purpose of this revision is three-fold: (1) Implement updates to the web-based system to improve performance, functionality, and accessibility, (2) add new data elements to the system and minimal revisions to the NVDRS coding manual; and (3) modify burden hours to account for the increase in violent deaths that have occurred in the U.S. since 2003.

Consequently, these revisions impact the number of responses per respondent, increasing it from 1,000 (as written in previous OMB requests) to 1,350, resulting in an increase in the total burden hours for retrieval of these records from 29,500 to 37,800. NVDRS has always had the goal to be a nationally representative surveillance system, operating in all 50 states, the District of Columbia, and U.S. territories. In the previous OMB package, we calculated the number of respondents to be 56, which included 50 states, the District of Columbia, and 5 U.S. territory health departments (Puerto Rico, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands (Northern Marianas, U.S. Virgin Islands). Our request is to continue with the number of respondents at 56, continuing to exclude large local health departments as an independent respondent in NVDRS. CDC requests approval for an estimated 37,800 burden hours, annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	No. responses per respondent	Average burden per response (in hours)	Total burden hours
Public Agencies	Retrieving and refile records (Att. 6)	56	1,350	30/60	37,800
Total					37,800

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23017 Filed 10–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19AWX]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled WISEWOMAN National Program Evaluation to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 30, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(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, call (404) 639–7570 or send an email to *omb@cdc.gov.* 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

WISEWOMAN National Program Evaluation—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC has supported the WISEWOMAN (Well-Integrated Screening and Evaluation for Women Across the Nation) program since 1995. The WISEWOMAN program is designed to serve low-income women ages 40–64 who have elevated risk factors for cardiovascular disease (CVD) and have no health insurance, or are underinsured for medical and preventive care services. Through the WISEWOMAN program, women have access to screening services for selected CVD risk factors such as elevated blood cholesterol, hypertension, and abnormal blood glucose levels; referrals to heathy behavior support programs; and referrals to medical care. WISEWOMAN participants must be co-enrolled in the CDC-sponsored National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

The WISEWOMAN program is administered through cooperative agreements with state, territorial, or tribal health departments. Each WISEWOMAN recipient submits to CDC an annual progress report that describes program objectives and activities, and semi-annual data reports (known as minimum data elements, or MDE) on the screening, assessment, and healthy behavior support services offered to women who participate in the program. Participant-level MDE are de-identified prior to transmission to CDC.

In 2018, CDC released the fifth funding opportunity announcement (FOA) for the WISEWOMAN program (DP18–1816), which resulted in five-year cooperative agreements with 24 state, territorial, and tribal health

departments, including six new and 18 continuing awardees from the previous NOFO. Key program elements were retained (*e.g.,* provision of screening services, promotion of healthy lifestyle behaviors, and linkage to healthy behavior support services and community based resources), but a number of changes were incorporated into the program at that time. The current FOA reflects increased emphasis on three strategies to reduce CVD risk and support hypertension control and management, including: (1) Tracking and monitoring clinical measures, (2) implementing team-based care, and (3) linking community resources and clinical services to support care coordination, self-management, and lifestyle change.

CDC seeks to conduct a one-time, multi-component evaluation to assess the effectiveness of the program on individual-, organizational-, and community-level outcomes. The in-depth assessment is designed to complement the routine progress and MDE information already being collected from WISEWOMAN program recipients. The new data collection will focus on obtaining qualitative and quantitative information at the organizational and community levels about process and procedures implemented, and barriers, facilitators, and other contextual factors that affect program implementation and participant outcomes. Data collection activities will include a Program Survey with all WISEWOMAN awardee programs, administered in the second and fourth program years, and a one-time site visit to each recipient spread across the three-year data collection effort. During site visits, semi-structured interviews will be conducted with WISEWOMAN staff members and staff at partner organizations, such as clinical providers and community-based resource providers, who are positioned to provide a variety of perspectives on program implementation.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The estimated annual burden is 84 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
WISEWOMAN Recipient Administrators	Program survey	18	1	1
	Site Visit Discussion Guide	8	1	90/60
	Innovation Site Visit Discussion Guide	2	1	45/60
Recipient partners	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60
Healthy behavior support staff	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60
Clinical providers	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4466]

Determination That PROAMATINE (Midodrine Hydrochloride) Tablets, 2.5 Milligrams, 5 Milligrams, and 10 Milligrams, Were 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 or Agency) has determined that PROAMATINE (midodrine hydrochloride) tablets, 2.5 milligrams (mg), 5 mg, and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows FDA to approve abbreviated new drug applications (ANDAs) for midodrine hydrochloride tablets, 2.5 mg, 5 mg, and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.

PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, is the subject of NDA 019815, held by Shire Development LLC (Shire), and initially approved on September 6, 1996, under the accelerated approval process (see 21