DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 5-010/S-047

Sanofi-Synthelabo
90 Park Avenue
New York, NY 10016

Attention: Jessica M. Dunn-Skorupski
Regulatory Specialist

Dear Ms. Dunn-Skorupski:

Please refer to your supplemental new drug application dated April 25, 2002, received April 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Demerol® (meperidine HCl, USP).

We acknowledge receipt of your submission dated February 19, 2003.

This "Changes Being Effected" supplemental new drug application provides updated labeling as requested in our July 24, 1997, approval letter for S-031.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter.

As agreed in our February 20, 2003, teleconference, the Agency will issue a separate request to submit a labeling supplement in which additional updates will be recommended.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 5-010/S-047." 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 Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Acting Director
Division of Anesthetic, Critical Care, and
Addiction 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/

Bob Rappaport

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