Under OMB's implementing regulations for the Paperwork Reduction Act, any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons. See 5 CFR 1320.3(c)(4)(i). OGE intends to submit all twelve qualified trust model certificates and model documents described above (all of which are included under OMB paperwork control number 3209–0007) for a three-year extension of approval without modification.

A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on June 5, 2025 (90 FR 23935). OGE did not receive any comments in response.

Request for Comments: Agency and public comments are invited specifically on the need for and practical utility of this information collection, on the accuracy of OGE's burden estimate, on the enhancement of quality, utility, and clarity of the information collected, and on minimizing the burden to the public. Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB approval. The comments will also become a matter of public record.

Specifically, OGE seeks public comment on the following:

- Do the model qualified blind trusts provide sufficient direction to establish a trust under the Qualified Trust Program? If not, what provisions could be clearer or what language should be changed?
- Do the model qualified diversified trusts provide sufficient direction to establish a trust under the Qualified Trust Program? If not, what provisions could be clearer or what language should be changed?
- Do the Additional Trust Documents provide sufficient information for individuals to comply with the logistical requirements (*e.g.,* procedure for securing approval of proposed communications) of the Qualified Trust Program? If not, what provisions could be clearer or what language should be changed?

Approved: August 6, 2025.

Shelley K. Finlayson,

Chief of Staff and Program Counsel, Office of Government Ethics.

[FR Doc. 2025–15116 Filed 8–7–25; 8:45 am]

BILLING CODE 6345–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance on Iron Sucrose; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a revised draft guidance for industry entitled ''Draft Guidance on Iron Sucrose.'' This revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for iron sucrose intravenous injectable.

DATES: Submit either electronic or written comments on the draft guidance by October 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Iron Sucrose.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the

heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993–0002, 240–402–1062, *PSG-Questions@fda.hhs.gov*.

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'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. This notice announces the availability of a revised draft product-specific guidance on generic iron sucrose intravenous injectable.

FDA initially approved new drug application (NDA) 021135 VENOFER (iron sucrose intravenous injectable) in November 2000 and NDA 205109 VELPHORO (sucroferric oxyhydroxide oral tablet) in November 2013.[1] In April 2016, Foley & Hoag LLP, on behalf of Vifor Fresenius Medical Care Renal Pharma France, holder of NDA 205109 VELPHORO, submitted a citizen petition requesting, among other things, that FDA grant five-year new chemical entity exclusivity pursuant to sections 505(j)(5)(F)(ii) and 505(c)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act to VELPHORO and stay the acceptance, receipt, filing, review, and/or approval of any ANDAs or 505(b)(2) applications referencing VELPHORO while FDA considers VELPHORO's new chemical entity exclusivity (Docket No. FDA–2016–P–1163, available at *https://www.regulations.gov*). On May 26, 2021, FDA issued a response to that citizen petition noting that the active ingredient of multiple iron products, including VELPHORO and VENOFER, is ferric oxyhydroxide.[2] [3]

In August 2021, Sidley Austin LLP, on behalf of Vifor (International) Inc., Switzerland (Vifor),[4] submitted a citizen petition requesting that FDA refrain from taking several actions, including changing the product label or labeling for VENOFER, modifying the existing product-specific guidance for VENOFER, and/or changing the established name of VENOFER from iron sucrose to ferric oxyhydroxide (Docket No. FDA–2021–P–0893, available *https://www.regulations.gov*). In September 2021, FDA issued a revised draft product-specific guidance for industry on generic ferric oxyhydroxide intravenous injectable and stated that FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance before responding to the petition.[5] In July 2024, FDA issued a memo to the Docket No. FDA–2021–P–0893 stating that FDA is reevaluating its determination that the active ingredient of the iron products subject to the May 26, 2021 citizen petition response is ferric oxyhydroxide. We are now issuing a revised draft guidance for industry on generic iron sucrose intravenous injectable. FDA is separately responding to Vifor's citizen petition (FDA–2021–P–0893).

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 current thinking of FDA on ''Draft Guidance on Iron Sucrose.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: August 1, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15082 Filed 8–7–25; 8:45 am]

BILLING CODE 4164–01–P

[1] The active ingredients were identified as iron sucrose and sucroferric oxyhydroxide, respectively, at the time of approval of these NDAs.

[2] See Letter to Areta Kupchyk, Foley Hoag LLP, from Patrizia Cavazzoni, M.D., Acting Director, Center for Drug Evaluation and Research, Docket No. FDA–2016–P–1163 (May 26, 2021).

[3] In March 2005, Sonnenschein, Nath & Rosenthal LLP submitted a citizen petition requesting, among other things, that FDA withhold approval of any ANDA or section 505(b)(2) application that references VENOFER unless certain conditions are satisfied, including conditions related to demonstrating BE. (Docket No. FDA–2005–P–0319). The issues raised by that petition are under review by the Agency, and FDA has not made a final decision on those issues.

[4] Vifor (International) Inc., Switzerland is a Swiss pharmaceutical company, which is the drug master file holder for iron sucrose and the owner of the VENOFER trademark and logo. Vifor licenses VENOFER in the United States to American Regent, Inc., the holder of the NDA for VENOFER. The NDA holder for VELPHORO is Vifor Fresenius Medical Care Renal Pharma France, which is a joint venture established by Vifor's parent company and Fresenius Medical Care.

[5] 86 FR 51898 (September 17, 2021).