NDA 19-281/S-013

Pharmacia & Upjohn Company
Attention: Ms. Roma J. Thomas
7000 Portage Road
Kalamazoo, Michigan 49001

27 MAR 2001

Dear Ms. Roma:

Please refer to your supplemental new drug application dated October 20, 2000, received October 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cykokapron® (tranex acid) Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes in the ADVERSE REACTIONS section, the "Worldwide Postmarketing Reports" subsection of the package insert: (1) the event of "acute renal cortical necrosis" was added (as requested in April 10, 2000 Agency letter); and (2) the name "tranexamic acid" was substituted for the name "Cyklokapron".

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 20, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Karen Oliver, Regulatory Project Manager, at (301) 827-7457.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research