CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

89-557/S-009

Generic Name:	Hydrocodone bitartrate and Acetaminophen Elixir 7.5mg/500mg per mL
Sponsor:	Mikart, Inc.
Approval Date:	July 26, 2004

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APPLICATION NUMBER:

89-557/S-009

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Reviews / Information Included in this ANDA Review.

Approval Letter(s)	X
Tentative Approval Letter(s)	
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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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APPLICATION NUMBER:

89-557/S-009

APPROVAL LETTER

89557 11.

509

ANDAs See attached

Mikart, Inc.
Attention: Jason Waldroup
1750 Chattahoochee Ave.
Atlanta, GA 30318

JUL 26 2004

Dear Sir:

This is in reference to your supplemental new drug applications, dated June 18, 2004, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications as shown in the attached list.

These supplemental applications, submitted as a "Changes Being Effected in 30 Days", provides for the revision of the testing specifications and procedures for Sorbitol Solution USP to comply with USP 27, Supplement 1.

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,

R. C. Adams for

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

ANDA Number	Drug Product
89-450/S-011	Acetaminophen and Codeine Phosphate Oral Solution USP
74-028/S-011	Amantadine Hydrochloride Syrup USP
74-759/S-005	Aminocaproic Acid Oral Solution USP
81-051/S-022	Hydrocodone Bitartrate and Acetaminophen Oral Solution
81-226/S-007	Hydrocodone Bitartrate and Acetaminophen Elixir
40-458/S-004	Carbinoxamine Maleate Oral Solution
40-482/S-003	Hydrocodone Bitartrate and Acetaminophen Oral Solution USP
75-039/S-003	Oxybutyin Chloride Syrup USP
89-557/S-009	Hydrocodone Bitartrate and Acetaminophen Elixir
40-251/S-003	Trihexyphenidyl Hydrochloride Elixir USP
40-387/S-005	Butalbital, Acetaminophen and Caffeine Oral Solution

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APPLICATION NUMBER:

89-557/S-009

CORRESPONDENCE

11.1

Mikart

ORIGINAL

June 18, 2004

NDA NO. 89-557 REF. NO. SCS-009-AT
NDA SUPPL FOR Control-Rev.

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 Place
Rockville, MD 20855-2773

Re: ANDA 89-557
Hydrocodone Bitartrate and Acetaminophen Elixir
5 mg/500 mg per 15 mL

SUPPLEMENT – CHANGES BEING EFFECTED IN 30 DAYS

Dear Mr. Buehler:

Mikart is supplementing the referenced application to revise the testing specifications and procedure for Sorbitol Solution USP. To comply with USP 27, Supplement 1, the following tests are being deleted: [redacted], Method I; and the following tests are being added: [redacted]. Additionally, the test procedures for Identification A, Residue on Ignition, Reducing Sugars and Assay have been revised to comply with USP 27, Supplement 1. Additionally, the testing for Limit of [redacted] will be performed by [redacted] which is previously designated as the test facility for certain [redacted] tests.

Per the Draft Guidance "Changes to an Approved NDA or ANDA" (April 2004), section VIII.C.1.e., we are submitting this change as a CBE-30 Supplement. The revised specification sheet, revised test procedure, a copy of the applicable USP reference, and a revised list of designated facilities is provided. These changes will be implemented no earlier than July 26, 2004.

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 me at (404) 351-4510 extension 236.

Sincerely,

Jason Waldroup

Jason Waldroup
Manager, Regulatory Affairs

Mikart, Inc. • Pharmaceutical Manufacturers
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404-351-4510 • Fax 404-350-0432