PRESERVATIVE FREE is indicated for treatment of megaloblastic anemia and to counteract the therapeutic and toxic effects of folic acid antagonists.

In a letter dated January 14, 2005, Hospira notified FDA that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Gordon Johnston, on behalf of Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated December 13, 2013 (Docket No. FDA–2013–P–1654), under 21 CFR 10.30, requesting that the Agency determine whether LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was withdrawn from sale for reasons of safety or effectiveness.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under § 314.161 that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, 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 We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, 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 LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, 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: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13906 Filed 6–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0011]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6 on Uniformity of Dosage Units General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6: Uniformity of Dosage Units General Chapter.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Uniformity of Dosage Units General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. The guidance is in the form of an annex to the core guidance on the Q4B process entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions'' (core ICH Q4B guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, CDER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4166, Silver Spring, MD 20993–0002, 301–796–1242; or Stephen Ripley, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Michelle Limoli, CDER, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input

from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER, CBER, and FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 17, 2009 (74 FR 7449), FDA published a notice announcing the availability of a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 6: Uniformity of Dosage Units General Chapter.'' The notice gave interested persons an opportunity to submit comments by April 20, 2009.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2013.

The guidance provides the specific evaluation results from the ICH Q4B process for the Uniformity of Dosage Units General Chapter harmonized text originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073405.pdf*) made available in the **Federal Register** of February 21, 2008 (73 FR 9575). The annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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.*

III. Electronic Access

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

Dated: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13908 Filed 6–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0731]

Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), in collaboration with the National Cancer Institute (NCI), is announcing a public meeting entitled ''Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting.'' The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, public health agencies, health care providers, and the general public concerning challenges in designing and implementing postapproval studies to evaluate the risk of cancer associated with use of non-oncological drugs and biological products. The input from this meeting and public docket will be used to inform the Agency on best study design and methodological options to consider when evaluating cancer risk in the postapproval setting.

Dates and Time: The public meeting will be held on September 10, 2014, from 8 a.m. to 5 p.m., and September 11, 2014, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at The DoubleTree by Hilton Hotel Washington DC—Silver Spring, The Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD 20910 (Metro: Silver Spring Station on the Red Line).

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9029, FAX: 301–796–9832, *Paul.Tran@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is free and available on a first-come, first-served basis. You must register online by August 27, 2014. Seating is limited, so register early. FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be available. To register for this meeting, please visit FDA's Drugs News & Events—Meetings, Conferences, & Workshops calendar at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* and select this meeting from the events list. If you need special accommodations due to a disability, please contact Paul Tran (see *Contact Person*) by September 3, 2014. Those without Internet access should contact Paul Tran to register.

This meeting includes a public comment session. If you would like to present at the meeting on topics related to challenges in designing and implementing postapproval studies to evaluate the risk of cancer associated with use of non-oncological drugs and biological products, please identify during registration the topic(s) you will address (see section II).

FDA will do its best to accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Following the close of registration, FDA will allot time for each presentation and notify presenters by September 3, 2014.