



NDA 20-304/S-022

Bayer Healthcare Pharmaceuticals
Mike D. Rozycki, Ph.D.
Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

Dear Dr. Rozycki:

Please refer to your supplemental new drug application dated November 20, 2006, received November 22, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TRASYLOL® (aprotinin) Injection.

We acknowledge receipt of your submissions dated November 21, 29, 2006. We also acknowledge receipt of your submissions dated December 1, 5, and 6, 2006.

This "Changes Being Effected" supplemental new drug application provides for revisions to the BOXED WARNING, INDICATIONS AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS AND DOSAGE AND ADMINISTRATION sections of the currently approved package insert (part number 01298181 dated 12/03 (control number 103501L).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We regard this approved labeling text as providing important drug warning information regarding Trasylol and we request that you expeditiously develop and issue a Dear Healthcare Professional letter that informs providers of the important alterations to the Trasylol labeling. Please be aware that additional Trasylol labeling alterations may be necessary contingent upon the findings from our ongoing review of information pertaining to Trasylol usage, including the findings from the i3 Drug Safety Study.

The final printed labeling (FPL) must be identical to the enclosed labeling.

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/these submission(s) "**FPL for approved supplement NDA 20-304/S-022.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit the final SPL of the agreed upon-labeling text.

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 are waiving the pediatric study requirement for this application.

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/ the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Amundson Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Tiffany Brown, Regulatory Health Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

George Mills, M.D.
Director
Division of Medical Imaging and
Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure (DRAFT LABELING)

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

/s/

Rafel Rieves

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