



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAR 7 2001

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Mr. Alan D. Kirsch  
Pharmaceutical Consulting  
16 Woodrow Wilson Drive  
Edison, New Jersey 08820

Re: Docket No. 00P-1510/CP1

Dear Mr. Kirsch:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on September 11, 2000, on behalf of CTS Chemical Industries, Ltd. Your petition requests that the Agency issue a regulation to classify echinacea extract as a GRAS ingredient for use as a technical formulation aid.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

00P-1510

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