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

includes: clarification that we are not asking sponsors to submit all raw data, addition of a link to CVM's Data Quality Resources website, and clarification on file format for data submitted in our eSubmitter platform. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 2024.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Raw Data for Safety and Effectiveness Studies.'' 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

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 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1360]

Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on its website of the proposed administrative order (proposed order) (OTC000038) entitled ''Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' This proposed order, if finalized, will permit minor dosage form changes, *i.e.,* from tablets or capsules to chewable tablets, orally disintegrating tablets, or films, of over-the-counter (OTC) monograph drugs that are in conformity with the requirements of the order, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and other applicable requirements, without the issuance of a separate order amending an applicable OTC monograph to add the new dosage form or otherwise finding the new dosage form to be generally recognized as safe and effective (GRASE).

DATES: Submit electronic comments on the proposed administrative order by October 3, 2025.

ADDRESSES: The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 3, 2025. Please note that late, untimely filed comments will not be considered. Instructions for submitting comments are contained in the proposed order OTC000038, which can be viewed in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* Comments must be submitted electronically.

FOR FURTHER INFORMATION CONTACT: Shannon Liu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–2484.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the proposed order OTC000038 pursuant to section 505G(c) of the FD&C Act (21 U.S.C. 355h(c)), which specifies FDA's proposed requirements for making a minor change in the dosage form of certain OTC monograph drugs, without the issuance of a separate order under section 505G(b) of the FD&C Act amending an applicable monograph to add the new dosage form or otherwise finding the new dosage form to be GRASE. Section 505G(c) of the FD&C Act applies to drugs described in section 505G(a)(1) or (a)(2) of the FD&C Act or that are otherwise the subject of an order under section 505G(b). More specifically, section 505G(c)(3) of the FD&C Act directs FDA to issue one or more administrative orders specifying the requirements for determining whether a minor dosage form change to a drug made by a sponsor pursuant to section 505G(c) of the FD&C Act will affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product.

This proposed order also fulfills a commitment made by FDA under the terms of the ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures,'' commonly referred to as the OMUFA commitment letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with the updated goal dates for fiscal years 2021 to 2025 can be accessed at *https://www.fda.gov/media/146283/download*). The OMUFA commitment letter specifies goals and timelines mutually agreed upon by FDA and industry with respect to various OTC monograph drug activities conducted by FDA. FDA committed to issuing a proposed order outlining key requirements to clarify which types of minor changes to solid oral dosage forms are permissible without the issuance of an order finding the new dosage forms to be GRASE (when the applicable OTC monograph does not already provide for these types of changes), together with related draft guidance (FDA is publishing notice of the draft guidance for industry ''Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs'' elsewhere in this issue of the **Federal Register**).

Consistent with section 505G(c)(3) of the FD&C Act, FDA proposes to specify the requirements for determining whether a particular minor dosage form change to a drug made by a sponsor