DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-707/S-004

Sanofi-Synthelabo, Inc.
Attention: Andrea Czeizinger, J.D.
Manager, Drug Regulatory Affairs
90 Park Avenue
New York, NY 10016

Dear Ms. Czeizinger:

Please refer to your supplemental new drug application (NDA) dated June 4, 2003, received June 5, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Skelid (tiludronate disodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for a revision to the Pregnancy subsection of the PRECAUTIONS section in response to our supplement request letter dated March 3, 2003.

We have completed our review of this supplemental new drug application, and it is approved effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on June 4, 2003.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research "Orange Book" staff at:

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Eric Colman
8/21/03 02:48:01 PM
Eric Colman for David Orloff