



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 5 2000

The Honorable Dan Burton
Chairman
Committee on Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Burton:

Thank you for your continued interest in the regulation of dietary supplements. This letter is in response to your letter of April 27, 2000 to Dr. Jane E. Henney, Commissioner, Food and Drug Administration (FDA or the Agency) regarding the Agency's recent Federal Register notices concerning dietary supplements containing ephedrine alkaloids. You raise several issues regarding the handling of Freedom of Information Act (FOIA) requests, data collection and dissemination, and the timing of a public meeting later this year.

We are pleased to inform you that the backlog of FOIA requests for these products has been nearly eliminated, with less than 10 FOIA requests remaining. We expect to fully eliminate this backlog soon. The Agency is making every effort to address such problems with the limited resources it has available, given the many competing priority projects.

With respect to your request to extend the comment period through December 31, 2000, and then hold a public meeting a month after the closing date, we believe this timeframe is too long given the potential public health issues in question. However, we have decided to extend the comment period by an additional 45 days - until July 3, 2000 - and will have another 30 day comment period following the public meeting. The public meeting itself is being scheduled for later in July. An announcement of the specific time and place of this public meeting will be issued to the dietary supplement community very shortly. A future Federal Register notice will provide more details about the public meeting, including the specific scientific questions to be addressed. As noted, interested persons will be provided an additional opportunity to submit to FDA's public docket (Docket No. 00N- 1200) data and analyses of data about the risks associated with the use of dietary supplements containing ephedrine alkaloids.

The Agency is using the public meeting as part of an open exercise in its process of risk assessment regarding the safety of these products. Possible regulatory actions are not the topics for this meeting. These deliberations will occur after we have satisfied ourselves that the available scientific information has been fully discussed. We believe we will have provided interested parties ample opportunity to participate in the process, but also believe the issues surrounding these products should be dealt with in as prompt a timeframe as possible to best serve the American consumer.

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Thanks again for your interest in this issue. If you have further questions about this, or any other matter, please let us know.

Sincerely,



Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform

Docket No. 00N-1200.