ANDA 78-596

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Interpharm, Inc. TEL: 631-656-7538

ATTN: Candis Edwards FAX: 631-299-3995

FROM: Dat Doan PROJECT MANAGER: (240) 276-8573

Dear Madam: 5 pages

This facsimile is in reference to your abbreviated new drug application dated November 7, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Metformin Hydrochloride Extended-release Tablets, 500 mg and 750 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-596

Interpharm, Inc.
Attention: Candis Edwards
Senior V.P., Regulatory Affairs
75 Adams Ave.
Hauppauge, NY 11788

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 7, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metformin Hydrochloride Extended-Release Tablets, 500 mg and 750 mg.

Reference is also made to your amendments dated April 23, June 8, June 14, August 31, September 5, November 2, December 12, and December 28, 2007. We also acknowledge receipt of your correspondence dated May 31, 2007, addressing the patent issues associated with this ANDA.

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 Metformin Hydrochloride Extended-Release Tablets, 500 mg and 750 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Glucophage XR Extended-Release Tablets, 500 mg and 750 mg, respectively, of Bristol Myers Squibb Company. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug (RLD) upon which you have based your ANDA, Glucophage XR Tablets, 500 mg and 750 mg, of Bristol-Myers Squibb Company, is subject to periods of patent protection. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"),

U.S. Patent Nos. 6,475,521 (the '521 patent) and 6,660,300 (the '300 patent) are both scheduled to expire on March 19, 2018.

Your ANDA contains paragraph IV certifications to the '521 and the '300 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Metformin Hydrochloride Extended-release Tablets, 500 mg and 750 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action was brought against Interpharm, Inc. (Interpharm) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Interpharm complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of either patent was brought against Interpharm within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii) of the Act.

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
1/3/2008 02:07:00 PM
for Gary Buehler