

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, email NFRRegistry@cdc.gov. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Firefighter Registry for Cancer (OMB Control No. 0920-1348)—Reinstatement—National Institute for Occupational Safety and Health

(NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In order to accurately monitor trends in cancer incidence and evaluate control measures among the U.S. fire service, Congress passed the Firefighter Cancer Registry Act of 2018. Under this legislation, CDC/NIOSH was directed to create a registry of U.S. firefighters for the purpose of monitoring cancer incidence and risk factors among the current U.S. fire service. Funding for the project was authorized through this legislation for five years as of fiscal year 2019 and has been reauthorized through 2028.

According to the Firefighter Cancer Registry Act of 2018, The main goal of the National Firefighter Registry for Cancer (NFR) is, “to develop and maintain . . . a voluntary registry of firefighters to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence.” Results from the NFR will provide information for decision makers within the fire service

and medical or public health community to devise and implement policies and procedures to lessen cancer risk and/or improve early detection of cancer among firefighters. NIOSH seeks a three-year renewal to enroll at least 33,333 firefighters annually. The overall enrollment goal of the NFR remains 200,000. Prior annual enrollment data has led to a more accurate annual burden estimation than prior approvals.

There are three corresponding documents to be completed as part of the enrollment process: Informed Consent, User Profile, and Enrollment Questionnaire. Select fire departments may have an additional Records Request. The estimated time burden for the Informed Consent and User Profile are five minutes each, an estimated 20-minute burden for the NFR Enrollment Questionnaire, and 16 hours for the Records Request (applicable to an estimated 30 firefighters). CDC requests OMB approval for an estimated 17,157 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
U.S. Firefighters	Informed Consent	33,333	1	5/60
U.S. Firefighters	NFR User Profile (web-portal registration)	33,333	1	5/60
U.S. Firefighters	NFR Enrollment Questionnaire	33,333	1	20/60
U.S. Firefighters	Records request	30	1	16

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026-10512 Filed 5-26-26; 8:45 am]

BILLING CODE 4163-18-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; Syntest D.S. and Syntest H.S. Tablets; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation 7661

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests for estrogen-androgen fixed-combination drug products under Docket FDA-1998-P-0083 (formerly 76N-0377) (DESI 7661) have been withdrawn. Therefore, as proposed in the April 14, 2003, notice of opportunity for hearing (NOOH), FDA finds that the products subject to this proceeding have not been shown to be effective for use under the conditions of use prescribed, recommended, or suggested in the labeling. Shipment in interstate commerce of any product identified in this docket (DESI 7661), 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) is unlawful as of the date of this notice.

DATES: This notice is effective June 26, 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

In 1962, Congress amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that “new drugs” (21 U.S.C. 321(p)) be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval (Drug Amendments of 1962 (Pub. L. 87-781)). These amendments also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA’s administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of products that were IRS (see 21 CFR 310.6(b)(1)) to the approved drug products and that had entered the market without FDA approval. All drugs covered by the DESI review are “new drugs” under the FD&C Act.

II. Final Resolution of Hearing Request Regarding Estrogen-Androgen Fixed-Combination Drug Products Under Docket FDA-1998-P-0083 (Formerly 76N-0377); DESI 7661

In a **Federal Register** notice published on September 8, 1972 (37 FR 18225), FDA announced its evaluation of reports received from the NAS/NRC under DESI 7661 regarding five fixed-combination drug products containing an estrogen and an androgen. FDA stated in that notice that it found these drugs to be effective “for the prevention of postpartum breast engorgement” and “for the menopausal syndrome in those patients not improved by estrogen alone.” With respect to the first indication, on December 17, 1998, FDA withdrew approval of estrogen-containing drug products insofar as they were indicated for postpartum breast engorgement, because estrogens were not shown to be safe for this use (63 FR

69631).¹ Given FDA’s findings in the December 17, 1998, **Federal Register** notice, the remainder of this notice focuses on the second indication in the September 1972 notice, *i.e.* “for the menopausal syndrome in those patients not improved by estrogen alone.”

In the **Federal Register** of September 29, 1976 (41 FR 43112), FDA announced that the menopausal indication for fixed-combination drugs containing an estrogen and an androgen (including the five drug products identified in the September 8, 1972, notice) was revised to read:

Moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone (There is no evidence that estrogens are effective for nervous symptoms or depression which might occur during menopause, and they should not be used to treat these conditions).

Id. at 43113.

In 1981, in response to requests from the sponsors, FDA determined that the effectiveness finding in the September 29, 1976, notice could be applied to two fixed-combination drug products that were not listed in the 1976 notice but were being marketed at the time: (1) conjugated estrogens and methyltestosterone, and (2) esterified estrogens and methyltestosterone. See 68 FR 17953, 17954 (April 14, 2003).

FDA took a renewed interest in both the safety and efficacy of estrogen-androgen products while reviewing potential new safety concerns about the products. As detailed in the **Federal Register** on April 14, 2003 (68 FR 17953), an Agency review of the literature led FDA to reclassify the September 1976 effectiveness finding for estrogen-androgen fixed combination drug products to lacking substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with menopause in patients not improved by estrogen alone. At the same time, FDA also issued a Notice of Opportunity for a Hearing (NOOH) to manufacturers and distributors of drug products affected by the notice, regarding FDA’s determination that such products lacked substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with menopause in patients not improved by estrogen alone. In response to the April 14, 2003, NOOH, two companies requested hearings: Syntho Pharmaceutical, Inc. (Syntho), 230

¹ For additional background information leading to the 1998 **Federal Register** notice, see 68 FR 17953 (April 14, 2003).

Sherwood Ave, Farmingdale, NY 11735, and Solvay Pharmaceuticals, since acquired by Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.

In response to the 2003 NOOH, Syntho filed a written notice of participation and request for a hearing on May 14, 2003, and submitted data in support of its hearing request on June 13, 2003. Syntho marketed Syntest D.S. (1.25 milligrams (mg) esterified estrogens/2.5 mg methyltestosterone) and Syntest H.S. (0.625 mg esterified estrogens/1.25 mg methyltestosterone), both labeled for use in treating moderate to severe vasomotor symptoms associated with the menopause in patients not improved by estrogen alone. In a letter dated January 31, 2011, FDA asked Syntho whether it was interested in pursuing its hearing request. Syntho affirmed its hearing request on March 1, 2011. By letter dated June 18, 2025, FDA again asked Syntho whether it wanted to pursue its hearing request regarding its Syntest D.S. and Syntest H.S. products. By letter dated August 1, 2025, Syntho stated that it had decided to withdraw its hearing request.

At the time of Solvay’s 2003 hearing request, the firm marketed Estratest and Estratest HS. On January 31, 2011, FDA sent a letter to Abbott asking whether it wanted to pursue the hearing request regarding its Estratest and Estratest HS products. On June 21, 2011, Abbott responded by withdrawing the hearing request previously filed by Solvay Pharmaceuticals before its acquisition by Abbott.

III. Conclusions and Order

There are no outstanding hearing requests regarding estrogen-androgen fixed-combination drug products under Docket FDA-1998-P-0083, DESI 7661. As proposed in the April 14, 2003, NOOH, 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. Shipment in interstate commerce of any drug product identified in this docket, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the effective date of this notice (see EFFECTIVE DATE). Any person who wishes to determine whether this notice covers a specific product should write to Amber McKinley at the Center for Drug Evaluation and Research (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the applicable date of this notice (see EFFECTIVE DATE), FDA intends to take enforcement action without further

notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

IV. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c). Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.57(b)). Questions on electronic drug listing updates should be sent to eDRLS@fda.hhs.gov. In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product National Drug Code number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Amber McKinley (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it identifies violative products for enforcement action.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-10479 Filed 5-26-26; 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: Rural Communities Opioid Response Program Performance Measures, 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 July 27, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 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 or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Rural Communities Opioid Response Program Performance Measures, OMB No. XXXX-XXX—New.

Abstract: HRSA administers the Rural Communities Opioid Response Program (RCORP), which is authorized by Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, including OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP—Northern Border Rural Workforce: This program aims to improve health care in rural areas within the Northern Border Regional Commission's service area by enhancing behavioral health workforce capacity.
- RCORP—Pathways: This program aims to create innovative new youth-focused behavioral health care support programs, while also offering behavioral health care career pathway opportunities in rural communities.
- RCORP—Overdose Response: This program addresses immediate needs in rural areas through improving access to, capacity for, and sustainability of

prevention, treatment, and recovery services for SUD.

Need and Proposed Use of the Information: Due to the growth in the number of grant initiatives included within RCORP, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a new ICR that includes performance measures for the new RCORP—Northern Border Rural Workforce, Pathways, and Overdose Response grant programs. HRSA developed performance measures to provide data on each RCORP initiative and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. This collection supplements the approved RCORP grantee data collection, which covers all other RCORP grant initiatives (OMB Control No. 0906-0044; expires February 28, 2029).

These measures cover the principal topic areas of interest to HRSA, including: (a) provision of, and referral to, rural behavioral health care services, including SUD prevention, treatment and recovery support services; (b) behavioral health care, including SUD prevention, treatment, and recovery process and outcomes; (c) provider prevention, treatment, and recovery services; (d) sustainability; and (e) development of workforce/career pathway programs. Performance measures for the RCORP initiative include common elements about consortium/network activities, direct services provided and service access, workforce, and sustainability while also capturing tailored measures for each specific program.

Likely Respondents: The respondents will be recipients of RCORP—Northern Border Rural Workforce, Pathways, and Overdose Response grant programs.

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.