DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021406/S-016

SUPPLEMENT APPROVAL

Upsher-Smith Laboratories, Inc.
Attention: Michele Heintz
Associate Director Regulatory Affairs
6701 Evenstad Drive
Maple Grove, MN 55369

Dear Ms. Heintz:

Please refer to your Supplemental New Drug Application (sNDA) dated January 25, 2010, received January 26, 2010, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FORTICAL® calcitonin-salmon (rDNA origin) Nasal Spray.

We acknowledge receipt of your amendment dated May 13, 2011. The May 13, 2011, submission constituted a complete response to our May 26, 2010, action letter.

This "Changes Being Effected" supplemental new drug application proposed changes to the Package Insert to incorporate safety related changes made to Miacalcin® (calcitonin-salmon) Nasal Spray. FORTICAL® Nasal Spray is a 505(b)(2) product and is not bioequivalent to Miacalcin® Nasal Spray; therefore, it is not appropriate to insert the same pharmacokinetics (PK) findings as in the labeling of the innovator Miacalcin® Nasal Spray. Appropriate **CLINICAL PHARMACOLOGY** language was recommended for this subsection in the physician 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 enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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, call Nenita Crisostomo, R.N., Regulatory Project Manager, at (301) 796-0875.

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(S):
Content of Labeling

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

/s/

GEORGE S BENSON
08/12/2011