

FAX

# United States Senate

WASHINGTON, DC 20510

May 4, 2000

Jane Henney, M.D.  
Commissioner of Food and Drugs  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Commissioner Henney:

We are writing to request that the public be provided no less than 180 days to comment on the information regarding dietary supplements containing ephedrine alkaloids published by the Food and Drug Administration in the Federal Register April 4, 2000.

As you know, the amount and complexity of the information published are substantial. The information published in the Federal Register establishes a new docket relevant to ephedra products which we understand contains 15,000 to 20,000 pages of material, about 10 linear feet of documents. The docket contains some 270 adverse event reports (AERs) as well as the results of two internal FDA reviews, seven external expert reviews, and their associated supporting material relevant to 140 of the AERs. It took FDA well over a year to complete this analysis, and the 130 most recent AERs have yet to be carefully analyzed.

As you know, the General Accounting Office was highly critical of the process and scientific soundness of the data and analysis used by FDA in preparing its proposed dosage limits on ephedra products. We commend you for taking these criticisms seriously and for beginning a new process for coming to a decision regarding these products. However, in order to address the GAO's criticisms, particularly those related to analysis and openness, and to ensure the best public health outcome, we believe it is essential that the public be given adequate time to review and carefully analyze the record. We also believe that public forums should be held after the 180 day comment period so there can be a full discussion of all relevant issues. We are concerned about the reports alleging adverse reactions related to ephedra consumption and believe that the process we have outlined will increase the ability of the agency to analyze the data and adopt the most appropriate regulatory response.

Thank you for your attention to our request. We look forward to your reply.

Sincerely,



Orrin G. Hatch  
U.S. Senator



Tom Harkin  
U.S. Senator

00N-1200

No. 00-3102

EXT 4