

B. Provide for confirmation the completed and signed attestation to the airline or other aircraft operator confirming that they have not been present in the Democratic Republic of the Congo (DRC) during the 21 days preceding their boarding a flight to the United States.

The required attestation text is attached to this Order as Attachment A. Unless otherwise permitted by law, a parent or other authorized representative may present the required documentation on behalf of a person required to submit such an attestation.

Any person who fails to provide this attestation, or submits false or misleading information, may face a delay of travel, denial of boarding, or denial of boarding on future travel.

Any person who fails to comply with the requirements of section 2, “Requirements for Persons Traveling via Transportation by Aircraft,” may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia*, 18 U.S.C. 1001. This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 270, 271; and 42 CFR 71.2. The U.S. Department of Justice in its discretion may prosecute any individual who knowingly and willfully submits a false statement in violation of 18 U.S.C. 1001.

#### Effective Date

This Order takes effect at 11:59 p.m. Eastern Standard Time on November 3, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing at or after 11:59 p.m. Eastern Standard Time on November 3, 2026.

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at \_\_\_\_\_, this October 28, 2026.

Dated:

Brian Christine,  
*Assistant Secretary for Health (ASH) and  
 Head of the United States Public Health  
 Service (USPHS) Commissioned Corps,  
 Department of Health and Human Services.*

#### Authority

The authority for this order is Sections 361, 365, 368, and 369 of the

Public Health Service Act (42 U.S.C. 264, 268, 270, and 271), as amended.

**Brian Christine,**

*Assistant Secretary for Health (ASH) and  
 Head of the United States Public Health  
 Service (USPHS) Commissioned Corps,  
 Department of Health and Human Services.*

[FR Doc. 2026–22211 Filed 10–29–26; 8:45 am]

**BILLING CODE 4163–18–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 January 28, 2027 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](mailto:patricia.love@fda.hhs.gov) or [combination@fda.gov](mailto: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.*

[FR Doc. 2026–22203 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–1998–P–0083 (formerly 76N–0377); DESI 7661]

#### Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Third Extension of Effective Date of Final Resolution of Drug Efficacy Study Implementation 7661

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

**ACTION:** Notice; third extension of effective date.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is extending the effective date of the notice published in the **Federal Register** on May 27, 2026, titled **Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Syntest D.S. and Syntest H.S. Tablets; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation 7661** (91 FR. 31462) (the “May 2026 Notice”), as previously extended by the notice published in the **Federal Register** on August 27, 2026 (91 FR 55348), by an additional 6 months. The effective date of the May 2026 Notice, as previously extended to November 4, 2026, is hereby further extended to May 4, 2027. This further extension is necessary to allow FDA sufficient time to consider issues raised by interested parties.

**DATES:** The effective date of the May 27, 2026, notice (91 FR 31462), as previously extended, is further extended to May 4, 2027.

**ADDRESSES:** 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 between 9 a.m. and 4 p.m., Monday

through Friday. Publicly available submissions may be seen in the docket.

The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

#### FOR FURTHER INFORMATION CONTACT:

Amber McKinley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5172, Silver Spring, MD 20993–0002, 301–796–0061, [Amber.McKinley@fda.hhs.gov](mailto:Amber.McKinley@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On May 27, 2026, FDA published a notice in the **Federal Register** (91 FR 31462) announcing the final resolution of Drug Efficacy Study Implementation (DESI) 7661 for estrogen-androgen fixed-combination drug products. The May 2026 Notice concluded that all outstanding hearing requests for estrogen-androgen fixed-combination drug products under Docket FDA–1998–P–0083 had been withdrawn, and that such products lack substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in patients not improved by estrogen alone. The May 2026 Notice stated that shipment in interstate commerce of any drug product identified in the docket, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) would be unlawful as of June 26, 2026.

FDA subsequently extended the effective date of the May 2026 Notice to September 24, 2026, and then to November 4, 2026, to allow the Agency sufficient time to consider issues raised by interested parties following publication of the May 2026 Notice. See 91 FR 38717 and 91 FR 55348.

##### II. Third Extension of Effective Date

FDA has determined that additional time is needed to fully consider the issues raised by interested parties. Accordingly, FDA is extending the effective date of the May 2026 Notice by an additional six months, from November 4, 2026, to May 4, 2027. See 21 CFR 314.200(h).

Grace R. Graham,

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–22175 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: AIDS Drug Assistance Program—Transformation: Optimization and Best Practices in the Evolving Health Care Landscape, OMB No. 0906–XXXX—New**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than December 29, 2026.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* AIDS Drug Assistance Program—Transformation: Optimization and Best Practices in the Evolving Health Care Landscape, OMB No. 0906–XXXX—New.

*Abstract:* HRSA’s HIV/AIDS Bureau administers the Ryan White HIV/AIDS Program, including the AIDS Drug Assistance Program (ADAP). ADAPs help low-income people with HIV access therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS, including measures for the prevention and