

The total burden is estimated to be 235.5 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data.

The cost burden is estimated to be \$12,312 annually.

#### EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form .....	85	1	3/60	4.25
Data Use Agreement .....	85	1	3/60	4.25
Medical Office Information Form .....	85	20	5/60	142
Data Files Submission .....	85	1	1	85
Total .....	NA	NA	NA	235.5

#### EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form .....	85	4.25	\$52.28	\$222
Data Use Agreement .....	85	4.25	52.28	222
Medical Office Information Form .....	85	142	52.28	7,424
Data Files Submission .....	85	85	52.28	4,444
Total .....	NA	235.5	NA	12,312

\* Mean hourly wage rate of \$52.28 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at [https://www.bls.gov/oes/current/naics4\\_621100.htm](https://www.bls.gov/oes/current/naics4_621100.htm).

#### Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 18, 2021.

**Marquita Cullom,**  
Associate Director.

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BILLING CODE 4160-90-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2021-N-0856]

##### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or 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 FDA on regulatory issues. Members will participate via teleconference. At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on September 30, 2021, from 8:30 a.m. to 3:40 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an

online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/VeknygU5MKM>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0856. The docket will close on September 29, 2021. Submit either electronic or written comments on this public meeting by September 29, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 29, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 29, 2021. 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.

Comments received on or before September 23, 2021, will be provided to the committee. Comments received after September 23, 2021, and by September 29, 2021, will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2021-N-0856 for "Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **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." FDA 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 Dockets Management Staff. If you do not wish your name and contact information 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 the 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.govinfo.gov/content/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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

#### **FOR FURTHER INFORMATION CONTACT:**

Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, 301-796-7864, [Kathleen.Hayes@fda.hhs.gov](mailto:Kathleen.Hayes@fda.hhs.gov), or 301-796-4620, [Monique.Hill@fda.hhs.gov](mailto:Monique.Hill@fda.hhs.gov), respectively; 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 website 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:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 30, 2021, under Topic I, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Bacterial Polysaccharides, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, and the Center for Biologics Evaluation and Research (CBER). Also, on September 30, 2021, under Topic II, CBER's VRBPAC will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2021 to 2022 southern hemisphere influenza season.

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 website prior to the meeting, background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** On September 30, 2021, under Topic I, from 8:30 a.m. to 10:45 a.m. the meeting is open to the public. On September 30, 2021, under Topic II, from 12:15 p.m. to 3:40 p.m. the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before September 23, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. under Topic I and from 2:10 p.m. and 2:40 p.m. under Topic II. 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 September 15, 2021. 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 September 16, 2021.

*Closed Committee Deliberations:* On September 30, 2021, from 10:45 a.m. to 11:45 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigator's research programs along with other information, will be discussed during this session. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

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 Kathleen Hayes ([CBERVBPAC@fda.hhs.gov](mailto:CBERVBPAC@fda.hhs.gov)) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> 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 18, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-18107 Filed 8-23-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0891]

#### Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is hosting a virtual public meeting entitled "Reauthorization of the Prescription Drug User Fee Act." The purpose of the public meeting is to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2023 through 2027. PDUFA authorizes FDA to collect user fees to support the process for the review of human drug applications. The current legislative authority for PDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. Following discussions with the regulated industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations, as necessary.

**DATES:** The public meeting will be held on September 28, 2021, from 9 a.m. to 2 p.m. Eastern Time, and will be held by webcast only. Submit either electronic or written comments on this public meeting by October 28, 2021.

**ADDRESSES:** Registration to attend the virtual meeting and other information can be found at <https://pdufaviireauthorization.eventbrite.com>. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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 28, 2021. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of October 28, 2021. 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, 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

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- For written/paper comments submitted to the Dockets Management Staff, 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-2021-N-0891 for "Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9