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CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-665

Trade Name:	Amphadase
Generic Name:	Hyaluronidase injection, USP
Sponsor:	Amphastar Pharmaceuticals, Inc.
Approval Date:	October 26, 2004
Indications:	Provides for the use of Amphadase (hyaluronidase injection, USP) as an adjuvant to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

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APPLICATION NUMBER:

21-665

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter(s)	
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EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	
Microbiology Review(s)	X
Clinical Pharmacology/ Biopharmaceutics Review(s)	X
Administrative Document(s) and Correspondence	X

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APPLICATION NUMBER:

21-665

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-665

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 new drug application (NDA) dated June 6, 2003, received July 7, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Amphadase (hyaluronidase injection, USP) 150 IU/mL.

We acknowledge receipt of your submissions dated December 18, 2003, and January 13, February 5, April 23, June 15, July 21, 26, and 30, August 12 and 23, and September 10, 16, and 17, 2004.

The April 23, 2004, submission constituted a complete response to our January 7, 2004, action letter.

This new drug application provides for the use of Amphadase (hyaluronidase injection, USP) as an adjuvant to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

We completed our review of this application, as amended. It is 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 August 12, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that this product was previously labeled for use in the pediatric population using published medical literature. Therefore, additional information for use in the pediatric population is not needed. The pediatric study requirement for this application has been fulfilled.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, contact Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca C. Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure