

**CENTER FOR DRUG  
EVALUATION AND  
RESEARCH**

**Approval Package for:**

**APPLICATION NUMBER:**

**81-051/S-020**

Trade Name: Lortab Elixir

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

Sponsor: Mikart, Inc.

Approval Date: December 12, 2002

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**APPLICATION NUMBER:**

**81-051/S-020**

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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	X
CSO Labeling Review(s)	
Medical Officer Review(s)	
Chemistry Review(s)	
Microbiology Review(s)	
Bioequivalence Review(s)	
Administrative Document(s)	
Correspondence	X

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**APPROVAL LETTER**

ANDA 81-051/S-020

DEC 12 2002

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

Dear Madam:

This is in reference to your supplemental new drug application dated November 20, 2002, submitted pursuant to 21 CFR 314.70(c) "Special Supplement - Changes Being Effected" regarding your abbreviated new drug application for Lortab® Elixir (Hydrocodone Bitartrate and Acetaminophen Oral Solution), 7.5 mg/500 mg per 15 mL.

The supplemental application provides for revised container labels, carton and package insert labeling, and patient information leaflet to incorporate changes requested in the Agency's correspondences of April 17, 2001, August 30, 2001, and May 20, 2002.

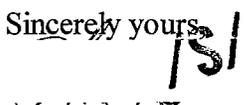
We have completed the review of this supplemental application and it is approved. Please note that you included the insert labeling revised October 2001, as your proposal for the side-by-side comparison while the final printed insert labeling was revised May 2002. Please be advised that you should use the most currently revised version for the side-by-side comparison.

We remind you that it is your responsibility to inform us of the date on which these changes will be implemented. We refer you to 21 CFR 314.70(c) for further guidance.

In addition, please be reminded 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,

  
Wm Peter Rickman

Director

Division of Labeling and Program Support

Office of Generic Drugs

Center for Drug Evaluation and Research

u 2/ 12/12/02

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**FINAL PRINTED LABELING**



**PHARMACIST:** Dispense in a tight, light-resistant container with a child-resistant closure.

NDC 50474-909-16 1 Pint (473 mL)

**USUAL DOSAGE:** See package insert for complete dosage recommendations.

Store at controlled room temperature, 15-30°C (59-86°F) [see USP].

**LORTAB<sup>®</sup> ELIXIR**

**WARNING:** May be habit forming.

**WARNING:** Keep this and all medications out of the reach of children.

**HYDROCODONE BITARTRATE AND ACETAMINOPHEN ORAL SOLUTION**  
**7.5 mg/500 mg per 15 mL**

Lot No.:  
Exp. Date:

Contains:	Per 5 mL	Per 15 mL
Hydrocodone Bitartrate .....	2.5 mg	7.5 mg
Acetaminophen .....	167 mg	500 mg
Alcohol .....	7%	7%



3 50474-909-16 4

Manufactured for  
**UCB Pharma, Inc.**  
Smyrna, GA 30080  
by **Mikart, Inc.**  
Atlanta, GA 30318

**Rx only**

Rev. 2E 10/2001  
P/N 1003813

540A16

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EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER:**

**81-051/ S-020**

**CORRESPONDENCE**



November 20, 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 Park Place  
Rockville, MD 20855-2773

Reference: ANDA 81-051  
Lortab® Elixir  
(Hydrocodone Bitartrate and Acetaminophen Oral Solution 7.5 mg/500 mg per 15 mL)

NDA NO. 81-051 REF. NO. SL-0201A  
NDA SUPP FOR Labeling Rev.

**SPECIAL SUPPLEMENT – CHANGES BEING EFFECTED**

Dear Mr. Buehler:

Mikart would like to supplement the above identified Abbreviated New Drug Application, pursuant to 21 CFR 314.70 in that we are seeking approval for revisions to container, insert and carton labeling per Agency fax dated May 20, 2002 and Agency letters dated August 30, 2001 and April 17, 2001 (copies enclosed).

The following information, per 21 CFR 314.94(a)(8), is included in support of this supplemental application:

1. Side-by-side comparison of proposed labeling with currently approved labeling.
2. Twelve of each of the following labeling pieces enclosed in labeled manila envelope.  
Carton, 1 pint container label, professional insert, and patient information leaflet.

In advance, we thank you for your efforts and cooperation in the review of this material. Should you have any questions, please do not hesitate to contact Ms. Judy Howard, Vice-President, Scientific Affairs at (404) 351-4510.

Sincerely,

Cerie B. McDonald  
President

CBM:jmw

RECEIVED

NOV 22 2002

OGD / CDER