## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–D–2560]**

### Essential Drug Delivery Outputs for Devices Intended To Deliver Drugs and Biological Products; Draft Guidance for Industry; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products.'' 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). The guidance describes FDA's recommendations related to the device design outputs that are essential for establishing and assessing drug delivery performance. FDA is providing recommendations for development and organization of device drug-delivery performance information to improve the consistency of this information in applications and submissions. The guidance is intended to facilitate and streamline development of drug delivery devices.

**DATES:** Submit either electronic or written comments on the draft guidance by September 30, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2560 for ''Essential Drug Delivery Outputs 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 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 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 draft guidance for industry entitled ''Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products.'' 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). The guidance describes FDA's recommendations related to the device design outputs that are essential for establishing and assessing drug delivery performance. Device drug-delivery performance information is intended to demonstrate that the device drug-delivery function consistently performs as intended. As discussed further in the guidance, essential drug delivery output (EDDO) refers to the device drug-delivery design outputs necessary to ensure the drug delivery function.

This guidance recommends an approach to identifying EDDOs, provides examples of EDDOs for specific types of devices, and describes the information and data related to EDDOs that is provided in an application or submission. Examples of products that are within the scope of this guidance include syringes, injectors (*e.g.,* autoinjector, on body injector), infusion products (*e.g.,* infusion pumps), nasal sprays, inhalers, nebulizers, and vaginal systems.

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 ''Essential Drug Delivery Outputs 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.

## 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 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 OMB control number 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 OMB control number 0910–0718. The collections of information in 21 CFR part 814 for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), subpart E for 510(k) 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 system regulation have been approved under OMB control number 0910–0073. The collections of information in 21 CFR part 807, subpart E for premarket notification have been approved under OMB control number 0910–0120. The collections of information for meetings 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 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.*

Dated: June 25, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** This notice informs the public of the availability of the complete lists of all geographic areas, population groups, and facilities designated as primary medical care, dental health, and mental health professional shortage areas (HPSAs) in a designated status as of April 15, 2024. The lists are available on the shortage area topic page on HRSA's *data.hrsa.gov* website. All currently designated HPSAs remain designated until final lists are published later this fall. HPSA designations that are currently proposed for withdrawal will remain in this status until the publication of the HPSA **Federal Register** notice on or before November 1, 2024. HPSAs proposed for withdraw will be re-evaluated before final publication if additional information is made available to HPSA by states. If these HPSAs do not meet the requirements for designation at the time of the publication of the HPSA **Federal Register** on or before November 1, 2024, they will be withdrawn.

**ADDRESSES:** Complete lists of currently designated HPSAs as of April 15, 2024, and include those proposed for withdraw, are available on the website at *https://data.hrsa.gov/tools/health-workforce/shortage-areas/frn.* Frequently updated information on HPSAs is available at *https://data.hrsa.gov/topics/health-workforce/health-workforce-shortage-areas.* Information on shortage designations is available at *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation.*

**FOR FURTHER INFORMATION CONTACT:** For further information on the HPSA designations listed on the website or to request additional designation, withdrawal, or reapplication for designation, please contact Matthew Patterson, Acting Branch Chief, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, *sdb@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

Section 332 of the Public Health Service (PHS) Act, 42 U.S.C. 254e, provides that the Secretary shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish lists of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.