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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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,

1/18/96

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-002

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	TRADE NAME	NONPROPRIETARY NAME
Relief of moderate to moderately severe pain	None	Hydrocodone Bitartrate and Acetaminophen

DOSAGE FORM	POTENCY	RX OR OTC
Elixir	7.5 mg/500 mg per 15 mL 5 mg/500 mg per 15 mL	℞

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
N/A	N/A	N/A

LABELING - N/A

BIOEQUIVALENCY STATUS - N/A

ESTABLISHMENT INSPECTION - N/A

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

[redacted]

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

Brought forward from previous review.

[redacted]

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-002

ADMINISTRATIVE DOCUMENTS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-002

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	(GRANTED)	

This form is to accompany the action package/jacket.

Thank you,

Signature ~~of CSO~~ and Date 7/19/95

CC:
ANDA
DIVISION FILE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-002

CORRESPONDENCE

ORIGINAL

MIKART, INC.
PHARMACEUTICAL MANUFACTURERS

NDA NO. _____ REF. NO. SC002
NDA SUPPL FOR Control Rec
SC002 A2

June 9, 1995

Appears to meet 21 CFR 314.70(c)(1)
D Shootak 7/7/95

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

Concur
7/19/95
CSO

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

1750 CHATTAHOOCHEE AVENUE, N.W., ATLANTA, GEORGIA 30318-2112 PHONE: 404-351-4510 FAX: 404-350-0432

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

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sw

1750 CHATTAHOOCHEE AVENUE, N.W., ATLANTA, GEORGIA 30318-2112 PHONE: 404-351-4510 FAX: 404-350-0432

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.

Cerie B. McDonald
Executive Vice-President

June, 1995

1750 CHATTAHOOCHEE AVENUE, N.W., ATLANTA, GEORGIA 30318-2112 PHONE: 404-351-4510 FAX: 404-350-0432