Designation Request Form, intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from FDA. The form is a simplified method for sponsors to provide only the information required by § 316.20 for FDA decision making. Orphan drug designation requests and related submissions (amendments, annual reports, etc.), humanitarian use device designation, and rare pediatric disease designation requests and submissions may be submitted electronically by email to the OOPD.

As communicated on our website at *https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products,* respondents may submit orphan drug designation requests electronically through the Center for Drug Evaluation and Research (CDER) NextGen portal, or by emailing the required information to *orphan@fda.hhs.gov;* or by mailing the required information to the OOPD at the address found on our website. New users of the CDER NextGen Portal must register for an account. For designation requests submitted by email, the Agency recommends using automated read receipt to verify receipt of the email.

Sponsors and others who plan to email information to FDA that is private, sensitive, proprietary, or commercial confidential are strongly encouraged to send it from an FDA-secured email address so the transmission is encrypted. The Agency will assume the addresses of emails received or email addresses provided as a point of contact are secure when responding to those email addresses. Sponsors and others can establish a secure email address link to FDA by sending a request to *SecureEmail@fda.hhs.gov.* There may be a fee to a commercial enterprise for establishing a digital certificate before encrypted emails can be sent to FDA.

Respondents to the information collection are sponsors who develop investigational drugs and biologicals for commercial use and who seek orphan drug designation, and upon approval or licensure, orphan drug exclusivity.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part or section; activity	Number of respondents	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Part 316 associated records	864	1	1,080	135	145,800
§§ 316.20, 316.21, 316.26 (Form FDA 4035)	864	1	1,080	32	34,560
§ 316.22; Notifications of changes in agents	305	1	305	0.5	153
§ 316.24(a); Deficiency letters and granting orphan-drug designation	756	1	756	2	1,512
§ 316.27; Submissions to change ownership of orphan-drug designation	110	1	110	3	330
§ 316.30; Annual reports	2,210	1	2,210	3	6,630
§ 316.36; Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug	1	3	3	15	45
Guidance Recommendations: Meeting requests to OOPD and related submission packages	800	1.5	1,200	4	4,800
Total			6,744		193,830

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

We base our burden figures on the number of submissions received and include those activities relating to: (1) requesting orphan drug designation; (2) responding to deficiencies letters with submissions of amendments; (3) keeping files current with contact information for agents and transfer of ownership, when applicable; (4) submitting annual reports while products have designation status; and (5) requesting and preparing for both informal and formal meetings. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government, we account for these activities cumulatively in table 1 above. Our burden estimate reflects a nominal increase of approximately 9% annually.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07423 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–3240]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions related to FDA's regulation on importation of prescription drugs.

DATES: Either electronic or written comments on the collection of information must be submitted by June 15, 2026.

ADDRESSES: You may submit comments as follows. 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 June 15, 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.

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–2026–N–3240 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs.'' 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.'' The Agency 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 to 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 this 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–1244, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Importation of Prescription Drugs—21 CFR Part 251

OMB Control Number 0910–0888—Extension

This information collection supports implementation of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384), and applicable regulations in part 251 (21 CFR part 251). The purpose of section 804 of the FD&C Act is to reduce the cost of covered products to American consumers without imposing additional risk to public health and safety. The regulations in part 251 set forth procedures Section 804 Importation Program sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada. The regulations also establish criteria for FDA review and authorization of a SIP proposal or supplemental proposal. Additionally, the regulations set forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs. Finally, the regulations provide for exempt eligible prescription drugs that meet certain requirements from section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

Description of Respondents: Respondents to the collection of information are SIP Sponsors (States or Indian Tribes, or in certain future circumstances, pharmacists or wholesale distributors, and any cosponsor(s)), importers (pharmacists or wholesaler distributors), and manufacturers of eligible prescription drugs.

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