



NDA 202211

NDA APPROVAL

Merck Consumer Care
Attention: Nancy Pierro
Director, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Pierro:

Please refer to your New Drug Application (NDA) dated and received March 26, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxytrol for Women (oxybutynin) transdermal system, 3.9 mg.

We acknowledge receipt of your amendments dated May 23, June 25, August 23, 28 and 30, September 4, 6, 7, and 17, October 1 and 9, November 2, December 3 and 7, 2012, and January 15 and 22, 2013.

This new drug application provides for the use of Oxytrol for Women (oxybutynin) transdermal system for the treatment of overactive bladder in women.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as it is available, but no more than 30 days after it is printed. The final printed labeling (FPL) must be identical to the enclosed labeling, 1-count immediate container (pouch) dated January 15, 2013 and the consumer information leaflet, 4-count carton (representative of the 2-, 8-, and 14-count cartons), 10-count carton, and the 14-count Club Store Backer Card dated January 22, 2013, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 202211.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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.

POSTMARKETING COMMITMENT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

2010-1: To change the text on the backing film of the drug product to a darker ink within one year from the date of this approval letter.

On December 3, 2012, you agreed to change the text on the backing film of the drug product to a darker ink within one year from the date of this approval letter. The supplement supporting this change is therefore due on or before January 25, 2014.

Under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol**,” “**Postmarketing Commitment Final Report**,” or “**Postmarketing Commitment Correspondence**.”

REPORTING REQUIREMENTS

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

EXPIRY DATE

Please note that your drug product has been granted a 24-month expiry.

If you have any questions, please call Melissa Furness, Chief of the Project Management Staff, at (301) 796-0893.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

and

{See appended electronic signature page}

Shaw Chen, M.D., Ph.D.
Deputy Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

Consumer Information Leaflet, Carton and Immediate Container Labeling

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

/s/

JULIE G BEITZ
01/25/2013

SHAW T CHEN
01/25/2013