

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	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
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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on September 13, 2017, from 8:30 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Serina Hunter-Thomas or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002; 240-402-5771, serina.hunter-thomas@fda.hhs.gov and 240-402-8072, rosanna.harvey@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On September 13, 2017, the VRBPAC will meet in an open session to discuss and make recommendations on the safety and effectiveness of Zoster Vaccine Recombinant, Adjuvanted, manufactured by GlaxoSmithKline Biologicals. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 6, 2017. Oral presentations from the public will

be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 29, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 30, 2017.

Web cast: For those unable to attend in person, the meeting will also be web cast and will be available at the following link: <https://collaboration.fda.gov/vrbpac0917/>.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 1, 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-2011-N-0085]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 the proposed extension of the collection of information concerning cooperative manufacturing arrangements for licensed biologics.

DATES: Submit either electronic or written comments on the collection of information by October 6, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 6, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 6, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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,