We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section 251; information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart B; SIP proposals and pre-import requests	40	1.5	60	72	4,320
Subpart C; Certain requirements for importation programs	40	1	40	43	1,720
Total			100		6,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have established a web page at *https://www.fda.gov/drugs/importation-program-under-section-804-fdc-act/section-804-importation-program-policies-and-authorizations* to communicate news and information about FDA efforts to implement the SIP. We assume the burden attributable to the required retention, reporting, and disclosure of records pertaining to these information collection activities will be distributed among respondents at an average of 100 responses and 6,040 hours annually. Based on a review of the information collection since our last request for OMB approval we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07421 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–P–4154]

Determination That CHEWTADZY (Tadalafil) Chewable Tablets, 5 Milligrams, 10 Milligrams, 20 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CHEWTADZY (tadalafil) chewable tablets, 5 milligrams (mg), 10 mg, 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for tadalafil, chewable tablets, 5 mg, 10 mg, 20 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Neerja Razdan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, (240) 402–1556, *Neerja.Razdan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, is the subject of NDA 218527, held by B Better, LLC, and initially approved on June 28, 2024. CHEWTADZY is indicated for the treatment of erectile dysfunction, the signs and symptoms of benign prostatic hyperplasia, and erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia.

B Better, LLC has never marketed CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated September 22, 2025 (Docket No. FDA–2025–P–4154), under 21 CFR 10.30, requesting that the Agency determine whether CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CHEWTADZY (tadalafil) chewable tablets, 5 mg, 10 mg, 20 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have

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]

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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