DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-406/S-007

Upsher-Smith Laboratories, Inc.
Attention: Kimberly Oakins
Regulatory Affairs Specialist
6701 Evenstad Drive
Maple Grove, MN 55369

Dear Ms. Oakins:

Please refer to your supplemental new drug application (NDA) dated August 18, 2006, received August 21, 2006, 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 a revised package insert (PI) to incorporate changes that have been made to the PI of the innovator product, Miacalcin Nasal Spray.

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 August 18, 2006.

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.
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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