DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-458/S-013

Sanofi Aventis
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807-0890

Attention: John Cook
US Regulatory Affairs Marketed Products

Dear Mr. Cook:

Please refer to your supplemental new drug application dated February 7, 2008, received February 8, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Talacen® (pentazocine hydrochloride, USP and acetaminophen, USP) Tablets.

This supplemental new drug application provides for revisions to the DESCRIPTION and OVERDOSAGE sections of the package insert.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. The following revision was agreed upon in an email on August 6, 2008.

> **OVERDOSAGE**
> The toxic effects of acetaminophen may be prevented or minimized by antidotal therapy with N-acetylcysteine. In order to obtain the best possible results, N-acetylcysteine should be administered ~~within approximately 16 hours of ingestion of the overdose~~ as soon as possible.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 18-458/S-013."

LETTERS TO HEALTH CARE PROFESSIONALS

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Tanya Clayton, Regulatory Project Manager, at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Sharon Hertz
8/7/2008 09:03:50 AM
Signing for Bob Rappaport, M.D.