TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
54.6	1,000	1	1,000	0.25	250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
54.4(b)	10,554	1	10,554	0.17	1,794

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

Dated: March 22, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–7405 Filed 3–27–12; 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Draft Guidance for Industry on Bioequivalence Recommendations for Iron Sucrose Injection; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Iron Sucrose.''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.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 29, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. 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: 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 draft BE recommendations for iron sucrose injection.

Venofer (iron sucrose injection), new drug application 021135, was initially approved by FDA in November 2000. There are no approved ANDAs for this product. FDA is now issuing a draft guidance for industry on BE recommendations for generic iron sucrose injection (Draft Iron Sucrose Injection BE Recommendations).

In March 2005, Luitpold Pharmaceuticals, Inc. (Luitpold), manufacturer of the reference listed drug (RLD), 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 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 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. 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. Electronic Access

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

Dated: *March 22, 2012.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–7456 Filed 3–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0577]

Guidance for Industry and Food and Drug Administration Staff; Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and de Novo Classifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications.'' This guidance is intended to provide greater clarity on FDA's decisionmaking process with regard to benefit-risk determinations in the premarket review of medical devices in the premarket approval and *de novo* pathways.

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: Submit written requests for single copies of the guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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:

For devices regulated by CDRH: Ruth Fischer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4424, Silver Spring, MD 20993–0002, 301–796–5735.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

There are many factors that go into assessing the probable benefit of a device versus its probable risk. This guidance sets out the principal factors FDA considers when making this determination and explains them in detail. This guidance also gives examples of how the factors interrelate and how they may affect FDA's decisions. By clarifying FDA's decisionmaking process in this way, we hope to improve the predictability, consistency, and transparency of the review process for applicable devices. The factors described in this guidance apply to devices submitted under premarket approval applications and *de novo* petitions.

This guidance also includes a worksheet that reviewers will use in making benefit-risk determinations for applicable devices. The worksheet is attached as Appendix B to the guidance, and examples of how reviewers might use the worksheet are attached as Appendix C to the guidance. This level of documentation is very helpful to maintaining the consistency of review across the different review divisions and better assuring that an appropriate decision is reached.

In the **Federal Register** of August 15, 2011 (76 FR 50483), FDA announced the availability of the draft guidance. Interested persons were invited to comment by November 14, 2011. FDA considered the comments and revised the guidance, as appropriate.

II. Significance of Guidance

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 factors to consider when making benefit-risk determinations in medical device premarket approval and *de novo* classifications. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability is available for all CDRH guidance documents at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at either *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications'' from CDRH, you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1772 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no new collections of information. The guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of