DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-449/S-019

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

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

Dear Dr. Ceruzzi:

Please refer to your supplemental new drug application dated February 18, 2002, received February 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Act for Taxotere (docetaxel) for Injection Concentrate, 20 mg and 80 mg.

This supplemental new drug application provides for changes to the instructions for preparation of the initial diluted solution in the PREPARATION AND ADMINISTRATION PRECAUTIONS section of the package insert.

We have completed the review of this supplemental 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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

We also refer to the July 9, 2002 approval letter for NDA 20-449/S-017. We remind you of your commitment to make the following changes:

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."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) with the exception to the above noted changes.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-449/S-019." 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 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

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

Enclosure

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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