



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

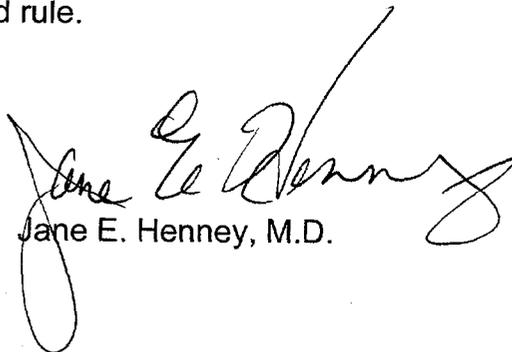
February 25, 2001 '00 FEB 25 PIZ:39

•MEMORANDUM TO: Docket Number 95N-0304

FROM: Commissioner of Food and Drugs

SUBJECT: FDA's Planned Course of Action on Portions of Proposed Rule

The Food and Drug Administration (FDA) is aware of the continued Congressional and public interest regarding the Agency's plans to regulate dietary supplements containing ephedrine alkaloids. FDA would like to provide members of Congress and the general public with an overview of the Agency's next steps concerning these products, including a decision the Agency has made with respect to the proposed rule issued on June 4, 1997 (62 FR 30678). Therefore, in accordance with §10.80(21 CFR §10.80), I am giving Melinda K. Plaisier, FDA's Associate Commissioner for Legislation, permission to send members of Congress a letter that describes FDA's decision to withdraw portions of that proposal, as part of the Agency's upcoming strategy for these products. A copy of this letter is attached to this memorandum so that it will be available to the public in the docket of that proposed rule.


Jane E. Henney, M.D.

Attachment

95N-0304

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FEB 25 2000

Dear Member:

Knowing of your continued interest regarding the Food and Drug Administration's (FDA or Agency) plans to regulate dietary supplements containing ephedrine alkaloids, we would like to provide you with an overview of the Agency's next steps concerning these products.

On February 11, 2000, FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued its Fiscal Year 2000 Program Priorities document. (A copy was provided to you on February 17, 2000.) In addition, a copy can be obtained on CFSAN's website at www.cfsan.fda.gov. This document sets forth CFSAN's 2000 workplan through September 30, 2000. In this workplan, CFSAN lists "Ephedra" as one of its "A" list (high priority) goals for dietary supplements. Specifically, CFSAN's stated goals for Ephedra include the following: "Develop a strategy following review, evaluation, and public availability of new safety information available since publication of the 1997 proposed rule."

To achieve this goal, FDA plans to issue a Federal Register notice announcing the availability of new information, e.g. adverse event reports (AER's), received after publication of the proposed rule on dietary supplements containing ephedrine alkaloids. These AER's will be made available in redacted form suitable for public disclosure under the Freedom of Information Act. FDA will also make available its analysis of these reports and related information. In addition, the Agency plans to announce its intention to hold a public forum to seek public input on this new information. FDA expects any future actions by the Agency to be based, in substantial part, on this new information.

FDA also plans to issue a Federal Register document withdrawing certain portions of the proposed rule, as described below. As you know, on August 4, 1999, the General Accounting Office (GAO) released a study titled "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids." In that study, 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. However, GAO expressed concerns about the use of the AER's in supporting the proposed dosing levels and duration of use limits, and concluded that the Agency needed additional evidence to support these restrictions. In light of GAO's conclusions, comments from others on the proposed rule, and having further considered the issues, FDA plans to withdraw these provisions from the proposed rule.

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It is the Agency's intention to make the new AER's and related information publicly available no later than March 31, 2000. FDA remains concerned about the potential health risks associated with these products. The Agency intends to use this new information and a public process to address this public health issue in an appropriate manner that best serves the consumer and public health.

Thank you for your continued interest. Please be assured we will apprise you as soon as the information is available.

Sincerely,

A handwritten signature in black ink, appearing to read "Melinda K. Plaisier". The signature is fluid and cursive, with a long horizontal stroke at the end.

Melinda K. Plaisier
Associate Commissioner
for Legislation