DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 17 1999

Keith E. Sharkin, Esq.
Nims, Howes, Collison, Hansen & Lackert
605 Third Avenue
Suite 3500
New York, New York 10158

Re: Docket No. 99P-1659/CP1

Dear Mr. Sharkin:

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 May 26, 1999, on behalf of Novartis Pharmaceutical Corporation asking FDA to withdraw approval of Urso unless the name of the product is changed.

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

Sincerely yours,

Janet Woodcock, M.D.
Director,
Center for Drug Evaluation and Research

99P-1659

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