DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021351/S-008
NDA 021351/S-009

SUPPLEMENT APPROVAL

Watson Pharmaceuticals
Attention: Paul G. Long, R.Ph., M.B.A.
Director, Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Mr. Long:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 21, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OXYTROL (oxybutynin transdermal system), 3.9 mg/day. This supplemental application provides for the revision of the labeling to conform with the requirements of the new Physician Labeling Rule (PLR) format.

We also refer to your sNDA dated and received July 17, 2012. This supplemental application provides for labeling revisions in response to our letter dated June 27, 2012, notifying you of new safety information that we believe should be included in the labeling for OXYTROL. This information pertains to the risk of somnolence and somnolence-related adverse reactions. The agreed upon changes to the proposed language in our June 27, 2012, letter are as follows (additions are noted by underline and deletions are noted by ~~strikethrough~~):

1) Under WARNINGS AND PRECAUTIONS, the following text was added:

   Products containing oxybutynin are (b) (4) associated with anticholinergic central nervous system (CNS) effects. A variety of CNS effects have been reported, including headache, dizziness, and somnolence. Patients should be monitored for signs of anticholinergic CNS effects, particularly after beginning treatment. Advise patients not to drive or operate heavy machinery until they know how Oxytrol affects them. If a patient experiences anticholinergic CNS effects, drug discontinuation should be considered.

2) Under the ADVERSE REACTIONS section, Postmarketing subsection, the following sentence was changed to:

   The following (b) (4) reactions (b) (4) have been (b) (4) identified during post approval use of (b) (4) OXYTROL (b) (4): dizziness and somnolence.

We also acknowledge receipt of your amendments dated March 29, 2012, and September 30, 2012, and refer to your email communication dated October 3, 2012, which conveyed your agreement to our additional revisions to the labeling.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, patient package insert, and Instructions for Use, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, M.D., M.M.Sc.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

HYLTON V JOFFE
10/10/2012