DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-230/S-035, NDA 15-197/S-043

Xanodyne Pharmaceuticals, Inc.
Attention: Arthur Ilse
Director, Regulatory Affairs
One Riverfront Place
Newport, KY 41071-4563

Dear Mr. Ilse:

Please refer to your supplemental new drug applications dated May 16, 2008, received May 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amicar® (aminocaproic acid) Tablets, 500 gm and 1000 mg and Amicar® (aminocaproic acid) Oral solution.

These supplemental new drug applications provide for revisions to remove references to Amicar Injection or information only related to the injectable use of aminocaproic acid.

We completed our review of these applications, as amended. These applications are 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) and/or submitted labeling (package insert submitted May 16, 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 these submissions "**FPL for approved supplements NDA 15-230/S-035, NDA 15-197/S-043**." Approval of these submissions by FDA is not required before the labeling is used.

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

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, Pharm.D., Regulatory Project Manager, at 301-796-2050.

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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