DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-406/S-003

Unigene Laboratories, Inc.
Attention: Brenda Marezi, Pharm.D.
Sr. Director, Regulatory Affairs
83 Fulton Street
Boonton, NJ 07005

Dear Dr. Marezi:

Please refer to your supplemental new drug application (NDA) dated October 31, 2005, received November 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortical (calcitonin-salmon) Nasal Spray.

This "Changes Being Effected" supplemental new drug application provides for revised container labels and carton labels, to comply with recommendations from the Division dated August 15, 2005, and corresponding changes to the package insert and patient package insert for consistency.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 31, 2005.

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

Enclosure

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

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