• The Revised Instrument and Instructions will include a chart for the financial plan and a chart for the existing centers that specifies what counties they serve, what entities oversee them, and what oversight processes apply.

• The Revised Instrument will include a signatures section.

These revisions were recommended by the technical assistance provider and analyzed by all the independent living program officers who work directly with SPILs.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows: 56 SILCs will respond to the requirement for a SPIL every three years. Each state's SILC will take approximately 240 hours to develop the SPIL for a total of approximately 13,440 hours. This estimate is based on program knowledge.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Statewide Independent Living Councils	56	1	240	13,440
Total	56	1	240	13,440

Dated: August 6, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–17172 Filed 8–9–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2290]

Determination That LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA or Agency) has determined that LEVITRA (vardenafil hydrochloride) tablets, 2.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel J. Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–4673, *Daniel.Ritterbeck@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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.

LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, are the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. LEVITRA is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction. LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

In a letter dated March 22, 2018, Bayer HealthCare Pharmaceuticals, Inc., notified FDA that LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Alembic Pharmaceuticals Limited submitted a citizen petition received on May 9, 2019 (Docket No. FDA–2019–P–2290), under 21 CFR 10.30, requesting that the Agency determine whether LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were withdrawn from sale for safety or effectiveness reasons and permit the filing of abbreviated new drug applications (ANDAs) referencing LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg.

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 LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LEVITRA (vardenafil hydrochloride) tablets, 2.5 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 this drug product was

not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LEVITRA (vardenafil hydrochloride) tablets, 2.5 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17212 Filed 8–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3453]

Promoting Effective Drug Development Programs: Opportunities and Priorities for the Food and Drug Administration's Office of New Drugs; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is holding a public meeting on November 7, 2019 entitled ''Promoting Effective Drug Development Programs: Opportunities and Priorities for FDA's Office of New Drugs.'' The purpose of the public meeting is to solicit specific, actionable policy suggestions that could be implemented in the near-term by the review staff of the Center for Drug Evaluation and Research's (CDER's) Office of New Drugs to promote effective drug development programs without compromising our regulatory standards for the assessment of safety and effectiveness.

DATES: The public meeting will be held on November 7, 2019, from 9 a.m. to 5 p.m. The public meeting may be extended or may end early depending on the level of public participation. Persons can attend the event in-person or via webcast. In-person attendees can also request to give a formal presentation as part of the registration process. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. Electronic or written comments will be accepted after the public hearing until January 7, 2020.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 7, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 7, 2020. 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.

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–2019–N–3453 for ''Promoting Effective Drug Development Programs: Opportunities and Priorities for FDA's Office of New 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.

- 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.gpo.gov/*