presentations with audio and video components to allow the presentation of materials for online participants in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before July 9, 2026, will be provided to the Committee. Oral presentations from the public will be scheduled following FDA presentations. FDA has allotted approximately one hour for open public hearing presentations, which will be split to allow for public remarks on each substance. The sessions will begin at approximately 10:15 a.m., 11:50 a.m., 2:15 p.m., and 4:00 p.m. on July 23, 2026 Eastern Time. The sessions will begin at approximately 10:20 a.m., 12:30 p.m., and 3:20 p.m. on July 24, 2026 Eastern Time. 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, whether they would like to present online or in-person, and an indication of the approximate amount of time requested to make their presentation on or before June 30, 2026. 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. FDA may also extend the time scheduled for open public hearing presentations depending on interest. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak and the timeframe for the presentation by July 1, 2026. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the HHS Press Room at *https://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 Takyiah Stevenson (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 in conjunction with the physical meeting room (see location). 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07361 Filed 4–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3500]

Notice of Approval of Product Under Priority Review Voucher; Material Threat Medical Countermeasure Priority Review Voucher; MRESVIA (Respiratory Syncytial Virus Vaccine)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat medical countermeasure (MCM) priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that MRESVIA (Respiratory Syncytial Virus Vaccine), approved May 31, 2024, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, *industry.biologics@fda.hhs.gov,* 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a material threat MCM priority review voucher. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that MRESVIA (Respiratory Syncytial Virus Vaccine), meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv.* For further information about MRESVIA (Respiratory Syncytial Virus Vaccine), go to the Center for Biologics Evaluation and Research Approved Products website at *https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07369 Filed 4–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–0501 and FDA–2025–E–0502]

Determination of Regulatory Review Period for Purposes of Patent Extension; UNLOXCYT

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has