

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

81-051/S-016; S-017

Trade Name: Lortab Elixir

Generic Name: Hydrocodone Bitartrate and
Acetaminophen Elixir; 7.5mg/500mg per
15 mL

Sponsor: Mikart, Inc.

Approval Date: October 27, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-016; S-017

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Reviews / Information Included in this ANDA Review.

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Chemistry Review(s)	X
Microbiology Review(s)	
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RESEARCH**

APPLICATION NUMBER:

81-051/S-016; S-017

APPROVAL LETTER

ANDA 81-051/S-016, S-017

Mikart, Incorporated
Attention: Cerie B. McDonald
1750 Chattahooche Avenue N.W.
Atlanta GA 30318

OCT 27 1999

|||||

Dear Madam:

This is in reference to your supplemental new drug applications dated April 13, 1999, submitted pursuant to 21 CFR 314.70, regarding your abbreviated new drug applications for Hydrocodone Bitartrate and Acetaminophen Elixir, 7.5 mg/500 mg per 15 mL.

The supplemental applications provide for:

- S-016 Provides for new containers made of _____ for the 1 oz and 16 oz package sizes.
- S-017 Provides for an expiration dating of 18 months for the product packaged in the new containers.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

FS
Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

10/27/99

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APPLICATION NUMBER:

81-051/ S-016; S-017

CHEMISTRY REVIEW(S)

ANDA 81-051/S-16, S-17

NAME AND ADDRESS OF APPLICANT

Mikart, Incorporated
Attention: Cerie B. McDonald
1750 Chattahooche Avenue N.W.
Atlanta GA 30318

PURPOSE OF AMENDMENT/SUPPLEMENT

S-016 Provides for new containers made of _____
_____ for the 1 oz and 16 oz
package sizes.

S-017 Provides for an expiration dating of 18 months for the
product packaged in the new containers.

DATE OF SUBMISSION

April 13, 1999

PHARMACOLOGICAL CATEGORY

Analgesic

TRADE NAME

N/A

NONPROPRIETARY NAME

Hydrocodone Bitartrate and Acetaminophen Elixir

DOSAGE FORM

Elixir

POTENCY

7.5 mg/500 mg per 15 mL

RX OR OTC

Rx

SAMPLES

N/A

STERILIZATION

N/A

RELATED IND/NDA/DMF

LABELING

N/A

BIOEQUIVALENCY STATUS

N/A

ESTABLISHMENT INSPECTION

N/A

Redacted 2

pages of trade

secret and /or

confidential

commercial

information

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APPLICATION NUMBER:

81-051/ S-016; S-017

CORRESPONDENCE



September 24, 1999

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

ANDA SUPPLEMENT
SCA 16
SCE 17 / AX

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen Elixir
7.5mg/500mg per 15mL
Supplement to an Approved Application

REQUEST FOR EXPEDITED REVIEW

Dear Mr. Sporn:

Mikart Inc. submitted the above supplement to this ANDA providing for additional container closure systems for our 1 oz and 16 oz packaging on April 13, 1999 (received by the Agency on April 16, 1999). This change was necessary because the current container ~~_____~~ was scheduled to be discontinued by the currently approved ~~_____~~. At this time we can no longer obtain bottles containing the current container ~~_____~~.

Mikart Inc. is requesting an expedited review because, as a small business, we face a severe economic hardship if the Agency's review of this supplement is delayed. We would be most appreciative if the Agency would review this supplement as soon as possible. Thank you for your cooperation in the review of this material. Please contact me if additional information is needed.

Sincerely,

Cerie B. McDonald
President



116
9-28-99



April 13, 1999

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

ANDA 81-051

REVISION

ANDA 81-051

REVISION

REF NO. SCA016
package 1d

SEE 07
Submission

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen Elixir
7.5 mg/500 mg per 15 mL
SUPPLEMENT TO AN APPROVED APPLICATION

Dear Mr. Sporn:

In accordance with 21 CFR 314.70 (b) (2), Mikart is submitting a supplement to this application to provide for additional container/closure systems for the 1 oz. And 16 oz. Packaging sizes. This change is necessary because the current container is scheduled to be discontinued by the currently approved bottle is.

This change represents a change to a similar configuration in that the new containers selected remain of the composition, and there is no change from the current closures. The data package being submitted in support of this change includes the following information:

1. General information regarding the
2. Notification of the change received from the
3. Information from each new container and applicable DMF authorizations.
4. Mikart specifications for containers, including drawings of the new containers, plus receipt information on the specific lots used in the exhibit packaging runs.
5. A summary of the container/closure systems used for the 1 oz. And 16 oz. configurations.
6. USP testing data for each container/closure system.
7. Exhibit packaging master records for each size illustrating all components used in the operations

RECEIVED

APR 16 1999

Handwritten signature
4-22-99

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue, Atlanta, Georgia 30318
Tel: 404-350-0430 Fax: 404-350-0432

GENERIC DRUGS



Mr. Douglas Sporn, Director
April 13, 1999
Page 2

8. Executed packaging records for the 1 oz. and 16 oz. sizes.
9. 90 day accelerated and available room temperature stability data.
10. Expiration dating proposal.

The revised container/closure system will be added to the current stability protocol, with the first lot packaged in each system being placed on both accelerated and long-term stability. This data is included in the supplement. Annual batches hereafter will be placed on long-term stability.

Thank you for your cooperation in the review of this material. Please contact me if additional information is required.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sl

APPEARS THIS WAY
ON ORIGINAL