



NDA 21-817/S-003

Novartis Pharmaceuticals Corporation
Attention: Lynn Mellor
Director, Drug Regulatory Affairs
One Health Plaza, Building 404
East Hanover, NJ 07636-1080

Dear Ms. Mellor:

Please refer to your supplemental new drug application dated and received February 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reclast[®] (zoledronic acid) Injection.

We further refer to our letter dated December 15, 2008, communicating to you that the goal date of your application was extended three months to allow sufficient time for a full review of your major amendment dated November 26, 2008.

We acknowledge receipt of your submissions dated June 2 and 12, July 8 and 17, August 6, September 2, 5 and 11, October 20, 24 and 30, November 4, 7, 14 and 26, December 12, 2008, January 6 and 14, February 12, 13 and 27, March 3 and 10, 2009.

This supplemental new drug application provides for the use of Reclast[®] (zoledronic acid) Injection for the indication of the treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months.

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.

The one-half page requirement for the HIGHLIGHTS FOR PRESCRIBING INFORMATION section of the label is waived based on multiple indications and multiple recent major changes.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-817/S-003." The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration

are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because there is evidence suggesting that the drug would be unsafe in all pediatric age groups. This is supported by the known and suspected long-term safety concerns of bisphosphonates coupled with the long half-life of zoledronic acid.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

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

Enclosure

**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
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