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AUG 20 2004

Food and Drug Administration
Rockville MD 20857

Barbara E. Kennedy-Neslusan
18 Hampshire Circle
Dover, NH 03820

Re: Docket No. 2004P-0088/CP1

Dear Ms. Kennedy-Neslusan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated February 27, 2004. Your petition requests that the Agency require that labeling for drug products declare the presence of inactive ingredients that may be food allergens.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0088

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