DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200675

Watson Laboratories, Inc.
Attention: Janie M. Gwinn
Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 13, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lidocaine Patch, 5%.

Reference is also made to your amendments dated January 6, January 13, March 12, June 25, July 10, October 11, and October 26, 2010; April 30, July 14, September 23, October 4, and December 22, 2011; and January 13, March 23, March 26, March 30, April 5, April 24, April 26, May 9, June 13, and June 14, 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 Lidocaine Patch, 5%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lidoderm Patch, 5%, of Teikoku Pharma USA, Inc. (Teikoku).

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:

Dissolution Testing should be conducted in 500 mL of Sodium Acetate Buffer, pH 4.0 at 32ºC ± 0.5ºC using USP Apparatus 5 (Paddle over Disk) at 50 rpm. The test product should meet the following "interim" specifications:

Sample Interval	Level 1 (n = 6) Individual (% Drug Release)
10 min.	(b) (4)
20 min.	
30 min.	
60 min.	
120 min.	

These “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” if 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, Teikoku’s Lidoderm Patch 5%, 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. 5,741,510 (the '510 patent) and 5,827,529 (the '529 patent) are scheduled to expire on March 30, 2014, and October 27, 2015, respectively.

Watson Laboratories, Inc. (Watson) is not required to submit a certification to the ‘510 patent because the agency has determined that this patent was late-listed with respect to this ANDA. See 21 CFR 314.94(a)(12)(vi).

With respect to the ‘529 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lidocaine Patch, 5%, under this ANDA. You have notified the agency that Watson complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Watson for infringement of the '529 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Endo Pharmaceuticals Inc., Teikoku Pharma USA, Inc. and Teikoku Seiyaku Co., Ltd. v. Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc., Civil Action No. 1:10-cv-00138-GMS]. You have also notified the agency that the court dismissed this case.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant for Lidocaine Patch, 5%, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Watson may be eligible for 180 days of generic drug exclusivity for Lidocaine Patch, 5%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Watson failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Watson’s eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Watson begins commercial marketing of Lidocaine Patch, 5%, or (b) at any time prior to the expiration of the ‘529 patent if Watson has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
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

08/23/2012

Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.