DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-204 **NDA APPROVAL**

Watson Laboratories, Inc.
Attention: Larry Ventura, DVM, MBA
Associate Director, Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Ventura:

Please refer to your new drug application (NDA) dated March 26, 2008, received March 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gelnique™ (oxybutynin chloride) 10% gel.

We acknowledge receipt of your submissions dated April 25, May 28, July 29, August 27, September 11, October 15 and 31, December 5 and 24, 2008, and January 5, 6, 12, 22 and 23, 2009.

This new drug application provides for the use of Gelnique™ (oxybutynin chloride) 10% gel, for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

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 enclosed content of labeling [21 CFR 314.50(l)] which is identical to the content of labeling in structured product labeling (SPL) format submitted on January 23, 2009. To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit this content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-204**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to those submitted on January 12, 2009, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 (October 2005)*. 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 Carton and Container Labels for approved NDA 22-204**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with Final Printed Labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

We are waiving the pediatric study requirement for ages 0 months to 5 years and 11 months because necessary studies are impossible or highly impracticable. This is because study endpoints are difficult to evaluate in this age group.

We are deferring submission of your pediatric studies for ages 6 years and 0 months to 16 years and 11 months for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81. and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below:

1. Deferred pediatric study(ies) under PREA for the treatment of overactive bladder in the subgroup of pediatric patients with neurologic disease ages 6 to 16 years, 11 months.

   Final Report Submission: August, 2015

Submit final study reports to this NDA. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated "**Required Pediatric Assessments**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package inserts, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more

information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

REPORTING REQUIREMENTS

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Jeannie Roule, Regulatory Health Project Manager, at (301) 796-3993.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

George Benson
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