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RESEARCH**

APPLICATION NUMBER:

022581Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

26 February 2010

NDA: 22-581/N000

Drug Product Name

Proprietary: Phoslyra

Non-proprietary: calcium acetate oral solution

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
20-JUL-2009	21-JUL-2009	23-OCT-2009	23-OCT-2009

Submission History (for amendments only) – NA

Applicant/Sponsor

Name: Fresenius Medical Care North America

Address: 920 Winter Street
Waltham MA 02451

Representative: J. Claude Miller, MS VP Regulatory Affairs

Telephone: (781) 699-2230

Name of Reviewer: Denise A. Miller

Conclusion: Approve

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA application
 - 2. SUBMISSION PROVIDES FOR:** This submission is for the manufacture of a (b) (4) solution.
 - 3. MANUFACTURING SITE:**
Lyne Laboratories
10 Burke Drive
Brockton MA 02301

Registration # 1224701
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
Dosage form: (b) (4) (b) (4), aqueous liquid
Route of Administration: oral
Strength/Potency: 667 mg/5 mL
 - 5. METHOD(S) OF STERILIZATION:** NA (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Control of hyperphosphatemia in patients with end stage renal disease.
- B. SUPPORTING/RELATED DOCUMENTS:** NA
- C. REMARKS:**
The application is a paper submission in CTD format.

filename: N022581N000R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** - Recommend to approve from a quality microbiology standpoint.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** - NA

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – Manufacture of an oral ^{(b) (4)} drug product.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** - NA

III. Administrative

- A. Reviewer's Signature** _____
Denise A. Miller, Microbiologist
- B. Endorsement Block** _____
Bryan S. Riley, Ph.D.
- C. CC Block**
N/A

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22581	ORIG-1	FRESENIUS BIOTECH NORTH AMERICA INC	PHOSLYRA(CALCIUM ACETATE)ORAL SOL 667MG/

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

/s/

DENISE A MILLER
03/03/2010

BRYAN S RILEY
03/03/2010
I concur.