

by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201. Written comments should be received within 30 days of this notice.

Dated: March 24, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Site Visit Protocols for the Multi-Site Evaluation of the Welfare-to-Work Grant Program—0990-0230—Revision—This data collection will provide site specific information for a sample of Welfare-to-Work (WtW) grant programs which will support the Office of the Assistant Secretary for Planning and Evaluation in its efforts to further document the status of the grants program and provide information on implementation issues as part of the Congressionally mandated evaluation of the WtW grants program. Respondents: Individuals, State, Local or Tribal Governments, Non-profit Institutions—Burden Information for Staff Interviews—Number of Responses: 360; Burden per Response: 1 hour; Total Burden for Staff Interviews: 360 hours—Burden Information for Focus Groups—Number of Responses: 350; Burden per Response: 1.5 hours; Total Burden for Focus Groups: 540 hours—Burden Information for Individual Tribal

Program Participants—Number of Responses: 50; Burden per Response: .5 hours; Total Burden for Tribal Participants: 30 hours—Total Burden—930 hours.

2. Follow-up Survey for the Multi-Site Evaluation of the Welfare-to-Work Grant Program—New—This information collection will support the Office of the Assistant Secretary for Planning and Evaluation in its efforts to evaluate the WtW grant program by obtaining detailed information on program participants circumstances and experiences with the program. Respondents: Individuals; Number of Respondents: 7225; Number of Responses: 12,750; Burden per Response: 46 minutes; Total Burden: 9819 hours; OMB Desk Officer: Allison Eyd.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

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Dated: March 24, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0304]

Dietary Supplements Containing Ephedrine Alkaloids; Administrative Docket Update; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of certain documents to update the administrative docket of the proposed rule on dietary supplements containing ephedrine alkaloids. This action is being taken to ensure that interested persons are aware of the

updated information. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing certain provisions of the proposed rule on dietary supplements containing ephedrine alkaloids, and establishing a new docket that will contain new adverse event reports and related information concerning these products.

FOR FURTHER INFORMATION CONTACT:

Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS-7), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301-827-6733.

SUPPLEMENTARY INFORMATION:

I. Background (Proposed Rule)

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule on dietary supplements containing ephedrine alkaloids (the "ephedrine alkaloids proposal"). That proposal would have established a finding that a dietary supplement is adulterated if it contains 8 milligrams or more of ephedrine alkaloids per single serving, required that the labels of products that contain ephedrine alkaloids state, "Don't use this product for more than 7 days," required certain warning statements, and affected other aspects of product labeling for such products. FDA proposed this action after receiving over 800 adverse events associated with the use of dietary supplements that contained, or were suspected to contain, ephedrine alkaloids, and reviewing scientific literature and other data concerning ephedrine alkaloids. FDA received approximately 14,775 comments in response to the ephedrine alkaloids proposal.

II. Updated Information

FDA is updating the docket for the ephedrine alkaloids proposal with additional information, most of which was received after publication of the proposal.

FDA received 270 additional adverse event reports between February and September 1997. FDA added these adverse event reports to the ephedrine alkaloids proposal's docket in two submissions without formal clinical analysis. FDA did not rely on these 270 reports in the ephedrine alkaloids proposal because FDA received them after it began its analysis for the proposal.

FDA has received additional documentation (e.g., copies of product labels and labeling, information on how the consumers used the products at issue and available medical or other clinical records) concerning