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.

[FR Doc. 00–8049 Filed 3–31–00; 8:45 am]

BILLING CODE 4150–04–M

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 Eydt.

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.

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.

[FR Doc. 00–8050 Filed 3–31–00; 8:45 am]

BILLING CODE 4150–04–M

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

approximately 17 of the 270 adverse event reports the agency put in the docket after publication of the ephedrine alkaloids proposal. Consequently, FDA has reorganized these 17 reports to include the additional documentation that the agency has received, and it has redacted the files. FDA is now placing the 17 reorganized and redacted adverse event charts in the ephedrine alkaloids proposal's docket.

Should FDA receive additional information on the adverse events that are part of the administrative docket for the ephedrine alkaloids proposal, the agency will include it in that docket.

This updated information may be seen by interested persons at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–8112 Filed 3–31–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1200]

Dietary Supplements Containing Ephedrine Alkaloids; Availability

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of certain new adverse event reports (AER's) and related information, the vast majority of which were received after publication of the proposed rulemaking on dietary supplements containing ephedrine alkaloids. The agency is also announcing its intention to participate in a public forum to address this new information. This document is being issued to ensure that interested persons are aware of the new information the agency has available on these products and its plans to seek public input on this new 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 making available certain documents to update the administrative docket of that proposal.

DATES: Submit written comments by May 18, 2000.

ADDRESSES: Submit written comments on the information in this docket to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–6733. A contact person for the public forum will be announced in the near future.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule on dietary supplements containing ephedrine alkaloids (hereinafter referred to as ''the ephedrine alkaloids proposal''). FDA proposed to establish a finding that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids (''dosing level'' or ''dietary ingredient level''), and to require the label of such supplement state that the product is not to be used for more than 7 days (''duration of use limit''). In addition, FDA proposed to require certain warning statements, and to affect other aspects of 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.

The House Committee on Science requested that the Government Accounting Office (GAO) examine the scientific bases for the ephedrine alkaloids proposal, and the agency's adherence to the regulatory analysis requirements for Federal rulemaking. On August 4, 1999, GAO publicly released its report entitled ''Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids.'' A copy of this report is available in Docket No. 95N–0304.

Generally, the GAO concluded that FDA was justified in determining that the number of AER's relating to dietary supplements containing ephedrine alkaloids warranted the agency's attention and consideration of steps to address safety issues. In addition, the GAO concluded that the available scientific information suggests that the use of products containing synthetic ephedrine alkaloids can result in adverse experiences for some individuals. However, GAO expressed concerns about the use of the adverse events in supporting the proposed dosing level and duration of use limit, and concluded that the agency needed additional evidence to support these restrictions.

GAO also concluded that FDA's economic analysis contained the basic elements expected in a Federal agency's cost-benefit analysis and that the ephedrine alkaloids proposal complied with regulatory flexibility analysis requirements under the Regulatory Flexibility Act. GAO noted, however, that FDA's cost-benefit analysis was not always transparent regarding why certain key assumptions were made, the degree of uncertainty involved in those assumptions, or the effect that alternative assumptions would have had on the agency's estimates of the costs and benefits of the proposed action.

GAO recommended that FDA ''provide stronger evidence on the relationship between the intake of dietary supplements containing ephedrine alkaloids and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits.'' In addition, GAO recommended that FDA improve the transparency of its cost-benefit analysis in its final rulemaking.

Before the GAO report was released, FDA had already begun accumulating and evaluating data on additional adverse events reported to the agency since the publication of the ephedrine alkaloids proposal as well as initiating a process to obtain outside scientific input and review. Since publication of the ephedrine alkaloids proposal and following release of the GAO report, FDA has continued to receive reports of adverse events, conducted its own independent evaluations and analyses, and continued to seek input from outside experts on these issues. FDA is now making available new information, the vast majority of which it has received since publication of the ephedrine alkaloids proposal.

II. New Information—Docket No. 00N–1200

To gain a better perspective on the significance of the public health concern and public health problems associated with the current use of dietary supplements containing ephedrine alkaloids, CFSAN applied its available resources towards conducting