ANDA 40-692

APR 27 2006

Mikart, Inc.
Attention: Pieter Groenewoud
Vice President, R&D
1750 Chattahoochee Ave, NW
Atlanta, GA 30318

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Oxycodone and Acetaminophen Tablets USP, 10 mg/400 mg.

Reference is also made to your amendment dated April 11, 2006. Reference is also made to the ANDA Suitability Petition (Docket No. 00P-1271/CP1) approved on September 9, 2000, under section 505 (j)(2)(c) of the Act. This petition allowed you to submit this ANDA to provide for a drug product that differs in strength from the reference listed drug product (RLD). Specifically, the acetaminophen component of the drug product proposed in your ANDA differs from that contained in the RLD, Percocet Tablets, 10 mg/650 mg of Endo Pharmaceuticals, Inc. (i.e., 400 mg v. 650 mg).

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The drug product, Oxycodone and Acetaminophen Tablets USP, 10 mg/400 mg, can be expected to have the same therapeutic effect as that of an equivalent dose of the listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Lumpkin for
4/27/2006

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 40-692
Division File
Field Copy
HFD-610/R. West
HFD-205
HFD-610/Orange Book Staff

Approved Electronic Labeling Located at:

**Satisfactory in FPL as of 4/11/06 submission**
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**PROFESSIONAL PACKAGE INSERT LABELING**

**Satisfactory in FPL as of 4/11/06 submission**
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Endorsements:
HFD-640/D.Roselle/ 4/26/06
HFD-647/G.Smith/ 4/26/06
HFD-617/T.Palat/03/15/06 4/26/06
HFD-613/C.Park/ for 4/26/06
HFD-613/L.Golson/ for 4/26/06

CMC on 4/26/06 RCA

Robert Lyndon 4/27/2006

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F/T by rad4/25/06

APPROVAL