DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020835/S-044

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Warner Chilcott (US), LLC
Attention: Matthew Lamb, PharmD
Senior Director, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Dr. Lamb:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Actonel (risedronate sodium) 5 mg, 30 mg, 35 mg, 75 mg, and 150 mg Tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 21, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Actonel (risedronate sodium) Tablets REMS.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Actonel (risedronate sodium) Tablets was originally approved on January 25, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Actonel (risedronate sodium) Tablets.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Actonel (risedronate sodium) Tablets outweigh its the risks.

Therefore, we agree with your proposal and a REMS for Actonel (risedronate sodium) Tablets 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, call Meredith Alpert, M.S., Acting Safety Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director for Safety
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/

AUDREY L GASSMAN
08/22/2011