DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-665/S-001
NDA 21-665/S-002

Amphastar Pharmaceuticals, Inc.
Attention: Stephen A. Campbell, Esq.
Senior Vice President, Regulatory Affairs
11570 Sixth Street
Rancho Cucamonga, CA 91730

Dear Mr. Campbell:

Please refer to your supplemental new drug applications dated December 2, 2004, received December 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amphadase (hyaluronidase injection, USP) 150 IU/mL.

We acknowledge receipt of your submission dated July 27, 2005, which constituted a complete response to our April 1, 2005, action letter.

These supplemental new drug applications provide for revised package insert, carton, and container labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft labeling submitted July 27, 2005.

However, if a future labeling supplement is submitted, the Usual Dosage section of the multi-vial carton label should be revised to read, "See enclosed information for dosing information."

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-665/S-001 & S-002**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Michael Puglisi, Project Manager, at (301) 796-1400.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective and
Ophthalmology Products, HFD-520
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Ng

11/3/2005 08:22:50 AM