for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cardiovascular disease (CVD), which includes heart disease, myocardial infarction, and stroke, is the leading cause of death for women in the United States, and is largely preventable. The WISEWOMAN program (Well-Integrated Screening and Evaluation for Women Across the Nation), administered by the Centers for Disease Control and Prevention (CDC), was established to examine ways to improve the delivery of services for women who have limited access to health care and elevated risk factors for CVD. The program focuses on reducing CVD risk factors and provides screening services for select risk factors such as elevated blood cholesterol, hypertension and abnormal blood glucose levels. The program also provides lifestyle interventions and medical referrals. On an annual basis, 15 grantees funded through the WISEWOMAN program have provided services to approximately 30,000 women who are already participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), also administered by CDC. CDC plans to increase the reach of the WISEWOMAN program by increasing the number of grantees from 15 to 21.

CDC currently collects information from WISEWOMAN grantees to support continuous program monitoring and improvement activities. CDC seeks to extend OMB approval for three additional years. The total estimated annualized burden will increase due to the increase in the number of funded grantees. However, the burden to each respondent will decrease due to a reduction in the frequency of data collection for items that were previously collected on a quarterly basis. During the next OMB approval period, all information will be collected twice per year.

Information reported to CDC includes baseline and follow-up data (12 months post enrollment) for all women served through the WISEWOMAN program. These data, called the minimum data elements (MDE), include data elements that describe risk factors for the women served in each program and data elements that describe the number and type of intervention sessions attended. Funded grantees compile the data from their existing databases and report the MDE to CDC in April and October of each year. The MDE data provide an assessment of how effective the WISEWOMAN program is at reducing the burden of cardiovascular disease risk factors among women who utilize program services. The information collected from grantees is also used to assess the cost-effectiveness and impact of the program. The overall program evaluation is designed to demonstrate how WISEWOMAN can obtain more complete health data on vulnerable populations, promote public education about disease incidence and risk-factors, improve the availability of screening and diagnostic services for under-served women, ensure the quality of services provided to under-served women, and develop strategies for improved interventions. The information reported to CDC also includes programmatic information related to grantee management, public education and outreach, professional education, service delivery, cost, and progress toward meeting stated programmatic objectives.

All MDE information will be submitted to CDC electronically. Progress reports will be submitted in hardcopy format. Because certain demographic information has already been collected as part of NBCCEDP, the additional burden on grantees will be modest. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
WISEWOMAN Grantees	WISEWOMAN MDEs	21	2	40	1,680
	Progress Report	21	2	16	672
Total					2,352

Dated: October 5, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–24522 Filed 10–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0484]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on guidance on reagents for detection of specific novel influenza A viruses.

DATES: Submit written or electronic comments on the collection of information by December 14, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget

(OMB) for each collection of information they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Reagents For Detection of Specific Novel Influenza A Viruses–21 CFR 866.3332–(OMB Control Number 0910–0584)–Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with 21 U.S.C. 360c(a)(1)(B), because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance.

The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary deems necessary'' (21 U.S.C. 360c(a)(1)(B)). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification will be codified in 21 CFR 866.3332, a regulation that will describe the new classification for reagents for detection of specific novel influenza A viruses and set forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation will refer to the special controls guidance document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents.

The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
513	10	2	20	10	200	$5,000

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 10 hours. This results in a total data collection burden of 200 hours (10 x 20= 200). FDA estimates that cost of developing standard operating procedures for each data collection is $500 (10 hours of work at $50/hour). This results in a total cost to industry of $5,000 ($500 x 10 respondents).

The guidance also refers to previously approved information collections found in FDA regulations. The information collections in 21 CFR part 820 have been approved under OMB control number 0910–0073.

Dated: October 5, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–0469]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and