DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 15 2003

Robert Pollock
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. 02P-0506/CP1

Dear Mr. Pollock:

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 December 6, 2002. Your petition requests that the Agency determine whether Wyerst Ayerst Laboratories' Wydase (hyaluronidase) injection 150 units/vial and 1500 units/vial was withdrawn from sale for reasons of safety or effectiveness.

We expect to conclude our evaluation shortly and will respond to your petition once that process is complete. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)).

Sincerely,

Jane A. Axelrad

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

02P-0506

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