CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-703

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

15 MAY 2006

NDA: 21-703

Drug Product Name
Proprietary: PrismaSol
Non-proprietary: N/A
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
27 SEP 2005	28 SEP 2005	10 OCT 2005	10 OCT 2005
07 APRIL 2006	10 APRIL 2006	10 APRIL 20076	N/A

Applicant/Sponsor
Name: Gambro Lundia AB
Address: PO Box 10 101
SE-220 10 Lund
Sweden
Representative: Fei Law
Telephone: 386-274-2811, ext. 143

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommend Approval.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** An original NDA

2. **SUBMISSION PROVIDES FOR:** New drug product.

3. **MANUFACTURING SITE:**
Gambro Renal Products
1845 Mason Ave.
Daytona Beach, FL 32771

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Solution
- Intravenous injection
- Multiple Strengths:
  #1 PrismaSol BK 0/3.5
  #2 PrismaSol BGK 2/0 mEq/L
  #3 PrismaSol BGK 2/3.5 mEq/L
  #4 PrismaSol BGK 4/3.5 mEq/L
  #5 PrismaSol BGK 4/2.5 mEq/L
  #6 PrismaSol BGK 4/0 mEq/L
  #7 PrismaSol BK 4/2.5 mEq/L
  #8 PrismaSol BGK 0/2.5 mEq/L
  #9 PrismaSol BK 0/0 mEq/L

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** For use in CRRT, as a replacement solution for HF and HDF [redacted]
Also for use in drug poisoning when CRRT is used to remove [redacted] filterable substances.

B. **SUPPORTING/RELATED DOCUMENTS:** Amendment to the subject submission dated 07 April 2006.

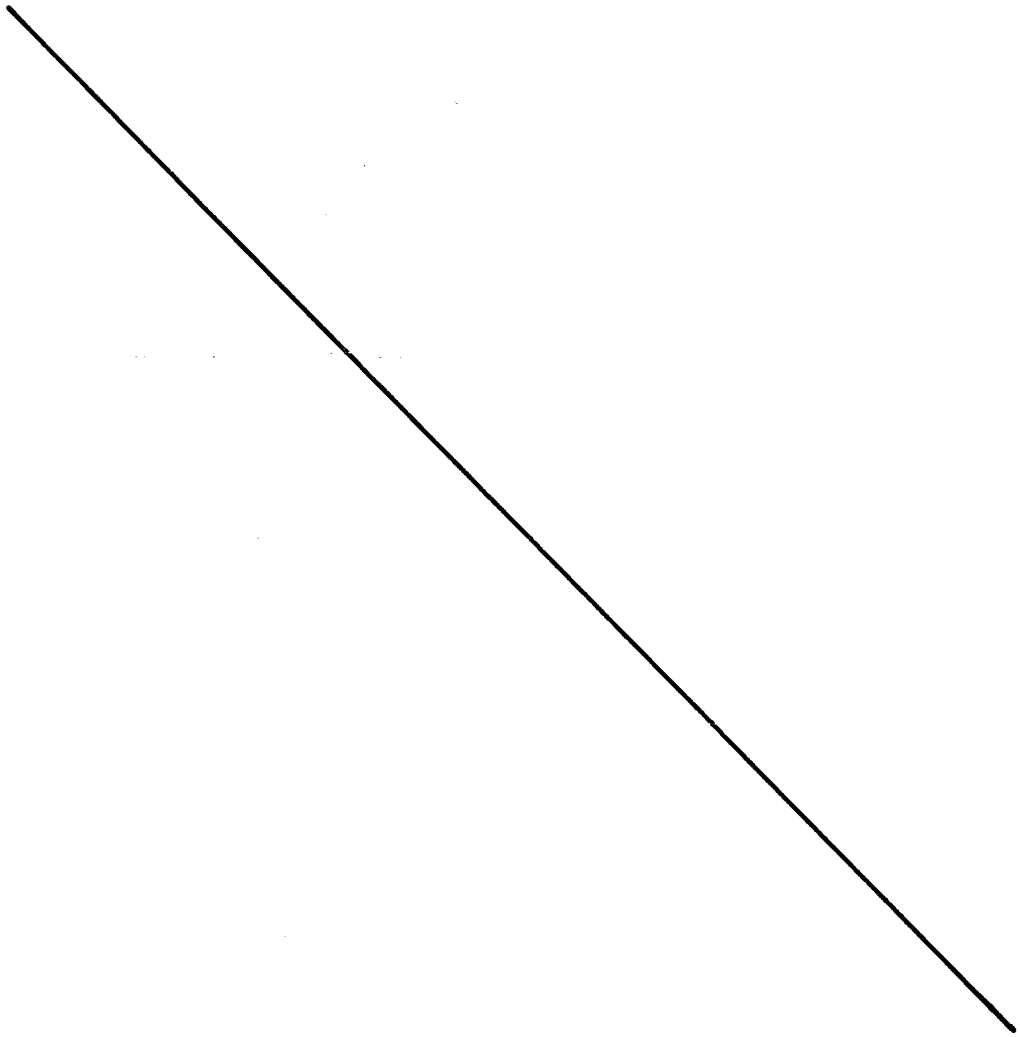
Appears This Way
On Original

Filename: N021703R1.doc

C. REMARKS:

An information request was forwarded to the applicant on 27 MAR 2006 with a list of questions resulting from this reviewer's initial review of the subject submission. Following is a copy of the information request which was directed to applicant:

The 27 September 2005 submission of NDA 21-703 (PrismaSol) has been reviewed by the Product Quality Microbiology Team. The following information requests resulting from this review are aimed at evaluating the sterility assurance of the subject drug product. Reference is made to the Agency's 1994 *Guidance for Industry for the Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products*.



A response to this information request was submitted by the applicant on 07 April 2006. Applicant responses to each question are incorporated into appropriate sections of this review.

Executive Summary

I. Recommendations

A. Recommendation on Approvability – NDA 21-703 is recommended for approval on the basis of microbiological product quality.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A.

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – [redacted]

B. Brief Description of Microbiology Deficiencies – There are no microbiology deficiencies.

C. Assessment of Risk Due to Microbiology Deficiencies – Not applicable.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Bryan Riley, Ph.D.

C. CC Block
N/A

13 Page(s) Withheld

X Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 1/1

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Metcalfe
5/19/2006 11:05:49 AM
MICROBIOLOGIST

Bryan Riley
5/19/2006 11:10:52 AM
MICROBIOLOGIST