DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079075

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) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fentanyl Buccal Tablets, 100 mcg, 200 mcg, (b) (4), 400 mcg, 600 mcg and 800 mcg. This ANDA was received on November 13, 2007.

Reference is also made to the tentative approval letter issued by this office on June 22, 2010, and to your amendments dated July 21, October 7, and December 21, 2010.

We have completed the review of this ANDA, including the risk management plan (RMP), 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 insofar as the 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg strengths[1] is **approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Fentanyl Buccal Tablets, 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Fentora Buccal Tablets of Cephalon, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

[1] (b) (4)

The RLD upon which you have based your ANDA, Cephalon's Fentora Buccal Tablets, 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. 6,200,604 (the '604 patent) and 6,974,590 (the '590 patent) are both scheduled to expire on March 26, 2019.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that both patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fentanyl Buccal Tablets, 100 mcg, 200 mcg, (b) (4), 400 mcg, 600 mcg, and 800 mcg, 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 litigation was initiated against Watson for infringement of the '604 and '590 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Cephalon, Inc., and CIMA Labs, Inc. v. Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc., Civil Action No. 08-330]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Fentanyl Buccal Tablets, 100 mcg, 200 mcg, (b) (4), 400 mcg, 600 mcg, and 800 mcg. Therefore, with this approval, Watson may be eligible for 180 days of generic drug exclusivity for Fentanyl Buccal Tablets, 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg. 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 Fentanyl Buccal Tablets, 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg, or (b) at any time prior to the expiration of the last listed 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. Additionally, any proposed change in the RMP must be discussed with FDA prior to institution. FDA will determine whether the proposed change is subject to FDA approval before implementation.

We 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.

Post marketing 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(s) 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.

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/

KEITH O WEBBER
01/07/2011