



NDA 22-206/S-001

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

Dear Mr. Long:

Please refer to your supplemental new drug application dated October 13, 2008, received October 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rapaflo™ (silodosin) Capsules, 4mg and 8mg.

We acknowledge receipt of your submission dated February 5, 2009.

This supplemental new drug application provides for the following changes:

- Addition of a new product logo to the labeling
- Revision of Usual Dosage information in container labels was changed from “1 capsule orally once daily with food” to “1 capsule orally once daily with a meal” to match text in Section 2, Dosage and Administration section of the approved Prescribing Information (PI)
- Addition of 90 count bottle for 4 mg capsules in Section 16, How Supplied section of the Proposed Labeling Text and addition of corresponding container labels
- Deletion of 100 count bottle for 4 mg capsules from Section 16, How Supplied section of the Proposed Labeling Text
- Revision of the introductory statement in the Highlights of Prescribing Information section of the Proposed Labeling Text to match the style sheet requirements for the Structured Product Labeling (SPL)
- Minor editorial changes overlooked in the last revision of the proposed labeling text submitted before approval of the NDA

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Olga Salis, Regulatory Project Manager, at (301) 796-0837.

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 (PI and Immediate Container and Carton Labels)

**This is a representation of an electronic record that was signed electronically and
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/s/

George Benson
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