DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-631/S-033

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

Dear Mr. Rothschild:

Please refer to your supplemental new drug application dated May 19, 2003, received May 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trental (pentoxifylline) 400 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes in the **ADVERSE REACTIONS** section of the package insert. The following changes were noted:

1. In the **DESCRIPTION** section, "benzyl alcohol NF" was deleted.

2. In the last paragraph under **CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism**, a previously superscripted 1 was changed to normal font.

3. Under **ADVERSE REACTIONS**, "aseptic meningitis" was added to post-marketing symptoms of the nervous system.

4. Under **ADVERSE REACTIONS**, quotation marks were deleted.

5. Under **HOW SUPPLIED**, "Rx only" was added.

6. Under **HOW SUPPLIED**, the name and address of the manufacturer was changed from,

   Hoechst-Roussel Pharmaceuticals
   Division of Hoechst Marion Roussel, Inc.
   Kansas City, MO 64137 USA

   To read,

   Aventis Pharmaceuticals NJ
   Bridgewater, NJ 08807

We note the inappropriate term, "and other ingredients" under the **DESCRIPTION** section. Change this to include the ingredients not listed at the time of the next printing.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 19, 2003.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, call Meg Pease-Fye, Regulatory Project Manager, at (301) 594-4312.

Sincerely,

*{See appended electronic signature page}*

Douglas C. Throckmorton, M.D.
Director
Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

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/s/

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Doug Throckmorton

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