DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-313/S-021

Novartis Pharmaceutical Corporation
Attention: Roxanne Tavakkol
Director, Regulatory Affairs
59 Route 10
East Hanover, NJ 07936

Dear Ms. Tavakkol:

Please refer to your supplemental new drug applications (NDA) dated January 21, 2003, received January 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Miacalcin (calcitonin-salmon) Nasal Spray.

We also refer to your submissions dated July 6, 2005, and January 4, 2006. The July 6, 2005 submission constituted a complete response to our August 21, 2003 action letter.

This supplemental new drug application proposes to add a "Geriatric Use" subsection to the **PRECAUTIONS** section of the package insert.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the text for the submitted labeling (package insert) submitted January 4, 2006). Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html. For administrative purposes, designate this submission "**FPL for approved NDA 21-313/S-021**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 796-1224.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
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 Parks

1/6/2006 05:23:12 PM