Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4212, Silver Spring, MD 20993–0002, 301–796–2270; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Non-Inferiority Clinical Trials to Establish Effectiveness.'' This guidance consists of four parts. The first part is a general discussion of regulatory, study design, scientific, and statistical issues associated with the use of NI studies to establish the effectiveness of a drug or biologic. The second part focuses on some of these issues in more detail, notably the statistical approaches used to determine the NI margin and to test for non-inferiority. The third part addresses commonly asked questions about NI studies. The fourth part includes four examples of successful and unsuccessful efforts to define NI margins and test for non-inferiority.

This guidance finalizes the draft guidance for industry, ''Non-Inferiority Clinical Trials,'' published in 2010. In addition, it supersedes the guidance for industry, ''Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval,'' also published in 2010, which will be withdrawn.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on NI clinical trials to establish effectiveness. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm; http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm;* or *http://www.regulations.gov.*

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26931 Filed 11–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–2674]

Determination That CALAN SR (Verapamil Hydrochloride) Extended-Release Oral Tablet, 180 Milligrams, Was 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 CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for verapamil hydrochloride extended-release oral tablet, 180 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

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.

CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, is the subject of NDA 019152 held by Pfizer Inc. CALAN SR is indicated for the treatment of hypertension, to lower blood pressure. CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Heritage Pharma Labs, Inc., submitted a citizen petition dated August 31, 2016 (Docket No. FDA–2016–P–2674), under 21 CFR 10.30, requesting that the Agency determine whether CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, was 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 CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CALAN SR (verapamil hydrochloride) extended-release oral

tablet, 180 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 CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 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.

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26932 Filed 11–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3631]

Ninth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Ninth Annual Sentinel Initiative Public Workshop.'' Convened by the Duke-Margolis Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an update on the state of FDA's Sentinel Initiative, including an overview of the current state of Sentinel System safety surveillance activities, and uses of the Sentinel System accomplished in 2016. In addition, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel Initiative projects.

DATES: The public workshop will be held on February 2, 2017, from 9 a.m. to 4:30 p.m., Eastern Standard Time (EST). Submit either electronic or written comments by March 2, 2017.

ADDRESSES: *Location:* The public workshop will be held at the Barbara Jordan Conference Center at the Kaiser Family Foundation, 1330 G St. NW., Washington, DC 20005. For additional travel and hotel information, please refer to *https://healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop.* FDA has verified the meeting Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**. There will also be a live Webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–3631 for ''Ninth Annual Sentinel Initiative; Public Workshop.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–3714, FAX: 301–796–9832, email: *SentinelInitiative@fda.hhs.gov.*