

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Information Collection Renewal; Comment Request for Qualified Trust Model Certificates and Model Trust Documents

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of request for agency and public comments.

SUMMARY: After this second round notice, the Office of Government Ethics (OGE) plans to request that the Office of Management and Budget (OMB) renew its approval under the Paperwork Reduction Act of an existing information collection, consisting of twelve model certificates and model documents for qualified trusts.

ADDRESSES: *Comments:* Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Jennifer Matis at the U.S. Office of

Government Ethics; telephone: 202–482–9216; TTY: 800–877–8339; Email: jmatis@oge.gov.

SUPPLEMENTARY INFORMATION:

Title: Executive Branch Qualified Trust Documents.

Type of Information Collection: Extension of a currently approved collection.

Type of Review Request: Regular.

Respondents: Any current or prospective executive branch officials who seek to establish or have established a qualified blind or diversified trust under the Ethics in Government Act of 1978 to avoid conflicts of interest while in office.

Estimated Average Annual Number of Respondents: 2.

Total Estimated Time per Response: 20 minutes to 100 hours (see table below for detailed explanation).

Estimated Average Total Annual Burden: 120 hours.

OMB Control Number: 3209–0007.

Abstract: OGE is the supervising ethics office for the executive branch of the Federal Government under the Ethics in Government Act of 1978 (EIGA). Accordingly, OGE administers the qualified trust program for the executive branch. Presidential nominees to executive branch positions subject to Senate confirmation and any other

executive branch officials may seek OGE approval for EIGA-qualified blind or diversified trusts as one means to avoid conflicts of interest. The requirements for EIGA-qualified blind and diversified trusts are set forth in section 13104(f) of the Ethics in Government Act, 5 U.S.C. 13104(f), and OGE’s implementing financial disclosure regulations at subpart D of 5 CFR part 2634.

In order to ensure that all applicable requirements are met, OGE is the sponsoring agency for twelve model certificates and model trust documents for qualified blind and diversified trusts. See 5 CFR 2634.402(e)(3), 2634.402(f)(3), 2634.404(e)–(g), 2634.405(d)(2), 2634.407(a); 2634.408(b)(1)–(3), 2634.408(d)(4), 2634.409, and 2634.414. The various model certificates and model trust documents are used by settlors, trustees, and other fiduciaries in establishing and administering these qualified trusts. OGE plans to submit these model certificates and model trust documents (described in detail in the table below) to OMB for renewed approval pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

The twelve model documents, along with their burden estimates, are as follows:

	Estimated burden
Model qualified trust documents:	
(A) Blind Trust Communications (Expedited Procedure for Securing Approval of Proposed Communications).	20 minutes per communication.
(B) Model Qualified Blind Trust Provisions	100 hours per model.
(C) Model Qualified Diversified Trust Provisions	100 hours per model.
(D) Model Qualified Diversified Trust Provisions (For Use in the Case of Multiple Fiduciaries)	100 hours per model.
(E) Model Qualified Blind Trust Provisions (For Use in the Case of an Irrevocable Pre-Existing Trust) ..	100 hours per model.
(F) Hybrid Version of the Model Qualified Diversified Trust Provisions	100 hours per model.
(G) Model Qualified Blind Trust Provisions (For Use in the Case of Multiple Fiduciaries)	100 hours per model.
(H) Model Qualified Diversified Trust Provisions (For Use in the Case of an Irrevocable Pre-Existing Trust).	100 hours per model.
(I) Model Confidentiality Agreement Provisions (For Use in the Case of a Privately Owned Business) ..	2 hours per agreement.
(J) Model Confidentiality Agreement Provisions (For Use in the Case of Investment Management Activities).	2 hours per agreement.
Model Trust Certificates:	
(K) Certificate of Independence	20 minutes per certificate.
(L) Certificate of Compliance	20 minutes per certificate.

These estimates are based on the amount of time imposed on professional trust administrators or private representatives. OGE notes that only one set of the various model trust provisions (items (B) through (H)) will be prepared for a single qualified trust, and only prior to the establishment of that qualified trust. Likewise, other model documents listed above are used in connection with establishing the qualified trust (items (I), (J), and (K)). The remaining model documents are used after the trust’s creation (items (A)

and (L)). Accordingly, OGE notes that the majority of the time burden for any given trust is imposed during the creation of the trust.

At the present time, there are no active qualified trusts in the executive branch. However, OGE anticipates possible limited use of these model documents during the forthcoming three-year period. OGE estimates that there may be an average of one individual per year who initiates a qualified trust using these model documents during calendar years 2026

through 2028. OGE has accordingly estimated the average annual number of respondents to be two, which represents one respondent establishing a qualified trust and one respondent maintaining a previously established qualified trust. Based on the above, OGE estimates an average annual time burden during the next three years of 120 hours. Using an estimated rate of \$300 per hour for the services of a professional trust administrator or private representative, the estimated annual cost burden is \$36,000.

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