CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

89-557/S-007

Generic Name:	Hydrocodone bitartrate and Acetaminophen Elixir 7.5mg/500mg per mL
Sponsor:	Mikart, Inc.
Approval Date:	August 13, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-007

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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89-557/S-007

APPROVAL LETTER

89557/507

ANDA See attachment

AUG 13 2002

10-1

Mikart, Incorporated
Attention: Judy Howard
1750 Chattahoochee Avenue N.W.
Atlanta, GA 30318

Dear Madam:

This is in reference to your supplemental new drug applications, dated April 2, 2002, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications for the products referenced in the attachment.

These supplemental applications, submitted as "Changes Being Effected in 30 Days", provides for the following change:

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,

8/13/02

for

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

450

ATTACHMET

APPLICATIONS AFFECTED BY THE CHANGE IN ANALYTICAL TEST FACILITY	
ANDA	APPLICATION NAME
40-062	Methazolamide Tablets USP 25 mg Methazolamide Tablets USP 50 mg
40-085	Butalbital, Acetaminophen and Caffeine Capsules USP 50 mg/500 mg/40 mg
40-090	Isoniazid Tablets USP 300 mg
40-090	Isoniazid Tablets USP 100 mg
40-109	Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules 356.4 mg/30 mg/16 mg
40-251	Trihexyphenidyl HCl Elixir 2 mg per 5 mL
40-316	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablets 712.8 mg/60 mg/32 mg
74-028	Amantadine HCl Syrup USP 50 mg/5mL
74-759	Aminocaproic Acid Syrup USP 25%
75-039	Oxybutynin Chloride Syrup 5 mg per 5 mL
75-602	Aminocaproic Acid Tablets 500 mg
81-051	Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL
81-067	Hydrocodone Bitartrate and Acetaminophen Capsules 5 mg/500 mg
81-068	Hydrocodone Bitartrate and Acetaminophen Capsules 5 mg/500 mg
81-069	Hydrocodone Bitartrate and Acetaminophen Capsules 5 mg/500 mg
81-070	Hydrocodone Bitartrate and Acetaminophen Capsules 5 mg/500 mg
81-223	Hydrocodone Bitartrate and Acetaminophen Tablets USP 10 mg/650 mg
81-226	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL
81-319	Pyrazinamide Tablets USP 500 mg
89-007	Butalbital, Acetaminophen and Caffeine Capsules 50 mg/325mg/40 mg
89-008	Hydrocodone Bitartrate and Acetaminophen Capsules 5 mg/500 mg
89-175	Butalbital, Acetaminophen and Caffeine Tablets USP 50 mg/325 mg/40 mg
89-231	Acetaminophen and Codeine Phosphate Tablets USP 650 mg/30 mg
89-238	Acetaminophen and Codeine Phosphate Tablets USP 300 mg/30 mg
89-244	Acetaminophen and Codeine Phosphate Tablets USP 300 mg/60 mg
89-271	Hydrocodone Bitartrate and Acetaminophen Tablets USP 5 mg/500 mg
89-363	Acetaminophen and Codeine Phosphate Tablets USP 650 mg/60 mg
89-450	Acetaminophen and Codeine Phosphate Oral Solution USP 120 mg/12 mg per 5 mL
89-451	Butalbital, Acetaminophen and Caffeine Tablets USP 50 mg/500 mg/40 mg
89-452	Phendimetrazine Tartrate Tablets USP 35 mg
89-557	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL
89-689	Hydrocodone Bitartrate and Acetaminophen Tablets USP 7.5 mg/650 mg
89-697	Hydrocodone Bitartrate and Acetaminophen Tablets USP 5 mg/500 mg
89-698	Hydrocodone Bitartrate and Acetaminophen Tablets USP 2.5 mg/500 mg
89-699	Hydrocodone Bitartrate and Acetaminophen Tablets USP 7.5 mg/500 mg
89-987	Butalbital and Acetaminophen Tablets 50 mg/325 mg
89-988	Butalbital and Acetaminophen Tablets 50 mg/650 mg

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CHEMISTRY REVIEW(S)

ANDA See attachment

NAME AND ADDRESS OF APPLICANT:
Mikart, Incorporated
Attention: Judy Howard
1750 Chattahoochee Avenue N.W.
Atlanta, GA 30318

PURPOSE OF AMENDMENT/SUPPLEMENT
S-004 Provides for [redacted]

DATE(S) OF SUBMISSION(S)
April 2, 2002

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
See attachment	See attachment	See attachment

DOSAGE FORM	POTENCY	RX OR OTC
See attachment	See attachment	

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

LABELING
N/A

BIOEQUIVALENCY STATUS
N/A

ESTABLISHMENT INSPECTION
Acceptable on 4/12/02 for [redacted]

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

[redacted]

PACKAGING
N/A

STABILITY
N/A

REMARKS AND CONCLUSION
Recommend approval.

RECALLS
N/A

Reviewer	Date Completed
M. Piñeiro-Sánchez, Ph.D.	August 6, 2002

ORDER OF REVIEW:
The application submission(s) covered by this review was taken in the date order of receipt Yes X
No_____

If no, explain reason(s) below.

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-007

ADMINISTRATIVE DOCUMENTS

Green, Wayne*

To: Min, Jeen; Washington, Edward*; Wiseman, Rosemarie*
Subject: RE: Correct a global withdrawal

Jeen,

The adjustments have been made.

Wayne

-----Original Message-----
From: Min, Jeen
Sent: Friday, August 16, 2002 9:53 AM
To: Green, Wayne*; Washington, Edward*; Wiseman, Rosemarie*
Subject: Correct a global withdrawal

Wayne,

Mikart sent in a global supplement dated April 2, 2002 for the addition of [redacted]
Only supplement number was assigned for [redacted] We need to add another supplement number for the other [redacted]

Also, I recently sent a withdrawal acknowledgement letter dated August 9, 2002 for the following supplements:

40-251/S-001	Trihexyphenidyl HCl USP, 2 mg/5 mL
74-028/S-009	Amantadine HCl Syrup USP, 50 mg/5 mL
74-759/S-003	Aminocaproic Acid Oral Solution, 1.25 mg/5 mL
75-039/S-001	Oxybutynin Chloride Syrup USP, 5 mg/5 mL
75-602/S-001	Aminocaproic Acid Tablets USP, 500 mg
81-051/S-018	Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL
81-226/S-005	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL
89-450/S-009	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL
89-557/S-007	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL

I referenced the wrong supplement numbers. Please delete the withdrawal code the for the above supplement numbers.

I will be sending out a corrected withdrawal letter referencing the correct supplements mentioned below.

40-251/S-002	Trihexyphenidyl HCl USP, 2 mg/5 mL
74-028/S-010	Amantadine HCl Syrup USP, 50 mg/5 mL
74-759/S-004	Aminocaproic Acid Oral Solution, 1.25 mg/5 mL
75-039/S-002	Oxybutynin Chloride Syrup USP, 5 mg/5 mL
75-602/S-002	Aminocaproic Acid Tablets USP, 500 mg
81-051/S-019	Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL
81-226/S-006	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL
89-450/S-010	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL
89-557/S-008	Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL

Thanks,

Jeen Min

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89-557/S-007

CORRESPONDENCE

Mikart

April 2, 2002

Mr. Gary Buehler, 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

REF. NO. SCB 007
SUPPL FOR Facility Add
AT

NDA NO. 89-557 REF. NO. SCB-008
NDA SUPPL FOR Facility Add. AT

Re: ANDA 89-557
Hydrocodone Bitartrate and Acetaminophen Elixir 5 mg/500 mg per 15 mL
CHANGES BEING EFFECTED SUPPLEMENT TO AN APPROVED APPLICATION

Dear Mr. Buehler:

This is a supplement to designate [redacted] previously tested by [redacted] in a letter received the last week of December, [redacted] notified Mikart that they would cease operations of their [redacted] Mikart proceeded to identify [redacted] by [redacted]

A local contractor, [redacted] was chosen to [redacted]. A [redacted] was needed because the [redacted], on a [redacted], needs to be started as soon as possible after it is obtained to minimize changes in the [redacted] was identified as a potential [redacted] for [redacted] We conducted a site audit in late January which determined that [redacted] was capable of performing the designated [redacted] and [redacted] began conducting the [redacted] the week of 02/04/02. The procedures used by [redacted] are the same as those used previously by [redacted] had a satisfactory FDA inspection in 02/2001. The [redacted] is generated on site at Mikart, and is released on a continual basis. Weekly monitoring of the [redacted] quality is conducted, with some testing performed at Mikart [redacted]), and [redacted]

Initially, it was believed that this change should be submitted in the annual reports for the affected applications. We recently became aware that this change requires submission of a CBE 30 Supplement per the guidance "Changes to an Approved NDA or ANDA"; therefore, information required for this product is being supplied as a CBE supplement. The revised specification sheets, a revised list of designated [redacted] and supporting information from the contract site(s) is provided. Contract site(s) chosen meet requirements presented in the aforementioned guidance document.

Thank you in advance for your cooperation in the review of this supplement. We apologize for any inconvenience caused.

Sincerely,

Judy H. Howard
Vice President, Scientific Affairs

RECEIVED
APR 0 8 2002
OGD / CDER

Mikart, Inc. • Pharmaceutical Manufacturers
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432