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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg, are the subject of NDA 22–331, held by Shionogi Pharma, Inc., initially approved on September 29, 2009. JENLOGA is indicated for the treatment of hypertension. Shionogi Pharma has never marketed JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg. In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), 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.

Actavis, Inc. submitted a citizen petition dated April 20, 2011 (Docket No. FDA–2011–P–0291), under 21 CFR 10.30, requesting that the Agency determine whether JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg, were withdrawn from sale for reasons of safety or effectiveness.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determined under § 314.161 that JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg, were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 mg, from sale. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, FDA will continue to list JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 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 JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 mg and 0.2 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. 2012–3222 Filed 2–10–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0701]

Determination That WILPO (phentermine hydrochloride) Tablets, 8 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) has determined that WILPO (phentermine hydrochloride) Tablets, 8 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 phentermine hydrochloride tablets, 8 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, 301–796–3472.

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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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.

WILPO (phentermine hydrochloride) Tablets, 8 mg is the subject of NDA 012737, held by Sandoz, Inc. WILPO is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

WILPO (phentermine hydrochloride) Tablets, 8 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

KVK–Tech, Inc. (KVK–Tech), submitted a citizen petition dated September 22, 2011 (Docket No. FDA–2011–P–0701), under 21 CFR 10.30, requesting that the Agency determine whether WILPO (phentermine hydrochloride) Tablets, 8 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 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]

BILLING CODE 4160–01–P

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