CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-001

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Reviews / Information Included in this ANDA Review.

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Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

89-557/S-001

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

Sponsor: Mikart, Inc.

Approval Date: July 25, 1995

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APPLICATION NUMBER:

89-557/S-001

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,

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:

89-557/S-001

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 - [redacted]

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 3

Page(s) of trade secret and /or confidential commercial information

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APPLICATION NUMBER:

89-557/S-001

CORRESPONDENCE

+1

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. 30001
NDA SUPPL FOR Controlled Rel

RE: ANDA 89-557 Hydrocodone Bitartrate and Acetaminophen Elixir
(5 mg/500 mg per 15 mL)
Supplement to an approved application

Dear Mr. Sporn,

Mikart would like to supplement the above application [redacted]. The information contained herewith is submitted as part of a multiple supplement.

Mikart has performed this test on all stability samples tested to date and the results obtained show that the [redacted] detected is always well within the established limits of NMT [redacted] The maximum value detected to date is [redacted] Results of [redacted] testing performed on stability samples have been analyzed in a regression analysis and no significant trending over time was noted.

In addition, please note that Mikart performs [redacted] testing on [redacted] in accordance with the requirements of the current USP monograph for [redacted] and this testing will continue. The data described above demonstrates that there has not been any evidence that [redacted] develops over time during the shelf-life of the finished product if it is not present in the [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.

RECEIVED
FEB 03 1995
GENERIC DRUGS

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 true 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

January, 1995

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