DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 14 2003

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

Re: Docket No. 03P-0021/CP1

Dear Mr. Campbell:

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 January 23, 2003. Your petition requests that the Agency determine whether Wyerst Ayerst Laboratories' Wydase (hyaluronidase) injection was withdrawn from sale for reasons of safety or effectiveness.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

03P-0021/

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