DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-230/S-037

Xanodyne Pharmaceuticals, Inc.
Attention: Milad Khan
Manager, Regulatory Affairs
One Riverfront Place
Newport, KY 41071-4563

Dear Mr. Khan:

Please refer to your supplemental new drug application dated October 17, 2008, received October 20, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amicar® (aminocaproic acid) Oral solution.

We acknowledge receipt of your submission dated November 13, 2008.

This "Changes Being Effected" supplemental new drug application provides for changes in the container label and the package insert to revise the expression of the strength of the drug product.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container label) and/or submitted labeling (package insert submitted on October 17, 2008 and immediate container label submitted on November 13, 2008).

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 15-230/S-037**." 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
Food and Drug Administration
Suite 12B05
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 Hyon-Zu Lee, Regulatory Health Project Manager, at (301) 796-2192.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
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/

Rafel Rieves

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