

requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from the reports required under sections 413.65(b)(3) and (c) is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. *Form Number:* CMS-R-240 (OMB control number: 0938-0798); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 2032; *Total Annual Responses:* 15,138,400; *Total Annual Hours:* 683,670. (For policy questions regarding this collection contact Emily Lipkin at 410-786-3633.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3698]

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 we) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (the committee). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The committee will discuss considerations related to the use of pertussis controlled human infection models (CHIMs) in pivotal studies to

demonstrate efficacy of pertussis vaccines for the purpose of licensure and will hear an overview of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) research program in the Center for Biologics Evaluation and Research (CBER). 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 virtually on September 20, 2024, from 8:30 a.m. to 5 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtube.com/live/IHObqjNpYc>.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-3698. The docket will close on September 19, 2024. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 19, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 12, 2024, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, 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-2024-N-3698 for "Vaccines and Related Biological Products Advisory Committee; 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: Sussan Paydar or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 202-657-8533, CBERVRBPAC@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 FDA’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 and/or video conferencing platform. On September 20, 2024, under Topic I, the committee will meet in open session to discuss considerations related to the use of pertussis CHIMs in pivotal studies to demonstrate efficacy of pertussis vaccines for the purpose of licensure. Under Topic II, the committee will meet

in open session to hear an overview of the LMPCI research program in the Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, and CBER. After the open session, the meeting will be closed to the public for committee deliberations.

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, the 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 and/or video conference meeting will be available at: <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: On September 20, 2024, from 8:30 a.m. to 3:10 p.m. Eastern Time for Topic I and from 3:10 p.m. to 4:10 p.m. Eastern Time for Topic II, 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 12, 2024, will be provided to the committee. Comments received on or after September 12, 2024, and by September 19, 2024, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:15 p.m. Eastern Time for Topic I, and 3:55 p.m. to 4:10 p.m. Eastern Time for 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, along with their names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on September 4, 2024. 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 6, 2024.

Closed Committee Deliberations: On September 20, 2024, the meeting will be closed from 4:10 p.m. to 5 p.m. Eastern Time 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 investigators’ 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 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 Sussan Paydar or Kathleen Hayes (see **FOR FURTHER INFORMATION CONTACT**) 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/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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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