DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-458/S-012

Sanofi-Synthelabo
90 Park Avenue
New York, NY 10016

Attention: Eileen De Micco, MA
Regulatory Specialist

Dear Ms. De Micco:

Please refer to your supplemental new drug application dated August 22, 2002, received August 26, 2002, submitted under section 202(b) of the Federal Food, Drug, and Cosmetic Act for Talacen (pentazocine HCl and acetaminophen) Caplets.

We acknowledge receipt of your submission dated June 4, 2003, which constituted a complete response to our February 26, 2003 action letter.

Reference is also made to the July 3, 2003, telephone conversation between you and Ms. Lisa Basham-Cruz of this Division.

This supplemental new drug application provides for a revised **PRECAUTIONS** section. A **"Geriatric Use"** subsection is added in accordance with the requirements of 21 CFR 201.57(f)(10).

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter. As agreed to by you, the immediate container label will be revised as follows:

> Each caplet contains pentazocine hydrochloride, USP equivalent to 25 mg base and acetaminophen, USP, 650 mg.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert and immediate container label) submitted June 4, 2003, with the revision listed above.

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 18-458/S-012." 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 Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Acting Division 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
7/10/03 11:28:33 AM