prospective nominees inform us of how they heard about the FDA Advisory Committees (e.g., attendance at a professional meeting, an article in a publication, our Web site, while speaking with a friend or colleague).

To further the Agency's goals of promoting transparency regarding the advisory committee process, FDA will also require that nominees to serve on advisory committees submit a consent form authorizing FDA to publicly post to FDA's Web site the CV submitted as part of their nomination materials if the nominee is selected to serve on an advisory committee. In the past, FDA has generally posted the CVs of FDA advisory committee members publicly on <http://www.fda.gov/AdvisoryCommittees/> after reviewing the CVs and redacting information that appeared to be confidential. However,