DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022204/S-004 **SUPPLEMENT APPROVAL**

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

Dear Mr. Ventura:

Please refer to your supplemental New Drug Application (NDA) dated December 20, 2010, received December 22, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GELNIQUE® (oxybutynin chloride) 10% gel.

We also refer to your amendment dated January 12, 2011.

This prior approval supplement provides for the addition of the following changes to the GELNIQUE® labeling as requested in the November 4, 2010, Prior Approval Supplement Request Letter:

In **HIGHLIGHTS:**
Contraindications:

~~Known hypersensitivity to GELNIQUE, including skin hypersensitivity.~~ Known serious hypersensitivity reaction to GELNIQUE, oxybutynin, or to any of components of GELNIQUE (4).

Warnings and Precautions:

(add third bullet) Angioedema: Angioedema has been reported with oral oxybutynin use. If symptoms of angioedema occur, discontinue Gelnique and initiate appropriate therapy. (5.3)

In **FULL PRESCRIBING INFORMATION:**
Contraindications:

~~Known hypersensitivity to GELNIQUE, including skin hypersensitivity.~~ Known serious hypersensitivity reaction to GELNIQUE, oxybutynin, or to any of components of GELNIQUE [see Warnings and Precautions (5.3, 5.4)]

Warnings and Precautions (new Warnings and Precautions 5.3)

> Angioedema requiring hospitalization and emergency medical treatment has occurred with the first or subsequent doses of oral oxybutynin. In the event of angioedema, oxybutynin containing products should be discontinued and appropriate therapy promptly provided.
> (Re-number the remaining Warnings and Precautions in sequential order (e.g., 5.4 Skin Hypersensitivity, 5.5 Skin Transference, 5.6 Flammable Gel)

CONTENT OF LABELING

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission "SPL for approved NDA 022204/S-004."

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 insert 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 insert(s), 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 http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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
> 5600 Fishers Lane, Room 12B05
> Rockville, MD 20857

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, call Eufrecina DeGuia, Senior Regulatory Health Project Manager, at (301) 796-0081.

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:
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/

GEORGE S BENSON
01/31/2011