DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201089

Watson Laboratories, Inc. - Florida
Attention: Janet Vaughn
Director, Regulatory Affairs
1945 West Corporate Lakes Blvd., Suite B
Weston, FL 33331

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 24, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Diclofenac Sodium and Misoprostol Delayed-Release Tablets, 50 mg/0.2 mg and 75 mg/0.2 mg.

Reference is also made to your amendments dated July 30, and November 10, 2010; September 16, and September 28, 2011; March 7, March 20, April 24, May 15, and May 29, 2012.

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 Diclofenac Sodium and Misoprostol Delayed-Release Tablets, 50 mg/0.2 mg and 75 mg/0.2 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Arthrotec Delayed-release Tablets 50 mg/0.2 mg and 75 mg/0.2 mg, respectively, of G.D. Searle LLC (Searle).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Medium: 0.1 N HCl for acid stage of Diclofenac; 750 mL 0.1 N HCl + 250 mL 0.2 M Phosphate Buffer pH 6.8 for buffer stage of Diclofenac.
Water (deaerated) for Misoprostol.

Volume: 750 mL for acid stage of Diclofenac;
1000 mL for buffer stage of Diclofenac.
500 mL for Misoprostol.

Temperature: 37°C ± 0.5°C

USP Apparatus: II (Paddle) for both Diclofenac and Misoprostol.

Rotation Speed: 100 rpm for Diclofenac;
50 rpm for Misoprostol.

Specifications: NMT 10% Diclofenac dissolved in 120 minutes (acid stage); and
NLT 75% (Q) Diclofenac dissolved in 45 minutes (buffer stage).
NLT 75% (Q) Misoprostol dissolved in 20 minutes.

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" when there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Searle's Arthrotec Delayed-release Tablets, is subject to a period 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. 5,601,843 (the '843 patent), is scheduled to expire on February 11, 2014.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '843 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Diclofenac Sodium and Misoprostol Delayed-Release Tablets, 50 mg/0.2 mg and 75 mg/0.2 mg, under this ANDA. You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of

section 505(j)(2)(B) of the Act, and that no action for infringement 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).

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) 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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in

the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

07/09/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.