



# The American Society for Clinical Nutrition, Inc.

THE CLINICAL DIVISION OF THE AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES

## *The American Journal of Clinical Nutrition*

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April 2, 2003

The Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 95N-0304

Dear Commissioner McClellan:

The American Society for Clinical Nutrition (ASCN), with 1300 members, consisting primarily of MD's and/or PhD's engaged in clinical nutrition research and education, thanks you for the opportunity to comment on the 1997 proposed rule dealing with dietary supplements containing ephedra. Our journal, *The American Journal of Clinical Nutrition*, remains the top peer-reviewed nutrition research and dietetics journal.

Although clinical trials indicate that ephedra-containing dietary supplements result in weight loss that is approximately two pounds per month greater than that with placebo in short-term studies for up to six months, there are no long-term studies assessing the effects of these supplements on weight loss. However, there are controlled clinical trials indicating that the use of ephedra-containing dietary supplements is associated with the risk of nausea, vomiting, palpitations, hyperactivity, anxiety and changes in mood. In addition ephedra-containing dietary supplements have been linked to heart attacks, strokes, and death.

In light of the above scientific evidence and the recent Rand report linking ephedra-containing dietary supplements with potentially serious side effects, the ASCN believes that the weight of scientific evidence of risks of consuming these products outweigh the possible short-term benefits. These dietary supplements pose a "significant or unreasonable risk of illness or injury" and should be removed from the market until further case-controlled studies are conducted. If the decision is made to keep these supplements on the market, a black box warning label indicating that they have been linked to heart attacks, strokes and deaths should be included on all ephedra-containing dietary supplements.

The American Society for Clinical Nutrition believes that Congress should change the existing law for dietary supplements to require that the manufacturer provide evidence of safety to the FDA before marketing any products covered by DSHEA. This evidence of safety could be similar to the review for new food ingredients currently regulated by the FDA.

Thank you again for this opportunity to comment on ephedra-containing dietary supplements.

Sincerely,

Robert Russell, MD  
President

95N-0304

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