**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-406/S-008

Upsher-Smith Laboratories, Inc.
Attention: Cynthia G. Farner
Director, Regulatory Affairs
6701 Evenstad Drive
Maple Grove, MN 55369-6026

Dear Ms. Farner:

Please refer to your supplemental new drug application dated and received March 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortical® [calcitonin-salmon (rDNA origin)] Nasal Spray.

We acknowledge receipt of your submissions dated December 19, 2008, June 19 and 20, 2009.

Your submission of December 19, 2008, constituted a complete response to our March 5, 2008, action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Patient Information Leaflet, under *Why is Fortical Nasal Spray in a brown bottle?* section, specifically:

- changes to enhance the administration instructions for the patient.
- add dosage form after proprietary name.
- add clarification of packaging component.
- editorial changes.
- updated revision number, consistent with Upsher-Smith labeling controls.

We 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 and with the agreed-upon pending graphic revisions to the Patient Instructions for Use (PIU) as listed below.

1. Enlarge the picture of the bottle and label each part of the bottle using the terms used throughout the PIU (i.e. bottle, cap and neck). Add a picture of the pump and label the parts (i.e. cap, feed tube, lock tab and grooves).
2. Move the numbers next to the pictures (that correspond to the numbered steps) from the bottom of the picture to the left of the picture so the numbers are more clearly shown. Label the numbers as "Step 1, etc.". Enlarge the picture of the bottle and label each part. Add a picture of the pump and label each part. For Step 2, add a picture to show the feed tube.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the Package Insert, Patient Package Insert, and Patient Instructions for Use to include the revisions previously listed. These revisions are terms of the approval of this application.

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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved NDA 21-406/S-008."

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) 796-9875.

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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George Benson
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