



OCT - 7 2004

Mr. David Seckman
Coalition to Preserve DSHEA
1220 19th Street, N.W.
Washington, DC 20036

Re: Docket No. 2004P-0169

Dear Mr. Seckman:

This letter responds to your citizen petition dated April 8, 2004, requesting that the Food and Drug Administration (FDA) reconsider its interpretations of section 201(ff) of the Federal Food, Drug, and Cosmetic Act with respect to the meaning of the term "dietary substance" in section 201(ff)(1)(E) of the act and status under section 201(ff)(1) of synthetic equivalents of specific constituents of botanical dietary ingredients.

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources.

Sincerely yours,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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