DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 3-444/S-020

Sanofi-Synthelabo
Attention: Eileen De Micco, M.A.
Regulatory Specialist
90 Park Avenue
New York, NY 10016

Dear Ms. De Micco;

Please refer to your supplemental new drug application dated August 27, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Drisdol (ergocalciferol, USP) 50,000 IU Capsules.

We acknowledge receipt of your submission dated July 3, 2003 which constituted a complete response to our February 14, 2003 action letter.

This supplemental new drug application provides for addition of a Geriatric subsection in the Precautions section of the package insert.

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 following minor editorial revision: As cited in 21CFR201.57 (i) and (j), the Overdosage section of the package insert should be listed before the Dosage and Administration section.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the submitted labeling (package insert submitted July 3, 2003). This revision is a term of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 3-444/S020." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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, call Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine
Drug Products, HFD-510
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/

David Orloff

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