

Agency records and based on the information we have at this time, FDA has determined under § 314.161 that WILPO (phentermine hydrochloride) Tablets, 8 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner KVK-Tech has identified no data or other information suggesting that WILPO (phentermine hydrochloride) Tablets, 8 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of WILPO (phentermine hydrochloride) Tablets, 8 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 We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list WILPO (phentermine hydrochloride) Tablets, 8 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 WILPO (phentermine hydrochloride) Tablets, 8 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: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-3232 Filed 2-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0083]

Draft Guidance for Industry on Heparin for Drug and Medical Device Use; Monitoring Crude Heparin for Quality; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Heparin for Drug and

Medical Device Use: Monitoring Crude Heparin for Quality.” This draft guidance is intended to alert manufacturers of active pharmaceutical ingredients (APIs), pharmaceutical and medical device manufacturers of finished products, and others to the potential risk of crude heparin contamination.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by April 13, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on the draft 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frank W. Perrella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4337, Silver Spring, MD 20993-0002, 301-796-3265; or Dennis M. Bensley, Jr., Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8268; or Jason Brookbank, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3558, Silver Spring, MD 20993-0002, 301-796-5770.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality.” This draft guidance provides recommendations that will help API manufacturers, pharmaceutical and medical device manufacturers of finished products, and others, to better control their use of crude heparin that might contain oversulfated chondroitin sulfate (OSCS) or non-porcine material

(especially ruminant material) contaminants. This draft guidance on crude heparin recommends strategies to test for contamination and should be used in addition to the United States Pharmacopeia (USP) monograph testing required for other forms of heparin to detect the presence of OSCS.

Following reports of serious adverse events (including deaths) among patients injected with heparin sodium in 2008, FDA identified the contaminant OSCS in heparin API manufactured in China. FDA is also concerned about the potential for contamination of heparin with the bovine spongiform encephalopathy (BSE) agent derived from ruminant materials. The control of the quality of crude heparin is critical to ensure the safety of drugs and devices and to protect public health. FDA developed this draft guidance to alert manufacturers to the risks of crude heparin contaminants and to recommend strategies to ensure that the heparin supply chain is not contaminated with OSCS or any non-porcine origin material, especially ruminant material (unless specifically approved or cleared as part of drug or medical device application).

The draft guidance recommends that manufacturers test and confirm the species origin of crude heparin in each shipment before use in the manufacture or preparation of a drug or medical device containing heparin. The test method should be qualified for use in testing crude heparin and for the identification of species origin. The method should be based on good scientific principles (e.g., sufficient accuracy and specificity) and possess a level of sensitivity commensurate with the current state of scientific knowledge and risk. Likewise, the draft guidance recommends that manufacturers test for OSCS in crude heparin in each shipment before use, using a qualified test method that is suitable for detecting low levels of OSCS concentrations and is based on good scientific principles. Manufacturers should reject for use and control or destroy crude heparin found to contain any amount of OSCS and notify FDA of any such finding. The draft guidance also recommends that manufacturers identify and audit crude heparin suppliers and heparin API suppliers to ensure conformance to current good manufacturing practice (CGMP), employ the controls described in the guidance for industry “Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,” and comply with the quality system regulations (as applicable).

This draft guidance is being issued consistent with FDA’s good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In the draft guidance, FDA advises drug and medical device manufacturers who receive and use crude heparin to manufacture drugs and medical devices to notify the Agency of crude heparin found to contain any amount of OSCS (for human drugs 21 CFR 314.81(b)(1)(ii); for animal drugs 21 CFR 514.80(b); for medical devices 21 CFR 803.50). The collections of information in 21 CFR 314.81(b)(1)(ii) have been approved under OMB control number 0910–0001; in 21 CFR 514.80(b) under OMB control number 0910–0284; and in 21 CFR 803.50 under OMB control number 0910–0437.

IV. 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/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: February 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft Guidance for Industry on Bioequivalence Recommendations for Rifaximin Tablets; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidances for industry entitled “Bioequivalence Recommendations for Rifaximin,” one for the 200-milligram (mg) strength (rifaximin-200) and one for the 550-mg strength (rifaximin-550). The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for rifaximin tablets.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft guidances by April 13, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

Submit electronic comments on the draft guidances 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:

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8608.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of two draft BE recommendations, one for rifaximin-200 and one for rifaximin-550.

Xifaxan (rifaximin) 200-mg tablets, approved by FDA in May 2004, are indicated for the treatment of patients (≥ 12 years of age) with travelers' diarrhea caused by noninvasive strains of *Escherichia coli*. Xifaxan (rifaximin) 550-mg tablets, approved by FDA in March 2010, are indicated for reduction in risk of hepatic encephalopathy recurrence in patients ≥ 18 years of age. Xifaxan, 200 mg, and Xifaxan, 550 mg, are designated the reference listed drugs (RLDs) and therefore any ANDAs for generic rifaximin-200 or rifaximin-550 must demonstrate BE to the relevant RLD prior to approval. There are no approved ANDAs for these products.

In November 2011, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for rifaximin-200 (Draft Rifaximin-200 BE Recommendations). FDA is now issuing a draft guidance for industry on BE recommendations for generic rifaximin-550 (Draft Rifaximin-550 BE Recommendations).

In May 2008, Salix Pharmaceuticals, Inc. (Salix), manufacturer of the RLD, Xifaxan (200 mg), filed a citizen petition requesting that FDA refuse to receive for substantive review, or approve, ANDAs for generic rifaximin-200 unless the ANDAs contain certain data to demonstrate BE (Docket No. FDA–2008–P–0300). FDA is reviewing the issues raised in the petition and will consider any comments on the Draft Rifaximin-200 BE Recommendations before responding to Salix's citizen petition and finalizing its BE recommendations for rifaximin-200.

These draft guidances are being issued consistent with FDA's good