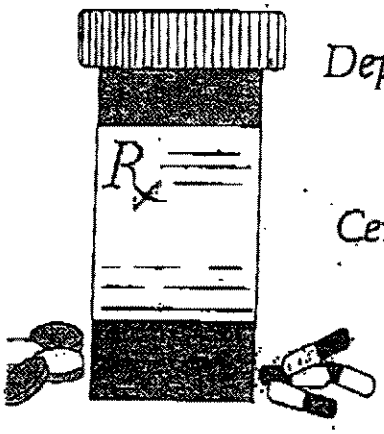
FAX COVER SHEET



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Rockville, Maryland

Date: 11/27/07

To: Candis Edwards

Phone: 631-65-67538 x183 Fax: 631 299 3995

From: Simon Eng

Phone: (301) 827-5848 FAX: (301) 594-0180

Number of pages: 4
(Including Cover Sheet)

Comments: Congrats !
40778 has been approved !

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 40-778

Interpharm, Inc.
Attention: Candis Edwards, Senior Vice President
Regulatory Affairs/Compliance
75 Adams Avenue
Hauppauge, NY 11788

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 3, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxycodone and Acetaminophen Tablets USP, 10 mg/325 mg.

Reference is also made to your amendments dated October 11, 2006; and January 17, February 16, June 19, and November 26, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Oxycodone and Acetaminophen Tablets USP, 10 mg/325 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Percocet Tablets, 10 mg/325 mg, of Endo Pharmaceuticals, Inc. 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 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,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
11/27/2007 08:57:04 AM
for Gary Buehler