

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74759

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. # 3

2. ANDA # 74-759

3. NAME AND ADDRESS OF APPLICANT

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

4. LEGAL BASIS FOR SUBMISSION

Reference drug: Amicar Syrup (Lederle - Immunex). The applicant states that as per Section 505 (j)(2)(vii) of the Food, Drug and Cosmetic Act, to the best of their knowledge the reference drug is not covered by any patent or marketing exclusivity. This drug product was reviewed under DESI ACT and determined to be acceptable for an ANDA.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None.

7. NONPROPRIETARY NAME

Aminocaproic Acid Syrup, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

Original Submission: 9/25/95
ANDA Original amendment: 11/17/95
Amendment: 4/25/96
ANDA Amendment: 12/15/97
Amendment: 4/9/98
Amendment: 5/19/98

FDA:

Refusal to file: 11/7/95
Date of filing: 11/27/95
Biowaiver granted: 3/28/96
Chemistry and Labeling deficiency letter: 4/12/96
Chemistry deficiency by fax: 3/10/98

10. PHARMACOLOGICAL CATEGORY

Enhancing hemostasis

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF (s)
NDA:
DMF:
13. DOSAGE FORM
Syrup
14. POTENCY
1.25 g/5 mL
15. CHEMICAL NAME AND STRUCTURE
Aminocaproic Acid
16. RECORDS AND REPORTS
N/A
17. COMMENTS
No outstanding Chemistry deficiencies found.
18. CONCLUSIONS AND RECOMMENDATION
ANDA recommended for approval.
19. REVIEWER: DATE COMPLETED:
Radhika Rajagopalan, Ph.D. 5/4/98