DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-518/S-003 **Approval Letter**

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

Dear Ms. Kannenberg:

Please refer to your supplemental new drug application dated December 20, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESIcare (solifenacin succinate) 5 and 10 mg tablets.

We acknowledge receipt of your submission dated May 23, 2007. This "Changes Being Effected" supplemental new drug application, as amended, provides a revised package insert (PI) in response to our Approvable Letter, dated April 18, 2007, requesting the addition of "hallucinations" to the Post-Marketing Surveillance subsection of the ADVERSE REACTIONS section.

> **ADVERSE REACTIONS**
>
> **Post-Marketing Surveillance**
>
> The following events have been reported in association with solifenacin use in worldwide postmarketing experience: *General*: hypersensitivity reactions, including angioedema, rash, pruritis, and urticaria; *Central Nervous:* confusion and hallucinations. Because these spontaneously reported events are from the worldwide postmarketing experience, the frequency of events and the role of solifenacin in their causation cannot be reliably determined.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 21-518/S-003**." Approval of this submission by FDA is not required before the labeling is used.

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 Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at (301) 796-0952.

Sincerely,

{See appended electronic signature page}

Mark Hirsch, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation 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/

Mark S. Hirsch

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