CFR 820.198, special controls are necessary to provide a reasonable assurance of safety and effectiveness of these devices. (Information collections associated with Quality System requirements under 21 CFR part 820 are approved under OMB control number 0910–0073.) We estimate it will take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit to FDA.

We assume a cost of $10 associated with the payment of an annual fee to maintain e-certification will apply to each respondent. We estimate a total operating and maintenance cost of $18,710 ($10 × 1,871 respondents).

Since the last OMB approval, we have adjusted the respondent and response estimates based on FY 2024 data. We also adjusted the Average Burden per Response for ''Exemptions—803.19'' and ''Importer Reporting, Death and Serious Injury—803.40 and 803.42'' from 0.1 hour to 1 hour to correct an error introduced in a previous request for extension of this information collection. These adjustments have resulted in an overall increase of 1,374,708 total responses, and a corresponding increase of 262,681 total burden hours.

We are revising this information collection to add the FDA guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' (August 2024; *https://www.fda.gov/media/163692/download*), which is intended to help manufacturers better understand and use the VMSR Program. The guidance does not affect the estimated burden estimates.

Dated: May 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08086 Filed 5–7–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1146]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—2025–2026 Formula for COVID–19 Vaccines for Use in the United States

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The committee will meet in an open session to discuss and make recommendations on the selection of the 2025–2026 Formula for COVID–19 vaccines for use in the United States. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on May 22, 2025, from 8:30 a.m. to 4:30 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 on the day of the meeting by visiting *https://www.fda.gov/advisory-committees.*

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–1146. The docket will close on May 23, 2025. 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 May 23, 2025. 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 noon by May 14, 2025, will be provided to the committee. Comments received after May 14 and by May 23, 2025 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–2025–N–1146 for ''Vaccines and Related Biological Products Advisory Committee''; Notice of Meeting; Establishment of a Public Docket; Request for Comments—2025–2026 formula for COVID–19 vaccines for use in the United States.''

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: CDR Valerie Marshall, MPH, PMP, USPHS, 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 May 22, 2025, the Committee will meet in open session to discuss and make recommendations on the selection of the 2025–2026 Formula for COVID–19 vaccines for use in the United States. FDA regrets that it was unable to publish this notice 15 days prior to the Vaccines and Related Biological Products Advisory Committee meeting due to technical issues. Because there is a need for an immediate meeting of the Committee, including the time-sensitive need for input and public discussion on the meeting subject, and because qualified members of the committee were available at this time and scheduled to participate in the meeting, the Agency concluded that there are exceptional circumstances that support holding this meeting without the customary 15-day public notice.

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 May 22, 2025, from 8:30 a.m. to 4:30 p.m. Eastern Time 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**) by noon of May 14, 2025, will be provided to the committee. Comments received after May 14 and by May 21, 2025, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:00 p.m. to 2:00 p.m. Eastern Time on May 22, 2025. Those individuals interested in making formal oral presentations should complete the online survey *https://qualtricsxmjqffz4ktl.qualtrics.com/jfe/form/SV_dnXIVPWod1OPwdU* 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 May 14, 2025. 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 May 16, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343.

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 CDR Valerie Marshall, MPH, PMP, USPHS at *CBERVRBPAC@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/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. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: May 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08083 Filed 5–7–25; 8:45 am]

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