DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-449/S-017

Aventis Pharmaceutical Products Inc.
Route 202-206
PO Box 6800
Bridgewater, New Jersey 08807-2800

Attention: Marion Ceruzzi, Ph.D.
US Regulatory Liaison

Dear Ms. Ceruzzi:

Please refer to your supplemental new drug application dated January 9, 2002, received January 10, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxotere (docetaxel) for Injection Concentrate, 20 mg and 80 mg.

We also refer to your submissions dated May 28, June 5 and 28, 2002.

This "Changes Being Effected" supplemental new drug application provides for additions to the ADVERSE REACTIONS section, Post-Marketing Experience subsection of the package insert.

We have completed the review of this supplemental 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 submitted final printed labeling (package insert and patient package insert submitted January 9, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

However, please make the following change in your labeling at the next printing:

Under **Post-marketing Experiences,** subsection **Gastrointestinal,** replace the last sentence "Rare occurrences of dehydration as a consequence to gastrointestinal events, gastrointestinal perforation, ischemic colitis, colitis, intestinal obstruction, ileus, and neutropenic enterocolitis have been reported." with the following:

> "Gastrointestinal: abdominal pain, anorexia, constipation, duodenal ulcer, esophagitis, gastrointestinal hemorrhage, gastrointestinal perforation, ischemic colitis, colitis, intestinal obstruction, ileus, neutropenic enterocolitis and dehydration as a consequence to gastrointestinal events have been reported."

Under **Post-marketing Experiences,** subsection **Opthalmologic,** replace the last sentence "Rare cases

of lacrimal duct obstruction resulting in excessive tearing have been reported primarily inpatients receiving other anti-tumor agents concomitantly." with the following:

> "Excessive tearing which may be attributable to lacrimal duct obstruction has been reported."

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

Please submit one market package of the drug product when it is available.

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 Ann Staten, Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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