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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 111

[Docket No. 95N-0304]

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DUPLICATE

62 FR 468968

9-18-97

Dietary Supplements Containing Ephedrine Alkaloids; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening from (*insert date of publication in the Federal Register*), to (*insert date 75 days after date of publication in the Federal Register*), the comment period on the proposed rule on dietary supplements containing ephedrine alkaloids that was published in the **Federal Register** of June 4, 1997 (62 FR 30678). This action is being taken to provide a renewed opportunity for public comment after the agency has rectified a number of inadvertent omissions from the administrative record. FDA is also providing an opportunity for comment on adverse event reports (AER's) that FDA has received since January 1997 and on new analytical data that FDA is adding to the administrative record. Finally, FDA is reopening the comment period in response to several requests for extensions of the comment period to permit interested persons to submit new scientific data.

DATES: Written comments by (*insert date 75 days after date of publication in the Federal Register*). 12/2/97

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Margaret C. Binzer, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-401-9859, FAX 202-260-8957 or E-mail "MBinzer@Bangate.fda.gov".

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1997, FDA published a proposed rule regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. FDA proposed this rule in response to serious illnesses and injuries, including multiple deaths, associated with the use of dietary supplement products that contain ephedrine alkaloids and in response to the agency's investigations and analyses of these illnesses and injuries. Interested persons were given until August 18, 1997, to comment on the proposal.

In the **Federal Register** of August 20, 1997 (62 FR 44247), FDA announced that it would reopen the comment period for the proposed rule because the agency had identified a number of inadvertent omissions (i.e., missing pages in several of the AER's and other minor problems) in the administrative record. FDA has reviewed each of the AER's to rectify these omissions, which included: Missing product labels or labeling, affidavits from consumers or health care professionals, investigator followup reports, and individual pages from medical records. FDA has recopied each of the AER files and placed them on display at the Dockets Management Branch. Any followup materials that the agency received after the AER's were made part of the administrative record for this rulemaking in June 1997 are now included in the corresponding AER. For convenience to the users of the administrative record, the agency has also organized the duplicate AER files to make it easier to locate them in the record.

As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplements that contained, or were suspected of containing, ephedrine alkaloids. Since that time, FDA has continued to receive additional AER's associated with the use of these products. FDA is adding the AER's that it received between January and August 1997 to supplement the administrative record. These documents are filed in the administrative record under the title: "AER's Associated with the Use of Dietary Supplements

Containing Ephedrine Alkaloids that FDA has Received Since the Preparation of the Docket Submission of January 17, 1997.’’

Since the time that the proposal was published, FDA has received the results of chemical analyses for several of the dietary supplement products associated with AER’s. When an adverse event appears to be clinically significant, FDA routinely requests from the consumer a sample of the remaining portion of the product related to the AER and has its laboratories analyze the sample. These analytical results provide supplementary data on levels of ephedrine alkaloids in the dietary supplements. FDA is adding these analytical results to the administrative record. A summary of these analytical results are filed in the administrative record under the title: ‘‘Analytical Results of Ephedrine Alkaloid-Containing Dietary Supplements Associated With Adverse Events, August 1997.’’ These documents will be placed on display in the Dockets Management Branch along with the rest of the administrative record that FDA has compiled to date.

In addition, FDA has received several requests for extensions of the comment period. These requests stated as grounds for an extension, among other things, that there is a need for additional time to review the clinical data and other information in the administrative record and to submit new scientific data to the agency. Several requests were for extensions of 180 days.

Having carefully considered these requests and given the fact that it has added material to the administrative record, the agency has decided to reopen the comment period until (*insert date 75 days after date of publication in the **Federal Register***). The reopening of the comment period will provide interested persons with a significant amount of additional time to evaluate all the information in the administrative record that underlies the proposal that FDA published in June 1997 and to formulate any comments that they deem appropriate. The agency particularly encourages small businesses to take advantage of this additional opportunity to participate in the regulatory process.

Because of the serious and significant adverse events associated with the use of dietary supplements containing ephedrine alkaloids, FDA is concerned about the adverse impact that a

prolonged comment period may have on the public health. For this reason, the agency decided not to grant the requests for an additional comment period longer than 75 days. The agency's decision to reopen the comment period for 75 days balances the needs of interested persons to review the data in the corrected administrative record and to submit comments to the agency with the important public health interests involved.

Moreover, the agency does not intend to provide any additional extensions of the comment period. Interested persons will have 75 days to consider these materials and comment to the agency, if desired. Interested persons already have had 75 days to review the concepts in the proposed rule and the data in the administrative record, which represent the great bulk of the material in the updated and corrected administrative record. Much of the material in the administrative record has been on display at the Dockets Management Branch since long before the proposed rule was published on June 4, 1997. A notice appeared in the **Federal Register** of September 21, 1995 (60 FR 49194), announcing: The availability of AER's associated with the use of dietary supplements containing ephedrine alkaloids; redacted copies of accompanying medical records, where available; and a bibliography of published medical and scientific literature relevant to the AER's. Much of the clinical data and other information has been in the administrative record either since October 1995, the date of the meeting of the Special Working Group on Dietary Supplements Containing Ephedrine Alkaloids (Working Group) or since August 1996, the date of the meeting of the Food Advisory Committee and Special Working Group. Other than the new information announced in this document, the agency has not added new data to the administrative record since January 1997. Nevertheless, for the reasons mentioned earlier in this notice, the agency is providing a new, full 75-day comment period that is equal to the comment period that FDA provided when it published the initial proposal. Thus, FDA is providing a total of 150 days for comment in this proceeding.

Interested persons may on or before (*insert date 75 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments

regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 12, 1997
September 12, 1997

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

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