DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-518/S-006

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 and received April 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VESIcare® (solifenacin succinate) 5mg and 10mg tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to physician sample labeling.

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 and with the minor editorial revisions listed below.

1. On the physician sample carton's principle display panel, revise the font for the product strength (i.e. 5 mg, 10 mg) statement to a larger, more prominent size than the net quantity. There is a lack of prominence of the dosage strength in relation to the net quantity. The "7 Tablets" statement located directly beneath the statement "Each tablet contains 5 mg (or 10 mg) of solifenacin succinate" is in a larger, more visible font than the "5 mg" (or 10 mg) product strength.

2. Add the statement "Each tablet contains 5 mg (or 10 mg) of solifenacin succinate" to the physician sample blister card labels to clarify the milligram amount contained in each tablet. This could also be achieved by revising the strength to read "xx mg per tablet." We request this clarification because not including this information has led patients to ingest the entire contents of sample packs such as this one.

3. Change the font for the statement "Sample-Not for Sale" to a larger, more prominent size on the physician sample blister foil label and the display trays. The current statement is small and difficult to read.

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 Celia Peacock, MPH, RD, Regulatory Project Manager, at (301) 796-4154.

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

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
10/29/2008 12:14:23 PM