

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-910

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 21910
Submission N000, September 26, 2005

N21910 is an application for approval of Normocarb Solutions as a replacement solution in hemofiltration and hemodialysis. The Normocarb solutions are essentially the same as Dialysis Solutions line of bicarbonate-buffered hemofiltration and hemodialysis solutions, which are approved for use by CDRH. This family of solutions has variations in bicarbonate levels that allow the physician to customize the solutions to the needs of the individual patient. The Normocarb solutions are intended to be utilized to replace blood volume lost in hemodialysis.

Normocarb solutions are basic physiologic saline solutions with varying concentrations of bicarbonate 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 and pH, there is nothing of Pharmacological/Toxicological concern at this time.

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/s/

James Willard
5/11/2006 01:51:16 PM
PHARMACOLOGIST

Albert Defelice
5/22/2006 03:40:14 PM
PHARMACOLOGIST