

Dated: May 3, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Quarterly Performance Report, ORR-6.

OMB No.: 0970-0036.

Description: Data gathered from the Quarterly Performance Report (Form ORR-6) are used by ORR to estimate the

number of months of Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) that ORR can provide based on appropriations; to determine priorities; and standards, budget requests, and assistance policies; to analyze data on service caseloads and program outcomes in order to monitor performance; and to compute refugee medical assistance (RMA) utilization rates.

Respondents: State, Local or Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Program Estimates (CMA)	48	4	3.875	744

Estimated Total Annual Burden Hours: 744.

Additional Information: Copies of the proposed collection may be writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Lori Schack.

Dated: May 3, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0123]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 7, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93 (OMB Control Number 0910-0331—Extension)

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement

provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other for-profit organizations.

In the **Federal Register** of February 4, 1999 (64 FR 5664), the agency requested comments on the proposed collections of information. No comments were received.

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