DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 15-197/S-036, 037, 038, 039

Xanodyne Pharmacal, Inc.
Attention: Jim Young, Ph.D.
Vice President, Product Development & Professional Services
7300 Turfway Road, Suite 300
Florence, KY 41042

Dear Dr. Young:

Please refer to your supplemental new drug applications dated April 22, 2003 and May 7, 2003, received April 24, 2003 and May 8, 2003, respectively submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amicar (aminocaproic acid) Tablets.

We acknowledge receipt of your submissions dated February 26, 2004 and June 23, 2004.

Your submission of February 26, 2004 constituted a complete response to our October 24, 2003 and September 8, 2003 action letters.

These supplemental new drug applications provide for 1) the addition of Mikart Inc. as an alternate site of manufacturing and testing, 2) for a change in the manufacture of Amicar® (aminocaproic acid) Tablets, 500-mg, from a solvent-based granulation process to an aqueous-based process, 3) the addition of Mikart, Inc. as an alternate site for packaging and new packaging components, and 4) manufacture, packaging, and testing of Amicar (aminocaproic acid) Tablets, 1000 mg at Mikart, Inc.

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 and with the minor editorial revision listed below.

Please add the text “Tablets” after “aminocaproic acid” to the immediate container labels.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated above, to the enclosed labeling (text for the package insert) and submitted labeling (immediate container labels submitted June 23, 2004). These revisions are terms of the approval of these applications.

Please submit the FPL electronically 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, 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, these submissions should be designated "FPL for approved supplement NDA 15-197/S-036, S-037, S-038, S-039.” 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, HFD-410
FDA
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 Ryan Barraco, Consumer Safety Officer, at 301-443-8017.

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

Enclosure

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

/s/

Robert Justice

6/24/04 05:34:32 PM