

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0280]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection on financial disclosure by clinical investigators.

DATES: Submit either electronic or written comments on the collection of information by May 29, 2012.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Financial Disclosure by Clinical Investigators (OMB Control Number 0910-0396)—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 54.4(a)(1) and (a)(2)—Form FDA 3454 | 902 | 1 | 902 | 1 | 902 |
| 54.4(a)(3)—Form FDA 3455 | 90 | 1 | 90 | 5 | 450 |
| Total | | | | | 1,352 |

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

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial

interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records with regard to clinical investigators,

including protocol agreements and investigator resumes or curriculum vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

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.

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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 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/Guidance/ComplianceRegulatoryInformation/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