DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19281/S-041

SUPPLEMENT APPROVAL

Pharmacia & Upjohn Company, a subsidiary of Pfizer, Inc.
Attention: Marcio De Godoy, MDA, MS, PharmD, PhD
Sr. Manager, Worldwide Safety and Regulatory
235 East 42nd Street, 219/9/2
New York, NY 10017

Dear Dr. De Godoy:

Please refer to your Supplemental New Drug Application (sNDA) dated November 14, 2017, received November 14, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cyklokapron® (tranexamic acid) Injection, 100 mg/mL.

We also refer to our letter dated October 16, 2017 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Cyklokapron. This information pertains to the risk of allergic/anaphylactic reactions in patients given tranexamic acid.

This supplemental new drug application provides for revisions to the labeling for Cyklokapron consistent with our October 16, 2017 letter.

APPROVAL & LABELING

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

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

REPORTING REQUIREMENTS

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 Ms. Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Barry W. Miller
Deputy Director for Safety (acting)
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

BARRY W MILLER
11/21/2017