DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 6, 2003

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

Re: Docket No. 02P-0506/CP1

Dear Mr. Pollock:

This formally responds to your citizen petition, dated December 5, 2002, requesting that the Food and Drug Administration (FDA) determine whether Wyeth-Ayerst's hyaluronidase injection 150 units/vial and 1500 units/vial was withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that Wyeth-Ayerst's hyaluronidase injection was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain Wyeth-Ayerst's hyaluronidase injection in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please call me at 301-594-2041.

Sincerely yours,

Carol Drew
Office of Regulatory Policy (HFD-7)
Center for Drug Evaluation and Research

Enclosure

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