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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-2560]

Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled "Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products." This revised draft guidance revises and replaces the draft guidance entitled "Essential Drug Delivery Outputs Intended to Deliver Drugs and Biological Products" announced in the *Federal Register* on July 1, 2024 (89 FR 54470). In accordance with its mission of protecting, promoting, and advancing public health, this guidance addresses key aspects of drug delivery performance information for devices, and combination products that include device constituent parts, intended for delivery of a human drug, including a biological product (herein referred to as *drug delivery devices*). This guidance provides recommendations for development and organization of device drug-delivery performance information and data to improve the consistency of this information in applications and to facilitate transparency and predictability in development and regulatory review. The guidance is intended to facilitate and streamline development and lifecycle management of drug delivery devices.

DATES: Submit either electronic or written comments on the revised draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance.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-2560 for "Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs

and Biological Products." 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 revised draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, 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 revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301-796-8930, patricia.love@fda.hhs.gov or combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products." This revised draft guidance revises and replaces the draft guidance entitled "Essential Drug Delivery Outputs Intended to Deliver Drugs and Biological Products" announced on July 1, 2024 (89 FR 54470). This guidance provides updates to clarify content on testing and controlling device drug-delivery performance and to align with the revised Quality Management System Regulation, 21 CFR part 820.

The guidance describes FDA's recommendations related to information that is essential for establishing and assessing drug delivery performance for drug delivery devices. Device drug-delivery performance information is intended to demonstrate that the device drug-delivery function consistently performs as intended. The guidance focuses on recommendations for the information and data to submit in investigational, marketing, and post-market change applications.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on "Essential Drug Delivery Performance Characteristics for

Devices Intended to Deliver Drugs and Biological Products." 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910-0014 and the collections of information in 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910-0078. The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications, including the collections of information contained in the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" have been approved under OMB control number 0910-0001. The collections of information in 21 CFR parts 601 and 610 for biologics license applications have been approved under 0910-0338. The collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under 0910-0718. The collections of information in 21 CFR part 814 for premarket approval applications have been approved under 0910-0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), 21 CFR part 807, subpart E for premarket notifications, have been approved under OMB control number 0910-0120. The collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910-0844. The

collections of information in 21 CFR part 211 for current good manufacturing practice for finished pharmaceuticals have been approved under OMB control number 0910-0139. The collections of information in 21 CFR part 820 for the quality management system regulation have been approved under OMB control number 0910-0073. The collections of information for meetings and controlled correspondence related to generic drug development have been approved under OMB control number 0910-0727. The collections of information in the guidance for industry and FDA staff entitled "Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with the Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

III. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents or https://www.regulations.gov.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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