

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

81-051/S-014

Trade Name: Lortab Elixir

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

Sponsor: Mikart, Inc.

Approval Date: July 24, 1996

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APPLICATION NUMBER:

81-051/S-014

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APPLICATION NUMBER:

81-051/S-014

APPROVAL LETTER

ANDA 81-051/S-014

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

JUL 24 1996

Dear Madam:

This is in reference to your supplemental new drug application dated June 28, 1996, submitted pursuant to 21 CFR 201.57 (c) (Special Supplement - Changes Being Effected) 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 revised carton labeling for the 1 ounce package size (6's).

We have reviewed 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,

/s/ 7-24-96
Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 81-051/S-014
Dup/Division File
HFD-613/CHoppes/AVezza/ (no cc:) */s/* 7/17/96
HFD-600/RF */s/* 7-24-96
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Approval Letter - Single Supplement

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FINAL PRINTED LABELING

LORTAB ELIXIR 

LORTAB ELIXIR 

HYDROCODONE* BITARTRATE AND ACETAMINOPHEN ELIXIR
7.5 mg/500 mg per 15 mL *Warning: May be habit forming

Six 1 fl oz bottles

Caution: Federal law prohibits dispensing without prescription.

APPROVED

JUL 24 1996

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LORTAB ELIXIR 

LORTAB[®] ELIXIR

HYDROCODONE^{*} BITARTRATE AND ACETAMINOPHEN ELIXIR
7.5 mg/500 mg per 15 mL. ^{*}Warning: May be habit forming

Usual Dosage: See package insert for complete dosage recommendations.

Storage: Store at controlled room temperature, 15°-30°C (59°-86°F).

SAMPLE—Not for Sale. Package not child-resistant.

Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Lot:

Exp:



17722010



Pharma

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

MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

June 28, 1996

NDA NO. 81051 REF. NO. 5L014

NDA SUPPL FOR Labeling Revision

**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**

RECEIVED

JUL 08 1996

GENERIC DRUGS

Re: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen Elixir
7.5 mg/500 mg per 15 mL
SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

Dear Mr. Sporn:

Mikart is implementing the use of a revised version of the carton labeling for the 1 oz. sample bottles of this product. The carton has been revised to add the warning, "_____"

This has been done in accordance with 21 CFR 314.70 (c) (2) (i) in order to strengthen the same warning already included on the 1 oz. container label. These trays will be implemented no sooner than July 10, 1996.

As required for a supplement of this kind, we are enclosing 12 copies of final printed carton labeling, three of which are mounted. The other nine copies are included in a separate envelope.

Thank you for your cooperation in the review of this material. Please do not hesitate to contact us should you require any additional information.

Sincerely,

C. B. Marshall

Cerie B. McDonald
Executive Vice-President

CBM/sw

Enclosures