

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

81-051/S-015

Trade Name: Lortab Elixir

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

Sponsor: Mikart, Inc.

Approval Date: July 31, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-015

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

**CENTER FOR DRUG
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RESEARCH**

APPLICATION NUMBER:

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APPROVAL LETTER

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This is in reference to your supplemental new drug applications dated January 6, 1998 submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug applications as listed in the Attachment.

6

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.

1

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

6. 7/31/98

ANDA

DRUG PRODUCT

74-028/008	Amanatadine Hydrochloride Syrup USP, 50 mg/5 mL
40-062/002	Methazolamide Tablets USP, 25 mg, 50 mg
40-085/011	Butalbital, Acetaminophen, and Caffeine Capsules, 50 mg/500 mg/40 mg
89-987/006	Butalbital and Acetaminophen Tablets, 50 mg/325 mg
89-988/005	Butalbital and Acetaminophen Tablets, 50 mg/650 mg
89-451/031	Butalbital, Acetaminophen and Caffeine Tablets, USP 50 mg/500 mg/40 mg
89-007/035	Butalbital, Acetaminophen and Caffeine Capsules, 50 mg/325 mg/40 mg
89-175/031	Butalbital, Acetaminophen and Caffeine Tablets, USP 50 mg/325 mg/40 mg
81-319/017	Pyrazinamide Tablets, USP 500 mg
40-109/002	Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg
81-226/004	Hydrocodone Bitartrate and Acetaminophen Elixir, 5 mg/500 mg per 15 mL
89-557/004	Hydrocodone Bitartrate and Acetaminophen Elixir, 5 mg/500 mg per 5 mL
81-118/001	Isoniazid Syrup, USP 50 mg/5 mL
81-051/015	Hydrocodone Bitartrate and Acetaminophen Elixir, 7.5 mg/500 mg per 15 mL
40-090/001	Isoniazid Tablets, USP 100 mg & 300 mg
89-008/046	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg
89-271/037	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/500 mg
89-699/026	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5 mg/500 mg
89-697/003	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/500 mg (blue)
89-689/038	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5 mg/650 mg
81-223/017	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/650 mg
81-070/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (gray/black)
81-067/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (gray/lavender)
81-068/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (yellow/orange)
81-096/004	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/30 mg
89-698/015	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 2.5 mg/500 mg
81-069/005	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (blue/aqua)

81-095/004	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/15 mg
89-450/008	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL
81-097/005	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/60 mg
89-363/004	Acetaminophen and Codeine Phosphate Tablets USP, 650 mg/60 mg
89-231/025	Acetaminophen and Codeine Phosphate Tablets USP, 650 mg/30 mg
89-238/013	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg
89-244/018	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg

cc: ANDA #s Attached List
Division Files
Field Copy
HFD-82
HFD-210/B.Poole

Endorsements:

HFD-647/ MPSelvam/ 6/12/1998
HFD-647/ UVVenkataram/6/12/98
HFD-647/TAmes/6/14/98
FT/njg/6/15/98
X:\wpfile\branch7\Selvam\40109s02.LMS
x:\new\firmsam\mikart\ltrs&rev\40109s02.apf
APPROVED

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11/31/98

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7/31/98

APPEARS THIS WAY
ON ORIGINAL

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

81-051/ S-015

CHEMISTRY REVIEW(S)

**OFFICE OF GENERIC DRUGS
REVIEW OF SUPPLEMENT TO
ABBREVIATED NEW DRUG APPLICATION**

1. ANDA NUMBER

40-109 and attached list of Mikart Supplements

2. NAME AND ADDRESS OF APPLICANT

Mikart, Inc.,
1750, Chattahoochee Ave, NW
Atlanta, GA-30318

3. PURPOSE OF AMENDMENT/SUPPLEMENT

These (Global) Supplements provide for an additional

4. DATE(S) OF SUBMISSION(S)

January 6, 1998- Original submissions

5. PHARMACOLOGICAL CATEGORY

See the attachment

6. TRADE NAME

See the attachment

7. NONPROPRIETARY NAME

See the attachment

8. DOSAGE FORM

See the attachment

9. POTENCY

See the attachment

10. RX OR OTC

See the attachment

11. RELATED IND/NDA/DMF

N/A

12. STERILIZATION

N/A

13. LABELING

Review Status: N/A

14. BIOEQUIVALENCY STATUS

Review Status: N/A

15. ESTABLISHMENT INSPECTION

Review Status: Acceptable; CDER Establishment Evaluation Report, 6/11/1998 based on profile.

16. COMPONENTS, COMPOSITION, MANUFACTURING & CONTROLS

No changes in Components, Composition, manufacturing or Controls proposed.

17. PACKAGING

Review Status: N/A

18. STABILITY

Review Status: N/A

19. REMARKS AND CONCLUSION

Supplements are Approved

20. ORDER OF REVIEW:

The application submissions covered by this review were taken in the date order of receipt

If no, explain reason(s) below:

New reviewer in training

SPOT? _____

If yes, complete form

21. REVIEWER AND DATE COMPLETED :

Mouna P.Selvam, Ph.D., / 12, June 1998

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APPLICATION NUMBER:

81-051/S-015

**ADMINISTRATIVE
DOCUMENTS**

5-015 81-

E L E C T R O N I C M A I L M E S S A G E

Date: 16-Jan-1998 03:57pm EST
From: Kassandra Sherrod
 SHERRODK
Dept: HFD-617 MPN2 113
Tel No: 301-827-5849 FAX 301-594-3839

8 addressees

C: 9 addressees

Subject: Mikart, Inc. Submits Multiple Supplements

On January 6, 1998, Mikart Inc. submitted 34 supplements to multiple applications to provide for an additional

These supplements may be reviewed as a "GLOBAL". The applications affected are as follows:

ANDA	DRUG PRODUCT	CHEMIST
BRANCH 3		
74-028/008	Amanatadine Hydrochloride Syrup USP,	Kang
	50 mg/5 mL	
40-062/002	Methazolamide Tablets USP, 25 mg, 50 mg	Nashed
BRANCH 5		
40-085/011	Butalbital, Acetaminophen, and Caffeine Langowski	
	Capsules, 50 mg/500 mg/40 mg	
89-987/006	Butalbital and Acetaminophen Tablets,	"
	50 mg/325 mg	
89-988/005	Butalbital and Acetaminophen Tablets,	"
	50 mg/650 mg	
89-451/031	Butalbital, Acetaminophen and Caffeine	Brown, R.
	Tablets, USP 50 mg/500 mg/40 mg	
89-007/035	Butalbital, Acetaminophen and Caffeine	"
	Capsules, 50 mg/325 mg/40 mg	
89-175/031	Butalbital, Acetaminophen and Caffeine	"
	Tablets, USP 50 mg/325 mg/40 mg	
BRANCH 6		
81-319/017	Pyrazinamide Tablets, USP 500 mg	Gregory
40-109/002	Acetaminophen, Caffeine and	"

	Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg	
81-226/004	Hydrocodone Bitartrate and Acetaminophen Elixir, 5 mg/500 mg per 15 mL	"
89-557/004	Hydrocodone Bitartrate and Acetaminophen Elixir, 5 mg/500 mg per 5 mL	"
81-118/001	Isoniazid Syrup, USP 50 mg/5 mL	"
81-051/015	Hydrocodone Bitartrate and Acetaminophen Elixir, 7.5 mg/500 mg per 15 mL	"
40-090/001	Isoniazid Tablets, USP 100 mg & 300 mg	Basaran
89-008/046	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg	Tang
89-271/037	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/500 mg	"
89-699/026	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5 mg/500 mg	"
89-697/003	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/500 mg (blue)	"
89-689/038	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5 mg/650 mg	"
81-223/017	Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/650 mg	"
81-070/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (gray/black)	"
81-067/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (gray/lavender)	"
81-068/006	Hydrocodone Bitartrate and Acetaminophen Capsules, 5 mg/500 mg (yellow/orange)	"
81-096/004	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/30 mg	"
89-698/015	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 2.5 mg/500 mg	"
81-069/005	Hydrocodone Bitartrate and Acetaminophen Shostak Capsules, 5 mg/500 mg (blue/aqua)	"
81-095/004	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/15 mg	"
89-450/008	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL	"
81-097/005	Acetaminophen, Aspirin and Codeine Phosphate Capsules, 150 mg/180 mg/60 mg	"
89-363/004	Acetaminophen and Codeine Phosphate Tablets" USP, 650 mg/60 mg	
89-231/025	Acetaminophen and Codeine Phosphate Tablets" USP, 650 mg/30 mg	
89-238/013	Acetaminophen and Codeine Phosphate Tablets" USP, 300 mg/30 mg	
89-244/018	Acetaminophen and Codeine Phosphate Tablets" USP, 300 mg/60 mg	

The majority of these supplements are assigned to branch 6. Therefore, they should be reviewed by a chemist in that branch as they appear on the queue.

APPEARS THIS WAY
ON ORIGINAL

**CENTER FOR DRUG
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RESEARCH**

APPLICATION NUMBER:

81-051/ S-015

CORRESPONDENCE



NDA NO. 81.051 REF. NO. SC 015
NDA SUPPL FOR

January 6, 1998

Mr. Douglas Sporn, 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: Multiple supplements for an additional

ANDAs included in this submission:

ANDA #	Product Name
40-062	Methazolamide Tablets USP 25mg & 50mg
40-085	Esgic Plus (Butalbital, Acetaminophen, and Caffeine Capsules 50mg/500mg/40mg)
40-090	Isoniazid Tablets USP 100mg & 300mg
40-109	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Capsules 356.4 mg / 30mg / 16mg
74-028	Amantadine Hydrocodone Syrup USP 50mg per 5mL
81-051	Hydrocodone Bitartrate and Acetaminophen Elixir 7.5mg / 500mg per 15mL
81-067	Hydrocodone Bitartrate and Acetaminophen Capsules 5mg / 500mg (gray / lavender)
81-068	Hydrocodone Bitartrate and Acetaminophen Capsules 5mg / 500mg (yellow / orange)
81-069	Hydrocodone Bitartrate and Acetaminophen Capsules 5mg / 500mg (blue / aqua)
81-070	Hydrocodone Bitartrate and Acetaminophen Capsules 5mg / 500mg (gray / black)
81-095	Acetaminophen, Aspirin, and Codeine Phosphate Capsules 150mg / 180mg / 15mg
81-096	Acetaminophen, Aspirin, and Codeine Phosphate Capsules 150mg / 180mg / 30mg
81-097	Acetaminophen, Aspirin, and Codeine Phosphate Capsules 150mg / 180mg / 60mg
81-118	Isoniazid Syrup USP 50mg / 5mL
81-223	Hydrocodone Bitartrate and Acetaminophen Tablets USP 10mg / 650mg
81-226	Hydrocodone Bitartrate and Acetaminophen Elixir 5mg / 500mg per 15mL
81-319	Pyrazinamide Tablets USP 500mg
89-007	Butalbital, Acetaminophen, and Caffeine Capsules 50mg / 325mg / 40mg
89-008	Hydrocodone Bitartrate and Acetaminophen Capsules 5mg / 500mg (white / white)
89-175	Butalbital, Acetaminophen, and Caffeine Tablets USP 50mg / 325mg / 40mg
89-231	Acetaminophen and Codeine Phosphate Tablets USP 650mg / 30mg
89-238	Acetaminophen and Codeine Phosphate Tablets USP 300mg / 30mg
89-244	Acetaminophen and Codeine Phosphate Tablets USP 300mg / 60mg
89-271	Hydrocodone Bitartrate and Acetaminophen Tablets USP 5mg / 500mg
89-363	Acetaminophen and Codein Phosphate Tablets USP 650 mg / 60mg
89-450	Acetaminophen and Codein Phosphate Oral Solution USP 120mg / 12mg per 5mL
89-451	Butalbital, Acetaminophen, and Caffeine Tablets USP 50mg / 500mg / 40mg
89-557	Hydrocodone Bitartrate and Acetaminophen Elixir 5mg / 500mg per 5mL
89-689	Hydrocodone Bitartrate and Acetaminophen Tablets USP 7.5mg / 650mg
89-697	Hydrocodone Bitartrate and Acetaminophen Tablets USP 5mg / 500mg (blue)
89-698	Hydrocodone Bitartrate and Acetaminophen Tablets USP 2.5mg / 500mg

RECEIVED

JAN 13 1998

GENERIC DRUGS
Mikart, Inc. is a manufacturer of generic drugs.
1750 Chattahoochee Avenue • Atlanta, Georgia 30318
404-351-4510 • Fax 404-350-0432

Mr. Douglas Sporn
January, 1998
Page 2

89-699	Hydrocodone Bitartrate and Acetaminophen Tablets USP 7.5mg / 500mg
89-987	Butapap Tablets 50mg / 325mg (Butalbital and Acetaminophen Tablets)
89-988	Butapap Tablets 50mg / 650mg (Butalbital and Acetaminophen Tablets)

Dear Mr. Sporn:

Mikart would like to supplement the above applications to add an additional _____
_____. Currently, Mikart and _____
_____ are the designated facilities for _____ Mikart
performs methods I & V, and _____ At this time, Mikart
would like to designate _____ to also, if necessary, be
able to _____ requiring
such testing.

We are aware that this change requires prior approval by the FDA in order to be implemented, in
accordance with 21 CFR 314.70 (b) (2) (vi). Following approval of these applications, Mikart
will add _____ as a designated _____
_____ specification sheet. The revised specification sheets will be submitted in
the annual report.

Thank you for your cooperation in the review of these supplements.

Sincerely,



Cerie B. McDonald
Executive Vice-President

CBM/lac