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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N-0304]

RIN 0901-AA59

62FR 44247  
8/20/97

Dietary Supplements Containing Ephedrine Alkaloids; Notification of Intent to Reopen Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will reopen the comment period for the proposed rule on dietary supplements containing ephedrine alkaloids that appeared in the FEDERAL REGISTER of June 4, 1997 (62 FR 30678). The agency intends to take this action because FDA has identified a number of inadvertent omissions in the administrative record. After the agency rectifies these omissions, it will announce in the FEDERAL REGISTER the reopening of the comment period for 75 days.

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 M.Binzer @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 reports of serious

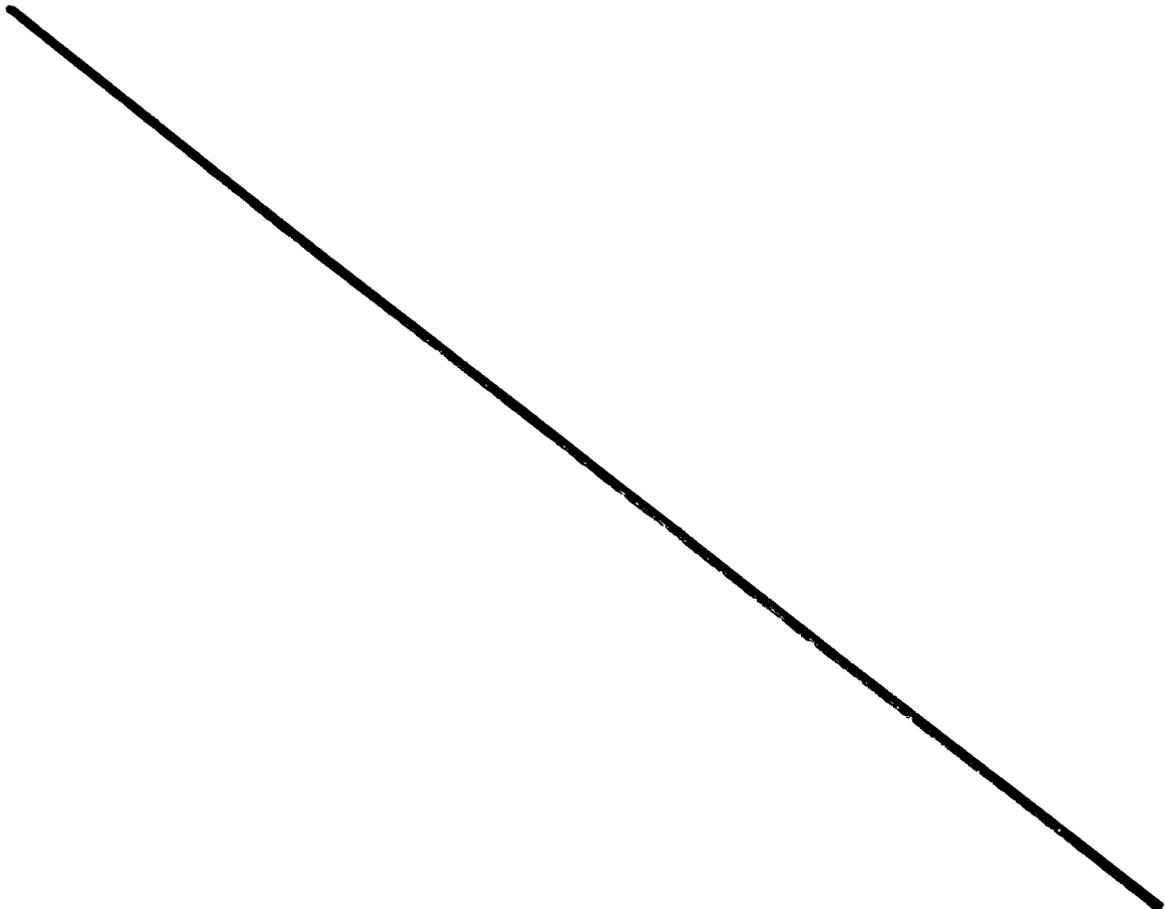
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illnesses and injuries, including multiple deaths, associated with the use of dietary supplement products that contain ephedrine alkaloids and the agency's investigations and analyses of these reports of illnesses and injuries. Interested persons were given until August 18, 1997, to comment on the proposal.

It has come to FDA's attention that there are omissions in the administrative record. The agency has identified a number of missing pages in some documents that were placed in the administrative record and other minor problems. FDA will rectify these omissions and problems and make the corrected administrative record available with ample time for interested



persons to review the record and prepare comments. Thus, the agency will correct the administrative record and will provide a new 75-day period for comment.

Dated: August 15, 1997  
August 15, 1997



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William K. Hubbard  
Associate Commissioner for Policy Coordination

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