CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 40-458

CHEMISTRY REVIEW(S)
APPROVAL PACKAGE SUMMARY 40-458

ANDA: 40-458

FIRM: Mikart, Inc.

DRUG: Carbinoxamine Maleate

DOSAGE: 

STRENGTH: 4 mg/5 mL

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 1/8/03.

BIO STUDY/BIOEQUIVALENCE: Bio waiver granted 2/14/02

METHOD VALIDATION: The drug substance is compendial. The drug product method validation is satisfactory 5/21/02

STABILITY: The firm has provided satisfactory 3 months accelerated stability data at 40°C/75%RH and 12 months room temperature at 25-30°C/Ambient Humidity for all packaging sizes. The stability samples were stored horizontal.

LABELING REVIEW STATUS: Labeling is acceptable 3/31/03.

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master manufacturing formula for the commercial production that reflected the same batch size as the exhibit batch. Also included a copy of the executed batch record #E010309 for — liters. The firm will be using the same drug substance manufacturer, same equipment and same process.

COMMENTS: The application is approvable.

REVIEWER: Nasheed E. Nashed, Ph.D.  DATE: 1/9/03
SUPERVISOR: James M. Fan  1/12/03

411/03
1. CHEMISTRY REVIEW NO. 1

2. ANDA # 40-458

3. NAME AND ADDRESS OF APPLICANT

Mikart, Inc.
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318

4. LEGAL BASIS FOR SUBMISSION

The listed drug Clistin Elixir (NDA 8-955) held by McNeil. Clistin Elixir is a discontinued drug product withdrawn by McNeil May 6, 1985. There are no un-expired patents or un-expired exclusivity for this product. There are no NDA specification available for review.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME 7. NONPROPRIETARY NAME

N/A Carboxinaxamine Maleate

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Original 11/15/01

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC

Antihistaminic Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM 14. POTENCIES

15. CHEMICAL NAME AND STRUCTURE

Ethanamine, 2-[(4-chlorophenyl)-2-pyi-dinylmethoxy]-N,N-dimethyl-, (Z)-2-butenedioate (1:1)
16. RECORDS AND REPORTS

17. COMMENTS

The firm will be asked to tighten their limits for related substances for the finished drug product based on their observed data.

The firm will be asked to tighten the limits for related substances for stability based on their observed data.

DMF is deficient.

Please revise your drug substance specifications to include specifications for individual and total impurities.

Please correct footnote on p.86 "liter tablet batch size".

18. CONCLUSIONS AND RECOMMENDATIONS

The application is deficient.

19. REVIEWER: Nashed E. Nashed, Ph.D. DATE COMPLETED: 3/6/02

Dates signed off: 2/20/02

Signatures: 3/7/02

Supervisor: James M. Fan 2/27/02
Redacted

Page(s) of trade secret and/or confidential commercial information
1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-458

3. NAME AND ADDRESS OF APPLICANT

   Mikart, Inc.
   1750 Chattahoochee Avenue, N.W.
   Atlanta, GA 30318

4. LEGAL BASIS FOR SUBMISSION

   The listed drug Clistin Elixir (NDA 8-955) held by McNeil. Clistin Elixir is a discontinued drug product withdrawn by McNeil May 6, 1985. There are no un-expired patents or un-expired exclusivity for this product. There are no NDA specification available for review.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME 7. NONPROPRIETARY NAME

   N/A  Carbinoxamine Maleate

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

   Original 11/15/01
   Amendment 10/17/02
   Amendment 11/21/02
   Telephone Amendment 8/03-12/02

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC

    Antihistaminic  Rx

12. RELATED IND/NDA/DMF(s)

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    4 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE

   Ethanamine, 2-[(4-chlorophenyl)-2-pyi-dinylmethoxy]-N,N-
   dimethyl-, (Z)-2-butenedioate (1:1)
16. RECORDS AND REPORTS

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:  DATE COMPLETED:

Nashed E. Nashed, Ph.D.  1/9/03

Supervisor: James M. Fan  1/12/03

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