DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-219

Watson Laboratories, Inc.
Attention: Ernest Lengle, Ph.D.
Executive Director, Regulatory Affairs
311 Bonnie Circle
Corona CA 92880

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 23, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Irinotecan Hydrochloride Injection, 20 mg/mL, packaged in 40 mg/2 mL and 100 mg/5 mL single-dose vials.

Reference is also made to the tentative approval letter issued by this office on May 4, 2007, and to your amendment dated November 7, 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 Irinotecan Hydrochloride Injection, 20 mg/mL, to be bioequivalent and therefore, therapeutically equivalent to the reference listed drug (RLD), Camptosar Injection, 20 mg/mL, of Pfizer, Inc.

The RLD upon which you have based your ANDA, Pfizer's Camptosar Injection, 20 mg/mL, 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. 6,403,569 (the '569 patent) and 6,794,370 (the '370 patent) are scheduled to expire (with pediatric exclusivity added) on October 28, 2020, and November 1, 2020, respectively.

As noted in our tentative approval letter, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '569 and '370 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Irinotecan Hydrochloride Injection, 20 mg/mL, 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 Watson Laboratories, Inc. (Watson) for infringement of the '569 or '370 patents. You have notified the Agency that Watson complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '569 or '370 patents was brought against Watson 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).[1]

FDA has determined that Watson was the first applicant to submit a substantially complete ANDA containing a paragraph IV certification to a listed patent for Irinotecan Hydrochloride Injection, 20 mg/mL. Therefore, Watson was eligible for 180-day generic drug exclusivity under section 505(j)(5)(B)(iv) of the Act for this drug product. However, due to the following set of circumstances, Watson's eligibility for 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(IV).

Your ANDA was received by the agency on July 26, 2004, and granted tentative approval on May 4, 2007. The ANDA filing date plus 30 months was January 26, 2007; therefore, this ANDA was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). We also have determined that the requirements for approval of this ANDA were not changed or reviewed after your ANDA was filed, nor was a related citizen petition submitted that would extend the 30-month period as described in section 505(q)(1)(G) of the Act. We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Irinotecan Hydrochloride Injection, 20 mg/mL, was forfeited by Watson.

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.

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[1] Your paragraph IV certification to the '370 patent was submitted in an amendment to your ANDA, as this patent was not listed until after the submission of your ANDA. Therefore, the 30-month stay provision of the Act would not have applied had a suit on the '370 patent been initiated within 45 days of notification. See section 505(j)(5)(B)(iii) of the Act.

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
2/20/2008 07:51:47 AM
for Gary Buehler