DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-624/S-003

Aventis Pharmaceuticals, Inc.
Attention: Philip E. Page, R.Ph.
Regulatory Affairs-CMC
10236 Marion Park Drive
P.O. Box 9720
Kansas City, MO 64134-0720

Dear Mr. Page:

Please refer to your supplemental new drug application dated October 14, 1998, received October 19, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anzemet® (dolasetron mesylate) Injection.

We acknowledge receipt of your submission dated October 11, 2002 that constituted a complete response to our June 6, 2000 action letter.

This supplemental new drug application provides for a 25 mL multidose vial to provide five (5 mL each) 100mg doses.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revision listed below. Accordingly the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert, immediate container, and carton labeling submitted October 11, 2002). These revisions are terms of approval for this application:

> Package Insert, HOW SUPPLIED Section: please delete the line for the 12.5 mg single-use vial, box of 6 from the table of marketed package sizes of ANZEMET Injection.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager, at (301) 827-7473.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
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/

Robert Justice
2/13/03 11:21:26 AM