one hour is needed to provide a copy of the current license agreement and redact any proprietary data, and to submit it to the government. It is estimated that this work would be completed by a mid-level program manager.

For FAR 52.227–9, data extrapolated from Federal Business Opportunties Web site indicates that there was a total of one solicitation. The Government estimates that there are an additional nine solicitations which were not accounted for in Federal Business Opportunties, totaling 10. It is further estimated that each solicitation would result in approximately one contract award, or 10 unique vendors. It is also estimated that each contract will have three subcontractors, for a total of 30 unique subcontractor vendors. Of the 40 (10 + 30) unique vendors, it is estimated that approximately 100 percent or 40 unique vendors would be required to submit a statement of royalties paid. It is estimated that there is an average of one response per solicitation, resulting in approximately 40 responses per year. 0.5 burden hours are estimated per response to submit a statement of royalties paid or required to be paid by the contract.

a. FAR 52.227–2:
Number of Respondents: 20.
Responses per Respondent: 1.
Total Responses: 20.
Average Burden Hours per Response: 2.
Total Burden Hours: 40.
b. FAR 52.227–6:
Number of Respondents: 44.
Responses per Respondent: 1.
Total Responses: 44.
Average Burden Hours per Response: 1.
Total Burden Hours: 44.
c. FAR 52.227–9:
Number of Respondents: 40.
Responses per Respondent: 1.
Total Responses: 40.
Average Burden Hours per Response: .5.
Total Burden Hours: 20.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0096, Patents, in all correspondence.

Dated: October 31, 2013.

Karlos Morgan, Sr.,

Acting Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2013–26578 Filed 11–5–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0631]

Determination That MOBAN (Molindone Hydrochloride) Tablets (5 Milligrams, 10 Milligrams, 25 Milligrams, 50 Milligrams, and 100 Milligrams) and Capsules (5 Milligrams, 10 Milligrams, and 25 Milligrams) Were 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 MOBAN (molindone hydrochloride (HCl)) tablets (5 milligrams (mg), 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 301–796–3381.

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 (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are the subject of NDA 017111, held by Endo Pharmaceuticals, and initially approved on January 18, 1974. MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are indicated for the management of schizophrenia. MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

CorePharma, LLC, submitted a citizen petition dated May 22, 2013 (Docket No. FDA–2013–P–0631), under 21 CFR 10.30, requesting that the Agency determine whether MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address MOBAN (molindone HCl) capsules (5 mg, 10 mg, and 25 mg), that dosage form has also been discontinued, and on our own initiative, we have also determined that MOBAN (molindone HCl) capsules (5 mg, 10 mg, and 25 mg) were not withdrawn for safety or effectiveness reasons.

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 MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 mg) were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules

(5 mg, 10 mg, and 25 mg) were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 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 these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) and capsules (5 mg, 10 mg, and 25 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 MOBAN (molindone HCl) tablets (5 mg, 10 mg, 25 mg, 50 mg, and 100 mg) or capsules (5 mg, 10 mg, and 25 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26550 Filed 11–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft Guidance for Industry on Bioequivalence Recommendations for Iron Sucrose; 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 ''Bioequivalence Recommendations for Iron Sucrose.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for iron sucrose injection. The draft guidance is a revised version of a previously issued draft guidance on the same subject.

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 comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 6, 2014.

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

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.

FOR FURTHER INFORMATION CONTACT: Kris Andre, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8866.

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 draft BE recommendations for iron sucrose injection (Draft Iron Sucrose Injection BE Recommendations of 2013).

Venofer (iron sucrose injection), new drug application 021135, was initially approved by FDA in November 2000. There are no approved ANDAs for this product.

In March 2012, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for iron sucrose injection (Draft Iron Sucrose Injection BE Recommendations of 2012). In that draft guidance, FDA recommended an in vivo fasting BE study with pharmacokinetic endpoints and in vitro studies. FDA has reconsidered the recommendations in the Draft Iron Sucrose Injection BE Recommendations of 2012 and has decided to revise it. At this time, FDA is withdrawing the Draft Iron Sucrose Injection BE Recommendations of 2012 and is issuing a revised draft guidance for industry, the Draft Iron Sucrose Injection BE Recommendations of 2013. In this revised draft guidance, FDA recommends that for the in vivo pharmacokinetic study the difference between total iron and transferrin-bound iron be used to demonstrate BE of generic iron sucrose injection products. FDA is no longer recommending baseline-adjusted total iron and baseline-adjusted transferrin-bound iron be used to demonstrate BE of generic iron sucrose injection products. The revised draft guidance also provides updated information about the recommended studies for in vitro characterization and criteria for waiver of in vivo testing.

In March 2005, Luitpold Pharmaceuticals, Inc. (Luitpold), manufacturer of the reference listed drug, Venofer, submitted (through its attorneys) a citizen petition requesting that FDA withhold approval of any ANDA or 505(b)(2) application for a generic iron sucrose injection unless certain conditions were satisfied, including conditions related to demonstrating BE (Docket No. FDA–2005–P–0319, formerly 2005P–0095/CP1). FDA is reviewing the issues raised in the petition and is also reviewing the supplemental information and comments that have been submitted to the docket for that petition. FDA will consider any comments on the Draft Iron Sucrose Injection BE Recommendations of 2013 before responding to Luitpold's citizen petition.

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 the design of BE studies to support ANDAs for iron sucrose injection. 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