DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022275/S-008

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Otsuka Pharmaceutical Company, Ltd.
Attention: Robert Ashworth, Ph.D.
V.P., Regulatory Affairs
1 University Square Dr., Suite 500
Princeton, NJ 08540

Dear Dr. Ashworth:

Please refer to your Supplemental New Drug Application (sNDA) submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Samsca (tolvaptan) 15 mg and 30 mg tablets.

We also refer to your risk evaluation and mitigation strategy (REMS) assessment dated September 23, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Samsca (tolvaptan) REMS.

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Samsca (tolvaptan) was originally approved on May 19, 2009, and the most recent REMS modification was approved on September 23, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Samsca (tolvaptan).

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Samsca (tolvaptan) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

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, please call:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

MARY R SOUTHWORTH
09/14/2012