

**CENTER FOR DRUG
EVALUATION AND RESEARCH**

APPLICATION NUMBER:

75-278

BIOEQUIVALENCE REVIEW

1.1
Brown

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA:75278

APPLICANT: Mylan Pharmaceuticals

DRUG PRODUCT: Paclitaxel Injection
6 mg/ml

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale Conner, Pharm. D.
Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

CC: ANDA 15-278
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-652/ Reviewer

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Endorsements: (Final with Dates)
HFD-652/ Reviewer
HFD-652/ Bio team Leader *LMH 6/15/98*
HFD-650/ D. Conner *ISL 6/16/98*

BIOEQUIVALENCY - ACCEPTABLE

submission date: December 19, 1997

1. WAIVER (WAI)

Strengths: 6 mg/ml

Outcome: AC

Outcome Decisions: AC - Acceptable

APPEARS THIS WAY
ON ORIGINAL

Paclitaxel
Injection, 6 mg/ml
ANDA # 75278
Reviewer: Andre Jackson
WP # 75278W.D97

Mylan Pharmaceuticals
Morgantown, W. VA.
Submission Date:
December 19, 1997

Review of a Waiver Request

The firm is requesting a waiver of the in vivo bioequivalence requirement for its Paclitaxel 6 mg/ml injection. The product is indicated for the treatment of metastatic carcinoma of the ovary. The reference product is Taxol manufactured by Bristol-Myers Squibb.

The formulations for the test and reference products are as follows:

Ingredient	Reference	Test
Paclitaxel	6 mg/ml	6 mg/ml
_____ Castor Oil ¹	527 mg/ml	527 _____ mg/ml
Alcohol, Dehydrated	49.7% (v/v)	_____
Sodium Metabisulfite	-----	_____
Sterile Water for Injection	-----	_____

¹The _____ Castor Oil¹ _____ is used in the test while _____ is used in the reference product

Comments:

1. [Comment for Chemist Only]

There are currently _____
_____ by _____. The one used by the
innovator is _____ while the other is _____
_____ which is a _____ with _____
_____ The Mylan product
uses _____ Meetings with the Division of
Chemistry have determined _____ to be a

Therefore the final acceptance of this application will

be pending approval of _____ by the chemistry reviewer.

2. The test product contains the _____ sodium metabisulfite in a concentration of _____ which is below that listed in the inactive ingredients guide at _____ for an intravenous injection.

3. The sterile water for injection is used only to solubilize the sodium metabisulfite.

4. The information submitted by Mylan Pharmaceutical indicates that its inactive ingredient sodium metabisulfite falls under 21 CFR 314.94(a)(9)(iii) in that the _____ does not affect the safety of the product.

5. Therefore the information submitted by Mylan Pharmaceuticals show that its Paclitaxel 6 mg/ml injection falls under CFR 320.24 (b)(6).

**APPEARS THIS WAY
ON ORIGINAL**

Recommendation:

The Division of Bioequivalence agrees that information submitted by Mylan Pharmaceuticals demonstrates that Paclitaxel 6 mg/ml injection, falls under 21 CFR Section 320.24 (b)(6) of the Bioequivalence Regulations. The waiver of in vivo bioequivalence study for Paclitaxel 6 mg/ml injection Of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable to be bioequivalent to Taxol 6 mg/ml manufactured by Bristol-Myers Squibb.

Andre Jackson, Ph.D.
Division of Bioequivalence
Review Branch I

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FT INITIALED YCHUANG

/S/

Date: 6/15/98

Concur: _____
Dale P. Conner, Pharm.D.
Director

/S/

Date: 6/16/98

Division of Bioequivalence
ANDA# 75-278 (original, duplicate), HFD 652 (Huang, Jackson),
Drug File, Division File, HFD-650 (Division Director)

APPEARS THIS WAY
ON ORIGINAL