

**CENTER FOR DRUG  
EVALUATION AND  
RESEARCH**

**Approval Package for:**

**APPLICATION NUMBER:**

**81-051/S-018**

Trade Name: Lortab Elixir

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

Sponsor: Mikart, Inc.

Approval Date: August 13, 2002

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**APPLICATION NUMBER:**

**81-051/S-018**

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Reviews / Information Included in this ANDA Review.

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Approval Letter(s)	X
Tentative Approval Letter(s)	
Final Printed Labeling	
CSO Labeling Review(s)	
Medical Officer Review(s)	
Chemistry Review(s)	
Microbiology Review(s)	
Bioequivalence Review(s)	
Administrative Document(s)	
Correspondence	

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**81-051/S-018**

**APPROVAL LETTER**

ANDA See attachment

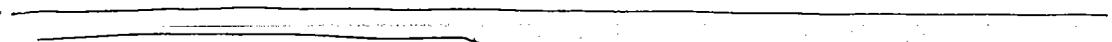
AUG 13 2002

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,

*Jos*

*FSI*

*8/13/02*

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

**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