DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20624/S-008

Aventis Pharmaceuticals, Inc.
Attention: Sima Patel
Sr. Regulatory Analyst, U.S. Regulatory Affairs
Somerset Corporate Center
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-2854

Dear Ms. Patel:

Please refer to your supplemental new drug application dated September 21, 2001, received September 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anzemet® (dolasetron) Injection.

This supplemental new drug application provides for revisions to the ampul and vial labels and cartons to incorporate the revisions recommended in our letter dated May 21, 2001.

We have completed the review of this application 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 with the minor editorial revisions 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 (ampul and vial immediate container and carton labels submitted September 21, 2001). These revisions are terms of the approval of this application.

1. Add the designation "USP" following "mannitol" on the ampul and vial carton labels.

2. Add Aventis' address following the phrase, "Mfd for Aventis Pharmaceuticals, Inc." on the Anagni vial immediate container label.

Please 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 mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically accordingly to the guidance for industry titled, *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-624/S-008". Approval of this submission by FDA is not required before the labeling is used.

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) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F.C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and
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/

Joyce Korvick
3/22/02 11:10:26 AM
for Dr. Victor Raczkowski