DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021817/S-013

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Novartis Pharmaceuticals Corporation
Attention: Monique Small, PharmD
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Small:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 8, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reclast® (zoledronic acid) Injection 5 mg in a 100mL ready-to-infuse solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated August 8, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Reclast (zoledronic acid) Injection 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 Reclast (zoledronic acid) Injection 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 Reclast (zoledronic acid) Injection.

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 Reclast (zoledronic acid) Injection outweigh its risks.

Therefore, we agree with your proposal and a REMS for Reclast (zoledronic acid) Injection 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}

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 S BENSON
08/15/2011