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*APPLICATION NUMBER:*

**50-796**

**PHARMACOLOGY REVIEW**

Memorandum to the File for NDA 50-796

From: Terry S. Peters, D.V.M.

Through: Robert E. Osterberg, Ph.D.

Through: Lillian Gavrilovich, M.D.

This memorandum is intended to serve as the preclinical review of NDA 50-796 from B. Braun Medical Inc. for Ceftriaxone for Injection and Dextrose Injection in the DUPLEX® Container. No new data are presented in this NDA submission. The sponsor makes reference to the Rocephin® for Injection NDA 50-585 for all relevant information as the B. Braun product makes no new claims or implied claims and they are filing a 505(b)(2) application. B. Braun intends to use the innovator label with omission of the references to intramuscular injection.

The label for Rocephin® is current and acceptable from a preclinical perspective. Thus, the label for Ceftriaxone for Injection and Dextrose Injection in the DUPLEX® Container is current and acceptable from a preclinical perspective.

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/s/  
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7/22/04 01:01:29 PM  
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7/27/04 01:02:30 PM  
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