

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

81-051/S-002

Trade Name: Lortab Elixir

Generic Name: Hydrocodone Bitartrate and
Acetaminophen Elixir; 7.5mg/500mg per
15 mL

Sponsor: Mikart, Inc.

Approval Date: March 2, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/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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APPROVAL LETTER

**CENTER FOR DRUG
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CHEMISTRY REVIEW(S)

ANDA 81-051/S-002 (1st review)

NAME AND ADDRESS OF APPLICANT:

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

PURPOSE OF AMENDMENT/SUPPLEMENT

S-002:

Facility addition - optional packaging facility at 1750
Chattahoochee Avenue, N.W., Atlanta, GA 30318-2112

DATE(S) OF SUBMISSION(S)

Firm: 11/4/94 - Original supplement
1/6/95 - Amendment, stability data.

FDA: 12/1/94 - Expedited review request denied.

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

R

SAMPLES

RELATED IND/NDA/DMF

STERILIZATION

N/A

81-226 (500 mg/5 mg per 15 mL)
89-557 (500 mg/5 mg per 15 mL)

N/A

LABELING - N/A

BIOEQUIVALENCY STATUS - N/A

ESTABLISHMENT INSPECTION - Satisfactory

S-002:

Sent for optional packaging facility on 2/8/95.
Acceptable on 2/8/95.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS - Satisfactory

S-002:

Optional packaging facility at 1750 Chattahoochee Avenue,
N.W., Atlanta, GA 30318-2112. Have complete batch record
including packaging at optional facility for Lot # G94665.

Brought forward from previous review.

Orig. Appvd. 8/28/92

Redacted 3

pages of trade

secret and /or

confidential

commercial

information

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**ADMINISTRATIVE
DOCUMENTS**

ESTABLISHMENT EVALUATION REQUEST

J

REQUEST TYPE (Check One) <input checked="" type="checkbox"/> Original <input type="checkbox"/> FollowUp <input type="checkbox"/> FUR	DATE February 8, 1995	PHONE NO. (301) 594-0305	EER ID # 7651
REQUESTORS NAME: Norman Gregory	DIVISION: Office of Generic Drugs		MAIL CODE: HFD-647
APPLICATION AND SUPPLEMENT NUMBER: ANDA 81-051/SC-002			
BRAND NAME:	ESTABLISHED NAME: Hydrocodone Bitartrate and Acetaminophen		
DOSAGE STRENGTH: 7.5 mg/500 mg per 15 mL			STERILE <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
PROFILE CLASS.: LIQ	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)		
APPLICANT'S NAME: Mikart, Inc.			
APPLICANT'S ADDRESS: 1750 Chattahoochee Avenue, N.W. Atlanta, GA 30318-2112			
COMMENTS :			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

RESPONSIBILITY

DMF NUMBER/
PROFILE CODE

FKEY
CIRTS ID

HFD-324 USE ONLY

(Name and Complete Address)	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY
1. Mikart, Inc. 1750 Chattahoochee Avenue, N.W. Atlanta, GA 30318-2112	Packaging of finished product.	LIQ	MIKA	AC 9/25/93
2.				
3.				
4.				
5.				

FOR HFD-324 USE ONLY:	CSO	DATE RECEIVED
CGMP COMPLIANCE STATUS	acceptable	DATE
		5/19/95
		2/8/95

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: ANDA 81-051/SC-002 HFD-647/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-647/JSimmons HFD-647/NGregory

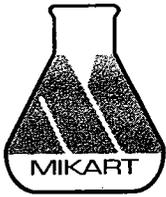
APPEARS THIS WAY
ON ORIGINAL

**CENTER FOR DRUG
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APPLICATION NUMBER:

81-051/S-002

CORRESPONDENCE



MIKART, INC.
PHARMACEUTICAL MANUFACTURERS

January 6, 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

orig
Expedited Review Requested
See document 12/1/94
151/2/24/95
NDA SUPPL AMENDMENT
SC002AL
SC002AX

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen
Elixir 7.5 mg/500 mg per 15 mL

Amendment to a supplemental application
EXPEDITED REVIEW REQUESTED

Dear Mr. Sporn:

As promised in our supplement for the addition of an optional packaging facility, Mikart is submitting additional accelerated stability data for the above-mentioned application. Please find attached 60 and 90 day stability results for each packaging size of Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL packaged at the new facility.

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

RECEIVED

JAN 10 1995

GENERIC DRUGS

Madine
1-19-95



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

November 4, 1994

NDA NO. _____ REF NO. _____

NDA SUPPL FOR Facility Add

SC 002
SC002 AX

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

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen
Elixir 7.5 mg/500 mg per 15 mL
Supplement to an approved application
EXPEDITED REVIEW REQUESTED

Dear Mr. Sporn:

Mikart would like to supplement the above-mentioned application to provide for the addition of an optional packaging facility. Enclosed is the following information in support of the addition of the new facility.

1. Floor plans and specifications for the new building, including schematics for the heating and air-conditioning, plumbing, and electrical systems.
2. An updated listing of designated facilities for processing the product. This replaces the previously submitted information.
3. Complete batch record for exhibit batch of Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL (Lot # G94665) packaged at the new facility.
4. Accelerated stability testing results (30 day) for Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL packaged at the new facility. The 60 day and 90 day results will be reported when they become available.

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NOV 10 1994

GENERIC DRUGS

Sporn
11-12-94

Mr. Douglas Sporn

November 4, 1994

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5. Stability commitment which provides for stability testing for future lots of Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL to be conducted as provided for in the current Stability Protocol.
6. Expiration date proposal which provides for the use of the same expiration date for each respective packaging size as is already in place for products packaged at the 2090 Marietta Blvd. N.W. facility.
7. Standard Operating Procedures which deal with material transfer between the 2090 Marietta Blvd. N.W. facility and the 1750 Chattahoochee Ave. N.W. facility. These procedures have been designed to limit the amount of time which materials spend in transit between the two locations.
8. The packaging instructions currently in use will be revised to include a requirement for packaging site designation. No other changes will be made to the currently approved manufacturing and processing instructions. The revised packaging instructions will be submitted in the annual report. A sample of packaging instructions which have been revised to include the facility designation is attached. For products for which both packaging sites are approved, the site used for a particular batch of product will be circled at the time of packaging.

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/seh