

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**64084**

**BIOEQUIVALENCY REVIEW(S)**

NOV 2 1993

**FILE COPY**

Sterile Bleomycin Sulfate  
(Bleosar) 15 and 30 Units/Vial  
ANDA # 64-084  
Reviewer: Man M. Kochhar  
A. 64084W.393

Adria Laboratories  
Columbus, Ohio  
Submission Date:  
March 24, 1993

Review of a Waiver Request

The firm has requested a waiver of in vivo bioequivalence study for its Sterile Bleomycin Sulfate (Bleosar) 15 and 30 units/vial injections based upon 21 CFR 320.22 (b) (1).

Comparative Formulation

<u>Ingredients</u>	<u>Adria</u>	<u>Bristol</u>
✓ Bleomycin Sulfate	15 units	15 units
✓ Water for injection	1 to 5 mL (IM)	1 to 5 mL (IM)
Sodium Chloride for injection	qs	qs
5% Dextrose for injection	qs	qs
FOR IV Physiologic saline or glucose	5 mL or more	5 mL or more

Deficiency: None

Comments:

1. The formulation of the test product and the innovator product Bleomycin sulfate (Blenoxane; Bristol) is similar in concentration of active and inactive ingredients.
2. The dosage form, route of administration (intramuscular, intravenous and subcutaneous), strength ( 15 units) and labeling of the test drug product are identical to those of the innovator product, Blenoxane. The company also wants to introduce 30 units/vial using the same route of administration and 10 mL of water for injection. The dosage of the test and reference products are same and instead of using two 15 units/vial the sponsor want to use one 30 units/vial. This change should not effect the bioequivalence of the product.
3. From the bioequivalence point of view, the waiver of in vivo bioequivalence study requirement should be granted based on 21 CFR 320.22 (b)(1). The batch size ranges between 100 to 1000 liters.

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Adria Laboratories on its Sterile Bleomycin Sulfate

**BEST POSSIBLE COPY**

15 and 30 units/vial injection falls under 21 CFR 320.22 (b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver of an vivo bioequivalence study for 15 and 30 units/vial injection of the test product is granted.

From the bioequivalence point of view, the Division of Bioequivalence deems the test injection of Bleomycin Sulfate 15 and 30 units/vial to be bioequivalent to Blenoxane 15 units/vial, manufactured by Bristol.

The firm should be informed of the recommendation.

/ /S/

Man M. Kochhar, Ph.D.  
Review Branch III  
Division of Bioequivalence

RD INITIALED RMHATRE  
FT INITIALED RMHATRE

~~/S/~~

11/2/93

MMKochhar/mmk/10-12-93/11-2-93/ 64084

cc: ANDA # 64-084 original, HFD-600 (Hare), HFD-630, HFD-658 (Mhatre, Kochhar), Drug File, Division File.