DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-631/S-034

Aventis Pharmaceuticals, Inc.
Attention: Mr. Kerry Rothschild
Director, Regulatory Affairs
200 Crossing Boulevard
P.O. Box 6890
Bridgewater, NJ 08807-0890

Dear Mr. Rothschild:

Please refer to your supplemental new drug application dated October 27, 2003, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trental (pentoxifylline) 400 mg Tablets.

We acknowledge receipt of your submission dated October 26, 2004. This submission constituted a complete response to our March 10, 2004 action letter.

This supplemental new drug application provides for revisions to the **DESCRIPTION** section, and the addition of a new **Geriatric** subsection to the labeling.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on October 26, 2004.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Meg Pease-Fye, M.S., Regulatory Project Manager, at (301) 594-5327.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I

Attachment: Labeling

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

/s/

Norman Stockbridge

4/7/05 04:50:23 PM