determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161)).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

FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, are the subjects of NDA 020140, held by Spectrum Pharmaceuticals, and were initially approved on April 29, 2011 (supplemental approval). FUSILEV is indicated for rescue after high-dose methotrexate therapy in osteosarcoma, to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists, and for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.

FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Spectrum Pharmaceuticals has never marketed FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL. In previous instances (see, e.g., 72 FR 9763 and 61 FR 25497), 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.

Lachman Consultant Services, Inc. (Lachman), submitted two citizen petitions, dated March 18, 2014, and May 14, 2014 (Docket Nos. FDA–2014–P–0315 and FDA–2014–P–0637, respectively), under 21 CFR 10.30, requesting that the Agency determine whether FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were withdrawn from sale for reasons of safety or effectiveness.

After considering the Lachman citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were not withdrawn from sale for reasons of safety or effectiveness. Lachman has identified no data or other information suggesting that FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal from sale of FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, 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 FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19961 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0745]

Reopening of Docket and Request for Comments on the Food and Drug Administration Safety and Innovation Act Action Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice: reopening of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the action plan issued as required by section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the reopening of a public docket for comments pertaining to the action plan.

DATES: Submit electronic or written comments by October 21, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonca Bull, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4239, Silver Spring, MD, 20993–0002, 301–796–8000, *jonca.bull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed FDASIA (Pub. L.112–144) into law. Section 907 of FDASIA requires that FDA report on and address certain information regarding clinical trial participation by demographic subgroups and subset analysis of the resulting data. Specifically, section 907(a) of FDASIA requires the Secretary of Health and Human Services (the Secretary), acting through the FDA Commissioner, to publish on FDA's Internet Web site a report ''addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA,'' and provide such publication to Congress. The report, entitled ''Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices,'' was posted on FDA's Internet Web site in August 2013 and is available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm*.

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on FDA's Internet Web site and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and applicability. The action plan is due not later than 1 year after the publication of the report described previously. The action plan entitled

''FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data'' is being issued with this notice and is available at *http://www.fda.gov/RegulatoryInformation/;Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm*.

FDA is reopening the docket for 60 days to provide an opportunity for interested individuals to submit comments on the action plan. When submitting comments please reference the section of the action plan to which your comments pertain. This docket is intended to ensure that stakeholders have an opportunity to provide comments and that such information submitted to FDA is available to all interested persons in a timely fashion.

II. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: August 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19881 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0817]

Evaluation of Sex-Specific Data in Medical Device Clinical Studies; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies.'' This document provides guidance on the study and evaluation of sex-specific data in medical device clinical studies, and it outlines the Center for Devices and Radiological Health's (CDRH's) and Center for Biologics Evaluation and Research's (CBER's) expectations regarding sex-specific patient enrollment, data analysis, and reporting of device study information. The guidance is intended to improve the quality and consistency of available data regarding the performance of medical devices in both sexes by encouraging appropriate enrollment by sex in clinical studies of devices, and appropriate interpretation and assessment if data from such studies are analyzed by sex. Evaluation of sex-specific data in medical device clinical studies can benefit patients, their medical providers, clinical researchers, and others.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1524, Silver Spring, MD 20993–0002, 301–796–6424; or Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3614, Silver Spring, MD 20993–0002, 301–796–6349; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this guidance is to outline CDRH's and CBER's expectations regarding sex-specific patient enrollment, data analysis, and reporting of medical device study information. The intent is to improve the quality and consistency of available data regarding the performance of medical devices in both sexes by encouraging appropriate enrollment by sex in clinical studies of devices, and appropriate interpretation and assessment when data from such studies are analyzed by sex. This information can benefit patients, their medical providers, clinical researchers, and others. The specific objectives of this guidance are to: (1) Encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the study design stage; (2) provide recommendations for study design and conduct to encourage appropriate enrollment of each sex (e.g., in proportions generally representative of the demographics of disease distribution, if appropriate); (3) outline recommended sex-specific statistical analyses of study data with a framework for considering sex-specific data when interpreting overall study outcomes; and (4) specify FDA's expectations for reporting sex-specific information in summaries and labeling for approved or cleared medical devices.

In the **Federal Register** of December 19, 2011 (76 FR 78670), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by March 19, 2012. Multiple comments were received with recommendations pertaining to the evaluation of sex-specific data in clinical studies. In response to these comments, FDA revised the guidance document to clarify the processes of sex-specific data evaluation in clinical studies and policies as appropriate. For more clarity, a decision framework for different clinical study designs was added to the guidance in response to comments received requesting additional information on when various sex-specific statistical recommendations would apply. Additionally, several comments requested that the recommendations in the guidance apply