DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-707/S-005

Sonofi-aventis U.S., L.L.C.
Attention: Emmanuel Hamon,
Regulatory Specialist, U.S. Regulatory Affairs Marketed Products
Somerset Corporate Boulevard
Bridgewater, N.J. 08807-0977

Dear Mr. Hamon:

Please refer to your supplemental new drug application dated May 25, 2006, received May 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelid (tiludronate disodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for a new subsection entitled **Musculoskeletal Pain** in the **PRECAUTIONS** section of the package insert and also adds two paragraphs related to osteonecrosis of the jaw to the **PRECAUTIONS** section of the package insert.

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 May 25, 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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