DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-642/S-005, S-006, S-007 and S-008

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 supplemental new drug applications dated February 23, 2006 (S-005 and S-006) and March 17, 2006 (S-007 and S-008), submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), regarding your abbreviated new drug application for Repraxain Tablets (Hydrocodone Bitartrate and Ibuprofen Tablets), 5 mg/200 mg and 7.5 mg/200 mg.

Reference is also made to your amendments dated March 17, October 26, and December 5, 2006; and March 22, 2007.

These supplemental applications provide for:

S-005: An additional strength - Repraxain Tablets 2.5 mg/200 mg (Hydrocodone Bitartrate and Ibuprofen Tablets, 2.5 mg/200 mg);

S-006: Updated labeling for the 2.5 mg/200 mg strength;

S-007: An additional strength – Repraxain Tablets 10 mg/200 mg (Hydrocodone Bitartrate and Ibuprofen Tablets, 10 mg/200 mg; and

S-008: Updated labeling for the 10 mg/200 mg strength.

Reference is also made to the ANDA Suitability Petitions (2001P-0442/CP1 and 2005P-0180/CP1) submitted on September 28, 2001, and May 11, 2005, respectively, under Section 505(j)(2)(c) of the Act regarding Hydrocodone Bitartrate and Ibuprofen Tablets, 10 mg/200 mg and 2.5 mg/200 mg. These petitions requested the agency to make determinations that your supplemental applications for Hydrocodone Bitartrate and Ibuprofen Tablets,

2.5 mg/200 mg, and Hydrocodone Bitartrate and Ibuprofen Tablets, 10 mg/200 mg were suitable for filing as an ANDA. These determinations were necessary because each of these strengths is not included in the labeling of the reference listed drug product upon which your ANDA is based. The agency reviewed the Suitability Petitions and determined that the changes in tablet strength you have requested are the type of changes that are authorized under the Act.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that your Hydrocodone Bitartrate and Ibuprofen Tablets 2.5 mg/200 mg and your Hydrocodone Bitartrate and Ibuprofen Tablets 10 mg/200 mg are safe and effective for use as recommended in the submitted labeling. Accordingly, these supplemental applications are approved, effective on the date of this letter. The Division of Bioequivalence has determined that your Hydrocodone Bitartrate and Ibuprofen Tablets, 2.5 mg/200 mg, and your Hydrocodone Bitartrate and Ibuprofen Tablets, 10 mg/200 mg, can be expected to have the same therapeutic effect as that of the reference 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.

The RLD upon which you have based your supplemental ANDAs, Vicoprofen Tablets, 7.5 mg/200 mg, of Abbott Laboratories, 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 No. 6,348,216 (the '216 patent) and 6,599,531 (the '531 patent) are scheduled to expire on June 10, 2017.

Your ANDA contains paragraph IV certifications to the '216 and '531 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '216 and '531 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of your Hydrocodone Bitartrate and Ibuprofen Tablets, 2.5 mg/200 mg or 10 mg/200 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 action was brought against Interpharm, Inc. (Interpharm) for infringement of the '216 and '531 patents that were the subjects of your 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 was brought against Interpharm within the statutory 45-day period, which action

would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, the agency has concluded that Interpharm was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the ‘216 and ‘531 patents for Hydrocodone Bitartrate and Ibuprofen Tablets, 2.5 mg/200 mg. Therefore, with this approval, the agency has determined that Interpharm is eligible for 180 days of generic drug exclusivity for Hydrocodone Bitartrate and Ibuprofen Tablets, 2.5 mg/200 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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

Post-marketing reporting requirements for this abbreviated application 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 for the new strength 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 20705-1266

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.

The materials submitted are being retained in our files.

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
10/19/2007 08:02:50 AM
for Gary Buehler