

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

89-557/S-002

Generic Name: Hydrocodone bitartrate and
Acetaminophen Elixir
7.5mg/500mg per mL

Sponsor: Mikart, Inc.

Approval Date: January 18, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-002

CONTENTS

Reviews / Information Included in this ANDA Review.

Approval Letter(s)	X
Tentative Approval Letter(s)	
Final Printed Labeling	
CSO Labeling Review(s)	
Medical Officer Review(s)	
Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	
Administrative Document(s)	X
Correspondence	X

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89-557/S-002

APPROVAL LETTER

ANDA 81-051/S-007 (7.5 mg/500 mg per 15 mL)
81-226/S-002 (5 mg/500 mg per 15 mL)
~~89-557~~/S-002 (5 mg/500 mg per 15 mL)

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

JAN 18 1996

Dear Madam:

This is in reference to your supplemental new drug applications dated June 9, 1995, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug applications for Hydrocodone Bitartrate and Acetaminophen Elixir.

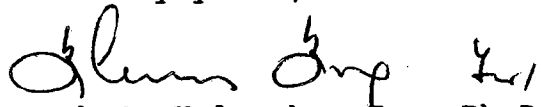
The supplemental applications provide for a change in measurement, from volume to weight, for Alcohol USP.

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,



Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

1/18/96

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CHEMISTRY REVIEW(S)

ANDA 81-051/S-007 (7.5 mg/500 mg per 15 mL, 1st review)
81-226/S-002 (5 mg/50 mg per 15 mL, 1st review)
~~89~~-557/S-002 (5 mg/50 mg per 15 mL, 1st review)

NAME AND ADDRESS OF APPLICANT:

Mikart, Inc.
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318-2112

PURPOSE OF AMENDMENT/SUPPLEMENT

81-051/S-007, 81-226/S-002 & 89-557/S-002:

Control revision - change in measurement, from volume to weight, for Alcohol USP.

DATE(S) OF SUBMISSION(S)

Firm: 6/9/95 - Original supplement, all three.

PHARMACOLOGICAL CATEGORY

Relief of moderate to moderately severe pain

TRADE NAME

None

NONPROPRIETARY NAME

Hydrocodone Bitartrate and Acetaminophen

DOSAGE FORM

Elixir

POTENCY

7.5 mg/500 mg per 15 mL
5 mg/500 mg per 15 mL

RX OR OTC

R

SAMPLES

N/A

RELATED IND/NDA/DMF

N/A

STERILIZATION

N/A

LABELING - N/A

BIOEQUIVALENCY STATUS - N/A

ESTABLISHMENT INSPECTION - N/A

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS - Satisfactory
Brought forward from previous review.

[]

Orig. Appvd. 8/28/92 (81-051), 10/27/92 (81-226) &
4/29/92 (89-557)

Brought forward from previous review.

[]

Orig. Appvd. 8/28/92 (81-051), 10/27/92 (81-226) &
4/29/92 (89-557)

Redacted 3

Page(s) of trade

secret and /or

confidential

commercial

information

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**ADMINISTRATIVE
DOCUMENTS**

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CORRESPONDENCE

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

7/19/95

FROM:

Timothy W. Ames

, Consumer Safety Officer

SUBJECT: Special Supplement - Changes Placed into Effect

TO:

Document Room

Please make the following entry in the MIS concerning the status of this Special Supplement - Changes Placed into Effect.

ANDA(s)

SUPPLEMENT(s)

GRANTED

DENIED

89-557

S-002

11

This form is to accompany the action package/jacket.

Thank you,

Timothy W. Ames

Signature of CSO and Date

7/19/95

CC:

ANDA
DIVISION FILE

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APPLICATION NUMBER:

89-557/S-002

CORRESPONDENCE



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

ORIGINAL

June 9, 1995

Mr. Douglas Sporn, Acting 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

NDA NO. _____ REF. NO. SC002

NDA SUPPL FOR Control Rev
SC002 A1

*Appear to meet 21 CFR 314.70(c)(1)
D. Shostak 7/17/95*

*Concur
JAS 8/19/95
CDO*

Re: ANDA 89-557 Hydrocodone Bitartrate and Acetaminophen
Elixir 5 mg/500 mg per 15 mL

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

Dear Mr. Sporn:

Mikart would like to supplement the above-mentioned application to provide for a change in measurement, from volume to weight, for the Alcohol USP _____, raw material. This submission is part of a multiple supplement for all liquid dosage form ANDA's containing this material.

Mikart is making this modification in accordance with 21 CFR 314.70 (c) (1). We are implementing the change in order to increase accuracy in the measurement of the raw material. The change applies only to the way in which the material is measured. No changes are being made to the formula. Manufacture of this product will follow the same process.

The change in measurement has already been made to the Master Manufacturing Formula and will be implemented August 1, 1995.

Please find attached the revised _____ production size Master Manufacturing Formula for Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL, which reflects the change described above. Only the usual production size master is being submitted. If necessary, masters for other sizes will be revised accordingly and submitted in the annual report. **RECEIVED**

JUN 20 1995

GENERIC DRUGS

*Madeline
6/27/95*

Mr. Douglas Sporn
June 9, 1995
Page 2

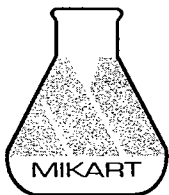
Thank you for your cooperation in the review of this material.
Please feel free to contact us if you require any additional
information.

Sincerely,

A handwritten signature in cursive script, appearing to read "Cerie B. McDonald".

Cerie B. McDonald
Executive Vice-President

CBM/sw



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

FIELD COPY CERTIFICATION

In accordance with the requirements of 21 CFR 314.70, Mikart hereby certifies that a field copy of this supplement to an approved abbreviated application, ANDA # 89-557 for Hydrocodone Bitartrate and Acetaminophen Elixir, 5 mg/500 mg per 15 mL, has been provided to the Atlanta District Office of the Food and Drug Administration.

A handwritten signature in cursive script, appearing to read "Cerie B. McDonald".

Cerie B. McDonald
Executive Vice-President

June, 1995