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*APPLICATION NUMBER:*

**50-789**

**CLINICAL PHARMACOLOGY AND  
BIOPHARMACEUTICS REVIEW(S)**

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NDA#	50-789
PRODUCT	Tobramycin sulfate
FORMULATION	Sterile lyophilized powder for injection, 1.2 grams/50 mL vial
SUBMISSION DATE	December 20, 2002
SUBMISSION TYPE	Original 505(b)(2) NDA
SPONSOR	American Pharmaceutical Partners, Inc., Melrose Park, IL 60160-1002
REVIEWER	Charles R. Bonapace, Pharm.D.
TEAM LEADER	Phillip M. Colangelo, Pharm.D., Ph.D.

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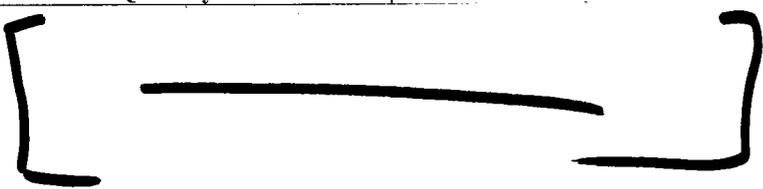
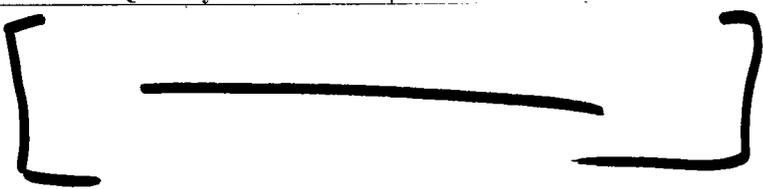
**CLINICAL PHARMACOLOGY & BIOPHARMACEUTICS REVIEW**

**BACKGROUND:**

American Pharmaceutical Partners, Inc. submitted a New Drug Application (NDA) to obtain approval to market tobramycin for injection, USP 1.2 grams/50 mL vial (1.2 grams/30 mL final concentration). On January 16, 2002 the Division of Anti-Infective Drug Products agreed that tobramycin for injection, USP is a suitable drug product for a 505(b)(2) NDA as an equivalent to the marketed IV formulation of Nebcin® (Tobramycin for Injection, USP) by Eli Lilly and Company, with the exception of Chemistry, Manufacturing, and Controls data.

In a teleconference between the Agency and the sponsor on March 26, 2002, the Agency agreed that no bioequivalence or bioavailability studies would be needed to support this application. Based on 21 CFR 320.22(b), the in vivo bioavailability or bioequivalence of the drug product may be self-evident if 1) it is a parenteral solution intended solely for administration by injection, and 2) contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application. The sponsor was reminded that they would need to provide information to substantiate why their product is the same as the innovator product.

A comparison of the formulations for Nebcin® (Tobramycin for Injection, USP, Eli Lilly and Company) and Tobramycin for Injection, USP (American Pharmaceuticals Partners, Inc) is shown in the table below.

Ingredient	Nebcin® (Tobramycin for Injection, USP) Quantity/vial	Tobramycin for Injection, USP Quantity/mL
Tobramycin		
Tobramycin Sulfate, USP		
Water for Injection, USP		





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Charles Bonapace  
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