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Application Date	5/19/00
Publication Date	5/22/00
Certifier	J. W. W. W.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1200]

Dietary Supplements Containing Ephedrine Alkaloids; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 3, 2000, the comment period for a notice published in the **Federal Register** of April 3, 2000, that announced the availability of new adverse event reports (AER's) and related information concerning dietary supplements containing ephedrine alkaloids. This action is being taken in response to requests for more time to submit comments to FDA.

DATES: Submit written comments on the notice of availability by July 3, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to "FDADockets@oc.fda.gov". 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 (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6733.

SUPPLEMENTARY INFORMATION:

I. Extension of Comment Period

In the **Federal Register** of April 3, 2000 (64 FR 17510), FDA published a notice announcing a new public docket that makes available new adverse event reports and related information

concerning dietary supplements containing ephedrine alkaloids. The **Federal Register** notice also announced FDA's intent to participate in a public forum to address safety information on such products.

Since publication of the April 3, 2000, **Federal Register** notice, FDA has received requests, both oral and written, to allow additional time for interested persons to comment. FDA believes that an extension of the comment period for an additional 45 days, until July 3, 2000, would be appropriate, in light of the amount of data FDA made publicly available on April 3, 2000. This extension will provide the public with a total of 90 days to submit data, analyses, and other relevant information.

Although the agency has reviewed the requests asking for extensions of the comment period, the longest of which is for an additional 1 year, FDA does not believe that such a lengthy delay is in the best interest of the public health. FDA believes that delaying the receipt of comments for more than an additional 45 days (for a total of 90 days) is too long given the public health concerns at issue.

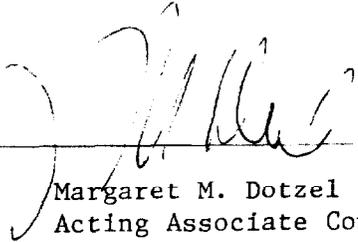
II. How to Submit Comments

Interested persons may, on or before July 3, 2000, submit written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to "FDADockets@oc.fda.gov". You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document,

except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/16/00

May 16, 2000


Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

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