DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 2 5 2001

Gordon R. Johnston
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. 00P-1548/CP1

Dear Mr. Johnston:

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 29, 2000, on behalf of Lachman Consulting Services. Your petition requests that the Agency determine whether Neoral® Soft Gelatin Capsules (Cyclosporine Capsules for microemulsion) 50 mg, (NDA No. N50715), by Novartis Pharmaceuticals Corp., have been voluntarily withdrawn or withheld from sale for safety and efficacy reasons.

FDA is in the process of drafting a notice to be published in the Federal Register. 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.

Sincerely yours,

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

00P-1548

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