CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-602

CORRESPONDENCE

Mikart

mailed KS
10/31/00

October 25, 2000

ORIG AMENDMENT
NIAM

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

RE: ANDA 75-602
Aminocaproic Acid Tablets USP, 500 mg

MINOR AMENDMENT
Responses to Chemistry and Labeling Deficiencies

Dear Sir/Madam:

Reference is made to the Agency's August 14, 2000 Not Approvable Letter to the above listed application. Reference is also made to Mikart, Inc.'s abbreviated new drug application dated March 17, 1999 and to the MAJOR amendment to the application dated March 21, 2000.

Mikart, Inc. herein submits a full and complete response to all items listed in the Not Approvable Letter. To assist in the review of this submission, all Agency comments are reprinted in full and in bold type, with the sponsor's point-by-point responses following. For additional reference, a copy of the Agency's Not Approvable Letter, dated August 14, 2000, is also included.

Thank you for your cooperation in the review of this material. If you have any questions or concerns regarding this submission please contact Andrew Kluessendorf, Manager, Regulatory Submissions at (404) 355-3343.

Sincerely,

Cerie B. McDonald
President

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 26 2000
OGD

10/26/00

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432

Mikart

January 31, 2001

Office of Generic Drugs
CDER, FDA
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT
N/AF

RE: ANDA 75-602
Aminocaproic Acid Tablets USP, 500 mg

FINAL PRINTED LABELING

Dear Sir/Madam:

Reference is made to the Agency's January 9, 2001 Labeling Deficiency facsimile to the above listed application. Reference is also made to Mikart, Inc.'s abbreviated new drug application dated March 17, 1999 and to amendments to the application dated March 21, 2000 and October 25, 2000.

Mikart, Inc. herein submits final printed copies of labels and labeling. The archival copy of this submission contains one (1) copy of the final printed labeling. The working copy contains twelve (12) copies of the final printed labeling. To assist in the review of this submission, a copy of the Agency's facsimile, dated January 9, 2001, is also included.

Thank you for your cooperation in the review of this material. If you have any questions or concerns regarding this submission please contact Andrew Kluessendorf, Manager, Regulatory Submissions at (404) 355-3343.

Sincerely,

Cerie B. McDonald
President

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432

Mikart

March 21, 2000

NDA ORIG AMENDMENT
N/AC

Mr. Douglas Sporn, Director
Office of Generic Drugs
Document Control Room
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II (MPN II)
Room 150
7500 Standish Place
Rockville, MD 20855-2773

Re: ANDA 75-602 Aminocaproic Acid Tablets USP 500 mg
MAJOR AMENDMENT TO AN UNAPPROVED APPLICATION

Dear Mr. Sporn:

This letter is in response to the deficiency letter dated November 1, 1999 regarding the aforementioned application. We would like to respond now to the issues raised. Please see the attached pages for both the agency comment and the Mikart response.

With the submission of this information, Mikart, Inc. trusts that there are no longer any outstanding deficiencies. Thank you for your cooperation in the review of this material. Please feel free to contact us should you require any additional information.

Sincerely,

Cerie B. McDonald
President

CBM/sw

Attachments

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432

ANDA 75-602

Mikart, Inc.
Attention: Cerie B. McDonald
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318-2112

JUN 23 1999

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to our "Refuse to File" letter dated April 28, 1999 and your amendment May 14, 1999.

NAME OF DRUG: Aminocaproic Acid Tablets USP, 500 mg

DATE OF APPLICATION: March 17, 1999

DATE (RECEIVED) ACCEPTABLE FOR FILING: May 17, 1999

We will correspond with you further after we have had the opportunity to review your application.

Please identify any communications concerning this application with the number shown above.

Should you have questions concerning this application contact:

Kassandra Sherrod
Project Manager
(301) 827-5849

Sincerely yours,

Harvey a Drealey
for

Robert L. West, M.S., R.Ph.
Director,
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Mikart

ack for filing
S. Middleton 6/15/99
505 (j)(2)(A)

BIOAVAILABILITY

May 14, 1999

Mr. Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II (MPN II)
Room 150
7500 Standish Place
Rockville, MD 20857-2773

ORIG AMENDMENT

N/AC

Re: ANDA #75-602 for Aminocaproic Acid Tablets USP 500 mg
Supplement to an unapproved application

Dear Mr. Sporn:

Mikart, Inc. would like to respond to the refusal to file letter dated April 28, 1999 regarding Aminocaproic Acid Tablets USP 500 mg. Please refer to the attached documents as supporting evidence for the bioequivalency study, including; pre-screening of patients, consent forms, medical records, clinical raw data and test article inventory. Also, a diskette in ASCII format containing pertinent pharmacokinetic data is included.

Accelerated stability was performed on batch B960222 and is included in the original submission. Accelerated stability was not performed on batch A980053 because it is Mikart's policy to perform accelerated stability only on the first batch of each formula. Additional accelerated stability studies are only performed when there is a change in the manufacturing formula, manufacturing or packaging procedures, or packaging components. Batch A980053 was manufactured and packaged under similar conditions as batch B960222. Please note that both batches are under long term ambient stability studies.

The master packaging instructions were included in the original submission on pages 1191-1206 for batch A980053 and pages 1428-1439 for batch B960222. Packaging reconciliation sheets for B960222 was included on page 1439 but was inadvertently omitted for A980053. The packaging reconciliation sheets are included herein.

Should you have any questions, please contact me at (404)-351-4510. Thank you for your cooperation in the review of this material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAY 17 1999
OGD

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432

ANDA 75-602

Mikart, Inc.
Attention: Cerie B. McDonald
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318-2112

APR 28 1999

Dear Madam:

Please refer to your abbreviated new drug application (ANDA) dated March 17, 1999 submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Aminocaproic Acid Tablets USP, 500 mg.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to file this ANDA under 21 CFR 314.101(d)(3) for the following reason:

Regarding the bioequivalence study, the following items have not been submitted in the study results:

- Pre-screening of patients
- Consent Forms
- Medical Records
- Clinical Raw Data
- Test Article Inventory

You have failed to provide 3 month accelerated stability data required to request a 24-month expiration date for batch A980053. We refer you to Policy and Procedure Guide 32-92.

Thus, it will not be filed as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Please submit a diskette in ASCII format containing pharmacokinetic data and the model codes used in statistical analyses. For each study, two separate files should be configured as follows:

(a) subj seq trt per AUC_{0-t} AUC_{inf} (Where applicable) C_{max} T_{max} K_{el} and $t_{1/2}$;...

(b) subj seq per trt C_1 C_2 C_3.....C_n,

where C is the concentration at various sampling times. Fields should be delimited by one blank space and each missing value should be denoted by a period (.).

Also, please provide a packaging reconciliation summary for the test batch which shows the amount packaged for each container size. Please be advised that the test batch must be completely packaged in the containers proposed for marketing.

Within 30 days of the date of this letter you may amend your application to include the above information or request in writing an informal conference about our refusal to file the application. To file this application over FDA's protest, you must avail yourself of this informal conference.

If after the informal conference, you still do not agree with our conclusion, you may make a written request to file the application over protest, as authorized by 21 CFR 314.101(c). If you do so, the application shall be filed over protest under 21 CFR 314.101(b). The filing date will be 60 days after the date you requested the informal conference. If you have any questions please call.

Saundra T. Middleton
Project Manager
(301) 827-5862

Sincerely yours,

Harvey A. Mearley for

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Mikart

RTF
S. Middleton
4/22/99

March 17, 1999

Mr. Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II (MPN II)
Room 150
7500 Standish Place
Rockville, MD 20857-2773

Re: Abbreviated New Drug Application for Aminocaproic Acid Tablets USP 500 mg
Original Submission

Dear Mr. Sporn:

Enclosed please find two copies of an Abbreviated New Drug Application for Aminocaproic Acid Tablets USP 500 mg for your review and approval. Also included are three additional bound copies of all methodologies pertinent to this product.

Aminocaproic Acid Tablets USP 500 mg is manufactured by Mikart, Incorporated of Atlanta, Georgia, in accordance with current good manufacturing practices.

Should you have any questions, please do not hesitate to call or write. Thank you for your cooperation in the review of this material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sl

Enclosures: duplicate bound ANDA
triplicate methodologies
5 volumes

RECEIVED
MAR 2 2 1999
GENERIC DRUGS

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432