CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

81-051/S-005

Trade Name:	Lortab Elixir
Generic Name:	Hydrocodone Bitartrate and Acetaminophen Elixir; 7.5mg/500mg per 15 mL
Sponsor:	Mikart, Inc.
Approval Date:	July 25, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-005

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)	
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-005

APPROVAL LETTER

ANDA 81-051/S-005 (7.5 mg/500 mg per 15 mL)
81-226/S-001 (5 mg/50 mg per 15 mL)
89-557/S-001 (5 mg/50 mg per 15 mL)

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

JUL 25 1995

Dear Madam:

This is in reference to your supplemental new drug application dated January 25, 1995, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Hydrocodone Bitartrate and Acetaminophen Elixir.

The supplemental application provides for [redacted]

We have completed the review of this supplemental application and it is 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,

/S/

7/25/95

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-005

CHEMISTRY REVIEW(S)

ANDA 81-051/S-005 (7.5 mg/500 mg per 15 mL, 1st review)
81-226/S-001 (5 mg/50 mg per 15 mL, 1st review)
89-557/S-001 (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-005, 81-226/S-001 & 89-557/S-001:
Control revision -

DATE(S) OF SUBMISSION(S)
Firm: 1/25/95 - 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	Rx

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 - N/A
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 4

pages of trade secret and /or confidential commercial information

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APPLICATION NUMBER:

81-051/S-005

CORRESPONDENCE

6.1 Waiver Request

MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

January 25, 1995

Mr. Douglas L. Sporn, Acting Director
Office of Generic Drugs
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. 2005
NDA SUPPL FOR Controlled Rel

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,

Mikart would like to supplement the above application to [redacted] in Hydrocodone Bitartrate and Acetaminophen Elixir (7.5 mg/500 mg per 15 mL). The information contained herewith is submitted as part of a multiple supplement.

[redacted]

The details of this supplement can be found in the following pages. Please let us know if you require any further information. Thank you for your cooperation in the review of this material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sw

RECEIVED
FEB 03 1995
GENERIC DRUGS

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