

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-703

PHARMACOLOGY REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 10, 2006

TO: Albert Defelice, Ph.D. Team Leader Pharmacology/Toxicology

FROM: James Willard, Ph.D. Pharm/Tox Reviewer

SUBJECT: NDA 21703
Submission N000, September 28, 2005

N21703 is an application for approval of PrismaSol Solutions as a replacement solution in hemofiltration and hemodialysis. The PrismaSol solutions are essentially the same as Gambro Renal Products PrismaSate line of hemofiltration and hemodialysis solutions, which are approved for use by CDRH. This family of solutions has variations in electrolyte and dextrose levels that allow the physician to customize the solutions to the needs of the individual patient. The PrismaSol solutions are intended to be utilized to replace blood volume lost in hemodialysis.

PrismaSol solutions are basic physiologic saline solutions with varying concentrations of specific electrolytes based on the patient's needs. As such, there are no ingredients of particular Pharmacological/Toxicological concern. Since this product is intended for use with hemofiltration and hemodialysis patients and will be administered by a physician who is closely monitoring serum electrolytes, there is nothing of Pharmacological/Toxicological concern at this time.

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