



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-518/S-007

Astellas Pharma US, Inc  
Attention: Judy Kannenberg  
Associate Director, Regulatory Affairs  
Three Parkway North  
Deerfield, IL 60015-2537

Dear Ms. Kannenberg:

Please refer to your supplemental new drug application dated May 15, 2008, and received May 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESIcare<sup>®</sup> (solifenacin succinate) 5mg and 10mg tablets.

We also refer to your submissions dated October 31 and November 18, 2008.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for changes to the ADVERSE REACTION section, Post-Marketing Surveillance subsection and the OVERDOSAGE section, Acute subsection of the physician package insert to reflect newly acquired adverse event information.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We also acknowledge receipt of the enclosed labeling in SPL format. We will transmit this version to the National Library of Medicine for public dissemination.

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

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

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 Meredith Alpert, M.S., Regulatory Project Manager, at (301) 796-1218.

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

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/s/

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George Benson

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