DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-230/S-028, S-029, S-030

Xanodyne Pharmacal, Inc.
Attention: Jennifer A. Richards
Regulatory Affairs Manager
7300 Turfway Road, Suite 300
Florence, KY 41042

Dear Ms. Richards:

Please refer to your supplemental new drug applications dated November 22, 2002, received November 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amicar® (aminocaproic acid) Syrup.

We acknowledge receipt of your submissions dated February 3, March 5, May 29 and August 1, 2003.

Your submissions of May 29 and August 1, 2003 constituted a complete response to our May 23, 2003 action letter.

These supplemental new drug applications provide for: (1) an alternate site of manufacturing, packaging, and testing, (2) a change in formulation, (3) new packaging components, and (4) a change in batch size.

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 submitted labeling (package insert submitted May 29, 2003, immediate container label submitted May 29, 2003). Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. You may also submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 15-230/S-028, S-029, and S-030." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your letter dated August 14, 2003. This commitment is listed below.

1. Develop limits for related substances, use the limits expressed in the stability protocols as target limits, and submit these specifications and limits to the Agency within 12 months following approval of the supplemental NDA (i.e., S-028, S-029, and S-030).

Protocol Submission:	Within 6 weeks of the date of this letter
Study Start:	Within 2 months of the date of this letter
Final Report Submission:	Within 11 months of the date of this letter

Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

We also 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 Ryan Barraco, Consumer Safety Officer, at (301) 827-0191.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick
9/2/03 11:54:08 AM
for Dr. Robert Justice