

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-262/S-024

CHEMISTRY REVIEW(S)

SPILLMAN

FEB - 3 1998

Chemistry Manufacturing Controls Review
Labeling Review

NDA: 20-262 / SE1-024 & 20-262/SE1-026
Product: Taxol (paclitaxel)
Applicant: Bristol-Myers Squibb
Date of Submission: June 30, 1997 & October 7, 1997
Stamp Data: August 19, 1997
Date of Review: February 2, 1998
Material Reviewed: TAXOL® (paclitaxel) for the Treatment of Advanced Non-Small Cell Lung Cancer (S-024, Vol. 1.2 and 2.2) & Ovarian Cancer (S-026, Vol. 1.2 and 2.2)
Other Documents: NDA 20-262 and its supplements

Drug Substance

Drug substance by the same manufacturer was approved more recently on March 5, 1997.

Manufacturer and Site

BMS-Swords and BMS Syracuse.

Method of Synthesis

More recently submitted in DMF and Supplement 17.

Specifications and Methods

More recently submitted in Supplement 17.

Stability Data

Submitted in Supplement 17.

Drug Product

Refer to NDA 20-262 and its supplements.

Environmental Assessment (EA)

Found satisfactory by N. Sager on 11/6/97.

Labeling:

Submitted on Vol. 1 under section of Labeling. Description, Dosage and Administration, Preparation and Administration, Preparation for Intravenous Administration, Stability, How Supplied, and Storage sections were not revised.

Conclusions and Recommendations.

No new CMC information is submitted in these supplements. Reference for CMC would have to be from previous approved application/ supplements. These reviews mainly concentrate in the EA and Labeling revisions.

/S/

Josephine M. Jee, Review Chemist, HFD-150, DNDC I ^{2/2/98}

/S/

Rebecca H. Wood, Ph.D., Chemistry Team Leader, HFD-150, DNDC I ²⁻³⁻⁹⁸

cc:

- NDA 20-262/SE1-024 & SE1-26
- HFD-150/Division File
- HFD-150/JJee/ 2-2-98
- HFD-150/RWood
- HFD-150/DSpillman
- F/T by JJee/ 2-2-98
- R/D by:
- File: 20262s24.lab