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**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

treatment of opportunistic infections and health care coverage assistance. As health care coverage environments, treatment options, and program financing mechanisms continue to evolve, ADAPs face increasing operational complexity related to eligibility determination; client enrollment and retention; health care coverage navigation; pharmacy management; rebate administration; and data infrastructure. HRSA currently lacks comprehensive, national-level information about how ADAPs manage these operational functions and address emerging challenges.

To address these information gaps, HRSA developed the ADAP Transformation: Optimization and Best Practices in the Evolving Health Care Landscape study. Through this effort, HRSA will collect program-level information from ADAPs nationwide through a web-based survey, qualitative interviews with a purposeful sample of ADAP staff, and virtual listening sessions with the broader ADAP community. The study will identify operational best practices, barriers, and opportunities for technical assistance to strengthen ADAP capacity and support

access to HIV care and treatment services. No client-level information, personally identifiable information, or protected health information will be collected.

*Need and Proposed Use of the Information:* The proposed information collection will provide HRSA with systematic information on operational and administrative practices across ADAPs nationwide. Survey, interview, and listening session data will help HRSA identify effective strategies for managing eligibility processes; client enrollment and recertification; health care coverage continuity; pharmacy operations; rebate management; cost-containment efforts; and data systems modernization.

Findings will support the development of tailored technical assistance, tools, guidance, and dissemination activities designed to strengthen ADAP operations. Results will also inform HRSA program planning and future data collection efforts. Study findings will be reported only in aggregate or de-identified form and will not be used for compliance monitoring or funding decisions.

*Likely Respondents:* Respondents will consist of staff from state and territorial

ADAPs, including program administrators, eligibility and enrollment staff, pharmacy and benefits coordinators, financial and rebate management staff, data systems personnel, and other staff responsible for ADAP operations. HRSA will also invite ADAP staff to participate in virtual listening sessions focused on validating and contextualizing study findings.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name                   | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|-----------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| Quantitative Survey .....   | 54                    | 1                                  | 54              | 0.5                                    | 27                 |
| Qualitative Interview ..... | 54                    | 1                                  | 54              | 1.5                                    | 81                 |
| Listening Sessions .....    | 177                   | 1                                  | 177             | 1.5                                    | 265.5              |
| Total .....                 | 285                   | .....                              | 285             | .....                                  | 373.5              |

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**  
*Director, Executive Secretariat.*  
[FR Doc. 2026–22220 Filed 10–29–26; 8:45 am]  
**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**[Docket No. HHS–OASH–2026–0496]**  
**RIN 0910–ZD94**

**Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances**

**AGENCY:** Office of the Secretary, Department of Health and Human Services.  
**ACTION:** Notice of availability.

**SUMMARY:** The Secretary of the Department of Health and Human Services (HHS) is announcing the availability of an “Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.” This document describes the Secretary of HHS’s enforcement policy regarding the use of

certain peptide bulk drug substances in compounding pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking.

**DATES:** This announcement is published in the **Federal Register** as of October 30, 2026.

**ADDRESSES:** Written comments can be submitted until 2 weeks after date of publication in the **Federal Register** via *regulations.gov* on Docket No. HHS–OASH–2026–0496

**FOR FURTHER INFORMATION CONTACT:** Victoria Marshall, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Washington, DC, 202–690–7694, *OASH-RFI@hhs.gov*

**SUPPLEMENTARY INFORMATION:**