DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-518/S-004

Astellas Pharma US, Inc.
Attention: Judy Kannenberg
Assistant Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015-2548

Dear Ms. Kannenberg:

Please refer to your supplemental new drug application dated September 21, 2007, received September 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESIcare® (solifenacin succinate), 5 mg and 10 mg tablets.

We also refer your submission dated January 29, 2008, in response to our advice letter dated January 2, 2008, requesting changes to the ADVERSE REACTIONS/ Post-Marketing Surveillance section, and the OVERDOSAGE/ Treatment of Overdosage section.

This "Changes Being Effected in 30 days" supplemental new drug application, as amended, provides for the requested revisions to the Package Insert (PI).

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.

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)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-518/S-004."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
2/8/2008 09:17:35 AM