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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.

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.

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