

System (OMB #0920-0612, exp. 1/31/2010)—Revision—National Center 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 of improving 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. The WISEWOMAN program serves women who are participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), also administered by CDC.

CDC requests OMB approval to continue collecting information from WISEWOMAN grantees for three years, with changes. There will be a net decrease in the total annualized burden hours. Although the number of funded grantees will increase from 15 to 21, the burden per respondent will decrease due to changes in the data collection plan and schedule. The collection of cost information will be discontinued and the Progress Report will be collected semi-annually instead of quarterly.

Twice per year, each grantee will electronically transmit a Minimum Data Elements (MDE) dataset that contains information about the women served through the WISEWOMAN program, including their demographics, health status, CVD risk factors, referrals and participation in lifestyle interventions.

In addition, each grantee will submit two written progress reports per year. The progress reports provide a narrative summary of grantee activities, as well as a discussion of each grantee's progress toward meeting stated programmatic objectives. The information collected from grantees is used to assess the impact of the WISEWOMAN 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.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,680.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--------------------------|-------------------------------------|-----------------------|------------------------------------|--|
| WISEWOMAN Grantees | Screening and Assessment MDEs | 21 | 2 | 16 |
| | Intervention MDEs | 21 | 2 | 8 |
| | Progress Report | 21 | 2 | 16 |

Dated: January 15, 2010.
Maryam I. Daneshvar,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0246]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.
DATES: Fax written comments on the collection of information by February 22, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0509. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile (OMB Control Number 0910-0509)—Extension

As a direct result of discussions that have been adjunct to the U.S./Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, in the **Federal Register** of June 22, 2005 (70 FR 36190), FDA announced the availability of a revised guidance document entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile." The guidance can be found at <http://www.cfsan.fda.gov/guidance.html>. The guidance document explains that FDA has established a list that is provided to the government of Chile and posted on <http://>

www.cfsan.fda.gov/~comm/expcllst.html, which identifies U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what

criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Web site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under the guidance, FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: (1) Name and address of the firm and the manufacturing plant; (2) name, telephone number, and e-mail address

(if available) of the contact person; (3) a list of products presently shipped and expected to be shipped in the next 3 years; (4) identities of agencies that inspect the plant and the date of last inspection; (5) plant number and copy of last inspection notice; and (6) if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

In the **Federal Register** of June 4, 2009 (74 FR 26867), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response, each containing one or more comments. The comments were outside the scope of the comment request in the notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|--------------------|-------------------------------|------------------------|--------------------|-------------|
| New written requests to be placed on the list | 15 | 1 | 15 | 1.5 | 23 |
| Biannual update | 88 | 1 | 88 | 1.0 | 88 |
| Occasional updates | 25 | 1 | 25 | 0.5 | 13 |
| Total | | | | | 124 |

¹ There are no capital or operating and maintenance costs associated with this collection of information.

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates and occasional updates is based on the FDA's experience maintaining the list over the past 4 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

To date, over 175 producers have sought to be included on the list. FDA estimates that, each year, approximately 15 new firms will apply to be added to the list. We estimate that a firm will require 1.5 hours to read the guidance, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list for a total of 22.5 hours, rounded to 23. Under the guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 88 firms (175 x 0.5 = 87.5, rounded to 88), will resubmit the information to

remain on the list. We estimate that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 88 hours. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 12.5 hours, rounded to 13.

Dated: January 15, 2010.

David Dorsey

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: