DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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March 4, 2013

Gretchen Trout
Head NA Policy & FDA Liaison
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Trout:

Your petition to the Food and Drug Administration requesting FDA not approve any Abbreviated New Drug Application (ANDA) seeking approval of a zoledronic acid injectable IV (infusion) product based on omitting protected information in Reclast labeling, was received by this office on 3/04/2013. It was assigned docket number FDA-2013-P-0247/CP1, and it was filed on 3/04/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)