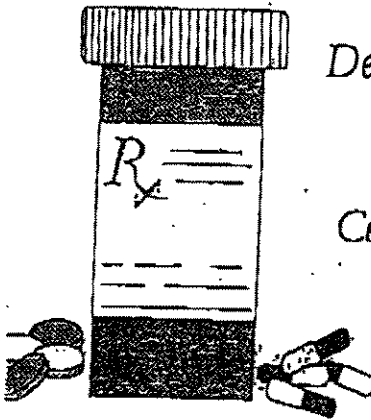
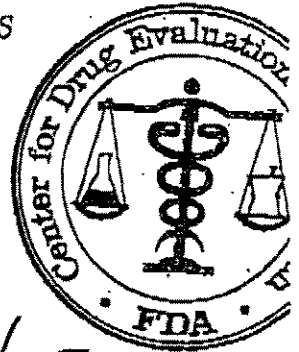


# FAX COVER SHEET



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: 11/27/07To: CandisPhone: 631 6567538X183 Fax: 631 2993995From: Simon Eng

Phone: (301) 827-5848

FAX: (301) 594-0180

Number of pages: \_\_\_\_\_  
(Including Cover Sheet)Comments: Congrats!40777 has been approved!

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail.

Thank you.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

ANDA 40-777

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, 5 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, 5 mg/325 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Percocet Tablets, 5 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.**  
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/s/

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Robert L. West  
11/27/2007 08:57:37 AM  
for Gary Buehler