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.

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: May 28, 2025.

Shelley K. Finlayson,

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

[FR Doc. 2025–10211 Filed 6–4–25; 8:45 am]

BILLING CODE 6345–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1528]

Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' This guidance provides information on the most frequently asked questions regarding transfer of ownership from one 510(k) holder to another. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 4, 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–2024–D–1528 for ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' This guidance provides information on the most frequently asked questions regarding transfer of ownership from one 510(k) holder to another. An owner or operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is generally required to register the establishment and submit listing information for all devices in commercial distribution.[1] Under section 510(k) of the FD&C Act, each person who is required to register their establishment must generally submit a 510(k) to FDA at least 90 days before proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use if the device is being introduced into commercial distribution for the first time.[2] When a 510(k) clearance for a specific device is sold or transferred from one person to another, the new 510(k) holder must list their device in the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), an internet-based registration and listing system, if engaged in activities requiring listing.[3] When listing, if the device is not significantly changed or modified,[4] the new 510(k) holder must supply the original FDA-assigned premarket submission number[5] unless submitting a new 510(k), in which case the new 510(k) holder would supply the new FDA-assigned premarket submission number.[6] The new 510(k) holder must, if not previously entered into an operation described in 21 CFR 807.20(a), register within 30 days after entering into such an operation and submit device listing information, including the FDA-assigned submission number,[7] at that time.[8] A device manufactured, prepared, propagated, compounded, or processed in an establishment that is not duly registered under section 510, or a device that is not included in a list required by section 510(j), is misbranded.[9]

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 ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' 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 any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001808 and complete title to identify the guidance you are requesting.

II. Paperwork Reduction Act of 1995

While this guidance contains no new 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 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

[1] 21 CFR 807.20(a); see FD&C Act subsections 510(b), 510(i), and 510(j). Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States is required to register and list in conformance with the procedures in 21 CFR 807.40, 21 CFR 807.41, and subpart B of 21 CFR part 807. The registration requirement does not apply to owners or operators that are exempt under section 510(g) of the FD&C Act or subpart D of 21 CFR part 807.

[2] 21 CFR 807.81(a)(2); also see FD&C Act section 513(i). Note that a 510(k) is not required for a device for which a premarket approval application under section 515 of the FD&C Act, or for which a petition to reclassify under section 513(f)(2) of the FD&C Act, is pending before FDA, or there is a predetermined change control plan (PCCP) cleared under section 515C of the FD&C Act, provided that the change is consistent with the PCCP. 21 CFR 807.81(b)(1).

[3] 21 CFR 807.25.

[4] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' and ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device.''

[5] The new 510(k) holder need not submit a new 510(k) because the new 510(k) holder is not proposing ''to begin the introduction or delivery for introduction into interstate commerce for commercial distribution'' of the device. See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977); see also 21 CFR 807.85(b)(2) (applies to those distributors and repackagers who are exempt from submitting a 510(k) if it was filed by another person).

[6] 21 CFR 807.25(g)(4).

[7] 21 CFR 807.25(g)(4).

[8] 21 CFR 807.22(a). See 21 CFR 807.22 for other registration and listing timing requirements.

[9] See FD&C Act section 502(o).

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
807, subparts A through D	Medical Device Registration and Listing	0910–0625

Dated: May 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10238 Filed 6–4–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1613]

Raw Data for Safety and Effectiveness Studies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #287 entitled ''Raw Data for Safety and Effectiveness Studies.'' This guidance provides information to animal drug sponsors (sponsors) on the use of raw data in the Center for Veterinary Medicine's (CVM) review of safety and effectiveness studies submitted in support of new animal drug applications. This guidance also describes our recommendations for submitting raw data.

DATES: The announcement of the guidance is published in the **Federal Register** on June 5, 2025.

ADDRESSES: You may submit comments on Agency guidances 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–2024–D–1613 for ''Raw Data for Safety and Effectiveness Studies.'' 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Fleischer, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20850, 240–402–0809, *steven.fleischer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 29, 2024 (89 FR 33371), FDA published the notice of availability for a draft guidance #287 entitled ''Raw Data for Safety and Effectiveness Studies,'' giving interested persons until June 28, 2024, to comment on the draft guidance. FDA received three comment submissions on the draft guidance, two from industry associations and one from a contract research facility. Those comments were considered as the guidance was finalized. A summary of changes