DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 6, 2003

Stephen A. Campbell, Esq.
Sr. Vice President, Regulatory Affairs
Amphastar Pharmaceuticals, Inc.
11570 Sixth St.
Rancho Cucamonga, CA 91730

Re: Docket No. 2003P-0021/CP1

Dear Mr. Campbell:

This formally responds to your citizen petition, dated January 8, 2003, requesting that the Food and Drug Administration (FDA) determine whether Wyeth-Ayerst's hyaluronidase injection was withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that Wyeth-Ayerst's hyaluronidase injection was not withdrawn from sale for reasons of safety or effectiveness.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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