reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07443 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–2025–N–6895]

Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List

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 Pharmacy Compounding Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on July 23, 2026, from 8:00 a.m. to 4:30 p.m. Eastern Time and July 24, 2026, from 8:00 a.m. to 3:50 p.m. Eastern Time.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, 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.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–6895. The docket will close on July 22, 2026. 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 on July 22, 2026. 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 July 9, 2026, 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 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–6895 for ''Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List.'' 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: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, email: *PCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line at 301–796–8220. 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 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 the meeting.

SUPPLEMENTARY INFORMATION:

Background: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

One of the conditions that must be satisfied for a drug product to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances (as defined in 21 CFR 207.3) that: (1) comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, are drug substances that are components of drugs approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under section 503A(c) of the FD&C Act (the 503A Bulks List) (see section 503A(b)(1)(A)(i) of the FD&C Act).

Agenda: FDA, invited attendees, and the public will be able to attend the meeting in-person at FDA's White Oak Campus (see **ADDRESSES**). The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On July 23, 2026, the Committee will discuss the following bulk drug substances being considered for inclusion on the 503A Bulks List: BPC–157-related bulk drug substances (BPC–157 (free base)/BPC–157 acetate), KPV-related bulk drug substances (KPV (free base)/KPV acetate), TB–500-related bulk drug substances (TB–500 (free base)/TB–500 acetate), and MOTs-C-related bulk drug substances (MOTs-C (free base)/MOTs-C acetate). The chart below identifies the use(s) FDA reviewed for each of the bulk drug substances being discussed at this advisory committee meeting. For nominated bulk drug substances, the nominators of these substances will be invited to make a short presentation supporting the nomination.

Bulk drug substance	Uses evaluated
BPC–157 (free base), BPC–157 acetate	Ulcerative colitis (UC).
KPV (free base), KPV acetate	Wound healing and inflammatory conditions.
TB–500 (free base), TB–500 acetate	Wound healing.
MOTs-C (free base), MOTs-C acetate	Obesity and osteoporosis.

On July 24, 2026, the Committee will discuss the following bulk drug substances being considered for inclusion on the 503A Bulks List: Emideltide (also referred to as delta sleeping inducing peptide (DSIP))-related bulk drug substances (Emideltide (free base)/Emideltide acetate), Semax-related bulk drug substances (Semax (free base)/Semax acetate), and Epitalon-related bulk drug substances (Epitalon (free base)/Epitalon acetate). The chart below identifies the use(s) FDA reviewed for each of the bulk drug substances being discussed at this advisory committee meeting. For nominated bulk drug substances, the nominators of these substances will be invited to make a short presentation supporting the nomination.

Bulk drug substance	Uses evaluated
Emideltide (free base), Emideltide acetate	Opioid withdrawal, chronic insomnia, and narcolepsy.
Semax (free base), Semax acetate	Cerebral ischemia, migraine, and trigeminal neuralgia.
Epitalon (free base), Epitalon acetate	Insomnia.

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 the location of the advisory committee meeting and 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 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