

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**20-449/S-018**

**Approval Letter(s)**



NDA 20-449/S-018

Aventis Pharmaceuticals, Inc.  
200 Crossing Boulevard  
P.O. Box 6890  
Bridgewater, New Jersey 08807-0890

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated February 1, 2002, received February 1, 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 acknowledge receipt of your submissions dated February 8; March 28; April 8; June 14 and 21; July 1; August 8, 13, 19, 20 and 29; September 5 and 30; and October 14, 17 and 28, 2002.

This supplemental new drug application provides for the use TAXOTERE in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition. It also proposes revisions in the Human Pharmacokinetics section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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 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-018." Approval of this submission by FDA is not required before the labeling is used.

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 the Division of Oncology Drug Products 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, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ann Staten, Regulatory Project Manager, at (301) 594-0490.

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  
11/27/02 02:26:57 PM