



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY 25 2000

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The Honorable Max Sandlin  
House of Representatives  
Washington, D.C. 20515-4301

Dear Mr. Sandlin:

Thank you for your continued interest in dietary supplements containing ephedrine alkaloids. This is in response to your letter of April 7, 2000, regarding the Food and Drug Administration's (FDA or the Agency) planned actions with respect to ephedra. In particular you urge the Agency to make public in advance its criteria for evaluation methods for reviewing ephedra products.

Regarding release of the Adverse Event Reports (AERS), we believe that it is important and appropriate to provide interested parties with our expert review and evaluation of the data we have available at the same time we make the information publicly available. This provides interested persons with an opportunity to consider the views our in-house and consultant experts have on the information available to us. The fact that there are opinions on the currently available information does not mean that FDA has predetermined any course of action until after we receive input on the public docket in response to our recent Federal Register notices and subsequent to a public meeting on this subject planned for later this year.

When FDA released the AERS on March 31, 2000, the criteria used by FDA to analyze the documents was also made public. The Federal Register notice does not explain the criteria FDA used to categorize the AERS. This information is included in Part II, section E, Appendices of the documents that went to the public docket 00N-1200. We are enclosing a copy of this Appendix that includes the criteria FDA used to evaluate the new case series of adverse event reports. We encourage you to comment on these criteria and submit your comments to public docket 00N-1200. We are sending a copy of your letter to the

00N-1200

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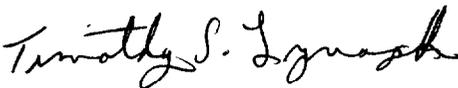
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docket and your comments will be considered in the Agency's decision making on this matter.

For your information we are also enclosing our "Dear Member" letter of February 25, 2000, which outlines the Agency's plans for addressing dietary supplements containing ephedrine alkaloids.

Thanks again for contacting us about this matter. Our single goal in this process is to make the best decisions possible for the well being of the American public. If you have any questions, please let us know.

Sincerely,

  
for Melinda K. Plaisier  
Associate Commissioner  
for Legislation

Enclosures

cc: Dockets Management Branch  
(Docket No. 00N-1200)

**MAX SANDLIN**  
1ST DISTRICT, TEXAS

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AND INFRASTRUCTURE**  
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April 7, 2000

Ms. Melinda K. Plaisier  
Associate Commissioner for Legislative Affairs  
Food and Drug Administration  
U.S. Department of Health and Human Services  
Parklawn Building  
5600 Fishers Lane, Room 15-55  
Rockville, MD 20857

Dear Ms. Plaisier:

I am writing regarding the Food and Drug Administration's (FDA) handling of dietary supplements containing ephedra.

I would like to express my support for the March 31, 2000 release of all new adverse effect reports (AER's) to the public, although I would have preferred that they be unaccompanied by analysis. While I appreciate the need for FDA to go back to the ephedra issue, it is essential the Agency assess the evaluation method that should be used to develop a policy position. I urge the Agency to propose and make public in advance criteria for evaluation methods that will define the process that is appropriate for reviewing ephedra products in light of the new AER's.

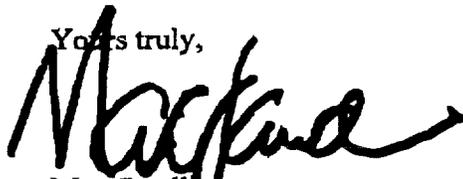
The March 31<sup>st</sup> release also announced FDA's intention to hold a public forum to seek public input on the new information. As I understand it, this forum will be held late this summer. Therefore, the FDA should have ample time to develop and establish an evaluation method before any final decisions are made.

No. 00-2454

I thank you for your consideration of my opinion on this issue. Should you have any further questions regarding my opinion on dietary supplements containing ephedrine alkaloids, please do not hesitate to contact me. I may be reached at (202)225-3035.

With kindest regards, I am

Yours truly,



Max Sandlin  
Member of Congress

MS/rc