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Congress of the United States
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AND OVERSIGHT
TEXAS REGIONAL WHIP

June 14, 2000

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

I understand that the FDA has its set of procedures for conducting its studies, but I am concerned that the FDA is not conducting an "open exercise in its process of risk assessment regarding the safety of [ephedra] products," as your staff member, Melinda Plaiser states in her letter to me dated May 10, 2000

The FDA deferred the release of the Adverse Event Reports (AERs) requested under FOIA for two years and took nine months to respond to the criticisms of the 1999 GAO report on this matter, yet I understand the agency has given the other interested parties only 90 days to respond to your findings. This suggests the FDA may not have the benefit of all the available scientific information and should reconsider the announced time line.

I believe each interested party must be given an appropriate amount of time to analyze the data. For this reason, I believe you should grant additional time to the comment period.

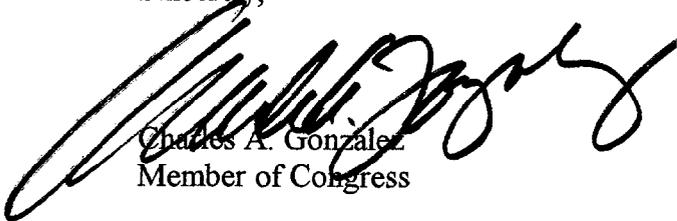
Your agency has stated in correspondence with me and other members of Congress that it has no predetermined conclusions regarding the dietary supplement industry. But, in some of those same letters, the FDA states that it "believes this time frame to be too long given the potential public health issues in question." Some people may imply that the agency has already determined, without obtaining all the relevant information, that dietary supplements containing ephedrine alkaloids are a threat to public health. I trust this is not the case. If the FDA is being responsive to the GAO's criticisms and is developing a policy only after you receive all of the relevant and available information, extending the comment period should not be a problem.

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Greg Daw
Health & A

Finally, I understand the FDA's recent announcement of a 45-day extension to the comment period, published in the Federal Register on May 22, 2000, came after the initial comment period had expired. Moreover, I know that the original 45-day deadline had already forced many companies to file initial comments where more time for responsible analysis was needed. This action appears to limit the information that will be available to the public and to me as a lawmaker. In light of this, I urge you to extend the comment period.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles A. Gonzalez", written in a cursive style.

Charles A. Gonzalez
Member of Congress

CAG:/ss