or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes them to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report on CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS–367a–e (OMB control number: 0938–0578); *Frequency:* Monthly, quarterly, and on occasion; *Affected Public:* Private sector; *Number of Respondents:* 840; *Total Annual Responses:* 16,160; *Total Annual Hours:* 606,932. (For policy questions regarding this collection contact Robert Giles at 667–290–8626.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care and Supporting Regulations; *Use:* The information that is required to be reported under 42 CFR part 438 is used by states for program administration and by CMS for program compliance monitoring and policy development. The three templates included in this collection of information request (Managed Care Program Annual Report (MCPAR), Medical Loss Ratio (MLR) Reporting Template, and Network Adequacy and Access Assurances Tool) are unchanged and are used for state reporting to CMS. States are also required to include certain requirements in their contracts with their managed care plans. Managed care plans must distribute certain information to their enrollees (*e.g.* handbooks and notices) and to their providers (*e.g.* practice guidelines and notices). *Form Number:* CMS–10108 (OMB control number: 0938–0920); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profit and not-for-profit institutions), and State, local or Tribal Government; *Number of Respondents:* 738; *Total Annual Responses:* 15,132,343; *Total Annual Hours:* 1,850,067. (For policy questions regarding this collection contact Amy Gentile at 410–786–3499.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–12945 Filed 6–25–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; TANF Contingency Fund Application

AGENCY: Office of Family Assistance, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Family Assistance, Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing to collect data for state requests of Temporary Assistance for Needy Families (TANF) Contingency Fund provisional payments through the TANF Contingency Fund Application.

DATES: Comments due August 25, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The TANF Contingency Fund Application is an optional request for funds submitted by states to ACF. The proposed information collection will standardize the mechanism through which states request provisional payments monthly. To reduce response time and minimize burden hours, the proposed form consolidates guidance and existing resources. The form will require states to demonstrate eligibility, describe how they will fulfill award requirements, and provide certification by the Governor or official designee. Authority to distribute provisional payments based on receipt of state requests for contingency funds is contained in section 403 of the Social Security Act (42 U.S.C. 603(b)(3), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, 110 Stat. 2105. States must submit a new application in the month prior to the month for which they request funds.

Respondents: The 50 states of the United States and the District of Columbia.

Annual Burden Estimates

The TANF Contingency Fund Application for the 50 states and the District of Columbia will create an optional monthly burden with an average of 15 states responding although up to 50 states and the District of Columbia may be eligible. We estimate the annual burden to be an average of 3 hours per response, with an estimate of 7 responses per respondent each year.

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Contingency Fund Application	15	7	3	315

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 603(b).

Mary C. Jones,

ACF OPRE Certifying Officer.

[FR Doc. 2026–12971 Filed 6–25–26; 8:45 am]

BILLING CODE 4184–36–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; 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; extension of effective date.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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''), by 90 days. The effective date of the May 2026 Notice is hereby extended from June 26, 2026, to September 24, 2026. This extension is necessary to allow FDA sufficient time to consider issues raised by interested parties following publication of the May 2026 Notice.

DATES: The effective date of the May 27, 2026, notice (91 FR 31462) is extended to September 24, 2026.

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, email: *Amber.McKinley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 27, 2026, FDA published a notice in the **Federal Register** (91FR 31462) announcing the final resolution of Drug Efficacy Study Implementation (DESI) 7661 for estrogen-androgen fixed-combination drug products, including Syntest D.S. and Syntest H.S. Tablets. 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.

The title of the May 2026 Notice mistakenly included reference to two products subject to this proceeding. However, because this proceeding is not specific to those two products, we have removed that language from the title of the current notice.

II. Extension of Effective Date

FDA has determined that additional time is needed before the May 2026 Notice takes effect in order to fully consider the issues raised by interested parties following publication of the May 2026 Notice. Accordingly, FDA is extending the effective date of the May 2026 Notice by 90 days, from June 26, 2026, to September 24, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12933 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4566]

Determination That RECTIV (Nitroglycerin) Ointment, 0.4%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that RECTIV (nitroglycerin) ointment, 0.4%, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain