

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

81-051/S-004

Trade Name: Lortab Elixir

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

Sponsor: Mikart, Inc.

Approval Date: March 6, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-004

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

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APPLICATION NUMBER:

81-051/S-004

APPROVAL LETTER

ANDA 81-051/S-004

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

MAR 6 1996

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 Lortab[®] Elixir (Hydrocodone Bitartrate and Acetaminophen Elixir) 7.5 mg/500 mg per 15 mL.

Reference is also made to your amendment dated October 12, 1995.

The supplemental application provides for container labels for the gallon container size.

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,

Jerry Phillips ^{3/6/96}
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 81-051/S-004 ³⁻⁵⁻⁹⁶
Dup/Division File
HFD-613/AVEZ ^{1/26/96} Gryce (no cc:)
HFD-600/RF ^{1/26/96}
HFD-82
aev 2/26/96 see x:\...ltrs&rev\81051S04.AP
Approval Letter - Single Supplement

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RESEARCH**

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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 _____

DATE(S) OF SUBMISSION(S)

April 2, 2002

PHARMACOLOGICAL CATEGORY

See attachment

TRADE NAME

See attachment

NONPROPRIETARY NAME

See attachment

DOSAGE FORM

See attachment

POTENCY

See attachment

RX OR OTC

SAMPLES

N/A

RELATED IND/NDA/DMF

N/A

STERILIZATION

N/A

LABELING

N/A

BIOEQUIVALENCY STATUS

N/A

ESTABLISHMENT INSPECTION

Acceptable on 4/12/02 for _____

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

[
N/A

STABILITY

N/A

REMARKS AND CONCLUSION

Recommend approval.

RECALLS

N/A

Reviewer

M. Piñeiro-Sánchez, Ph.D.

Date Completed

August 6, 2002

ORDER OF REVIEW:

The application submission(s) covered by this review was taken
in the date order of receipt

If no, explain reason(s) below.

APPEARS THIS WAY
ON ORIGINAL

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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RESEARCH**

APPLICATION NUMBER:

81-051/S-004

CORRESPONDENCE



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

October 12, 1995

Mr. Charles Ganley, 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
NDA SUPPL AMENDMENT
52004 AZ

approval letter
2/26/96
15/1
00

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL
AMENDMENT TO A SUPPLEMENTAL (S-004) APPLICATION

Dear Mr. Ganley:

Mikart has received your letter dated June 8, 1995 regarding the above application. Enclosed are twelve copies of final printed labeling. Please note that Mikart has not used these labels to date.

Thank you for your cooperation in the review of this material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sw

Enc.

RECEIVED

OCT 17 1995

GENERIC DRUGS

ANDA 81-051/S-004

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

JUN 8 1995

Dear Madam:

Reference is made to your supplemental new drug application dated January 25, 1995, submitted pursuant to Section 314.70 of the Regulations, regarding your abbreviated new drug application for Lortab® Elixir (Hydrocodone Bitartrate and Acetaminophen Elixir) 7.5 mg/500 mg per 15 mL.

The supplemental application provides for container labels for the gallon container size.

We have completed our review of this supplemental application and it is approvable. However, before the supplemental application may be approved, it is necessary that you supply 12 final print labels as an amendment to this supplemental application.

Please note we believe this supplement was inappropriately submitted as a Special Supplement - Changes Being Effected, because final print labeling must be submitted. We refer you to 21 CFR 314.70(c) for further guidance.

The changes provided for in this supplemental application may not be initiated until you have been notified in writing that the supplemental application is approved.

Sincerely, *[Signature]*

Jan 1
Yana Ruth Mille
Acting Director, Division of
Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

6-8-95



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

orig

January 25, 1995

NDA NO. _____ REF. NO. SL004
NDA SUPPL FOR Label Rev
SL004A1

Mr. Douglas L. 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

*appropriate letter
TSI - 3/10/95
gallon labels
substantively*

Re: ANDA 81-051 Lortab Elixir (Hydrocodone Bitartrate and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL)
Supplement to an approved application
CHANGES BEING EFFECTED

Dear Mr. Sporn:

Mikart intends to introduce customer labeling in the gallon packaging size for the above application. Since customer labeling has not been printed previously for this packaging size, Mikart created the draft following the 12/93 FDA Labeling Guidance for Hydrocodone Bitartrate and Acetaminophen. This package label will replace the current approved labeling for this packaging size which was previously not revised to the updated guidance. These changes will go into effect March 1, 1995. Four copies of draft labeling are attached.

If you need any additional information, please do not hesitate to contact us. Thank you for your cooperation in the review of this material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/jas

Enc.

RECEIVED

FEB 03 1995

GENERIC DRUGS