

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
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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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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. JUL 25 1995
Atlanta, GA 30318-2112

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.

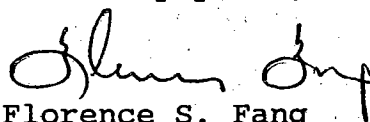
The supplemental application provides for _____

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,



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

7/25/95

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APPLICATION NUMBER:

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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

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 - N/A

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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APPLICATION NUMBER:

89-557/S-001

CORRESPONDENCE

7.1



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. 80001
NDA SUPPL FOR Control Rev.

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 _____

_____. 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 _____
detected is always well within the established limits
of NMT _____. The maximum value detected to date is _____.
Results of _____ 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 _____
testing on _____ in accord-
ance with the requirements of the current USP monograph for
_____ and this testing will continue. The data described
above demonstrates that there has not been any evidence that _____
develops over time during the shelf-life of the
finished product if it is not present in the _____

The details of this supplement can be found in the following
pages. Please let us know if you require any further informa-
tion. 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



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