DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-316/S-015

Sanofi-Synthelabo, Inc.
Attn: Yau-Kit Lam
Associate Director CMC of Drug Regulatory Affairs
90 Park Avenue
New York, NY 10016

Dear Mr. Lam:

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 Primaquine Phosphate Tablets, USP.

We acknowledge the receipt of your submissions dated September 5, and October 4, 2002.

This supplemental new drug application provides for the addition of a new *Geriatric Use* subsection at the end of the **PRECAUTIONS** section of the package insert in accordance with the August 27, 1997 final rule and 21 CFR 201.57(f)(10).

The changes were as follows. Added text is double underlined.

> ***Geriatric Use:*** *Clinical studies of Primaquine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.*

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted October 4, 2002).

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 ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 8-316/S-015." 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, HF-2
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 Christine Lincoln, RN, MS, MBA, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht

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