DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205109

NDA APPROVAL

Vifor Fresenius Medical Care Renal Pharma France
Attention: Ms. Florence Dupre
President of VFMCRP France
7-13, Boulevard Paul-Emile Victor
92521 Neuilly-sur-Seine, France

Dear Ms. Dupre:

Please refer to your New Drug Application (NDA) dated January 31, 2013, received February 1, 2013, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Velphoro (sucroferric oxyhydroxide) Chewable Tablet, 500 mg.

We acknowledge receipt of your amendments dated February 15, 17, 18, March 8, 11, 13, 15, 28, April 3, 9, 19, 29, May 30, June 4, 17, July 4, 23, 25, August 7, 9, 13, 19, 22, 27, 29, September 3, 19, 24, October 18, 30, November 1, 20, and 26, 2013.

This new drug application provides for the use of Velphoro (sucroferric oxyhydroxide) chewable tablet for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. Please delete the cover letter.
2. In HIGHLIGHTS under Adverse Reactions, please include a phone number and web address.
3. In Section 17, the last sentence under bullet #1, please do not italicize Velphoro.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for*

Content of Labeling Technical Qs and As, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your November 26, 2013 submission containing final printed carton and container labels.

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels and carton and immediate container labels submitted on November 26, 2013, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 205109"** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

We are waiving the pediatric study requirement for ages from birth to less than one month because the necessary studies are impossible or highly impracticable. This is because the number of eligible patients in the age group of 0 to 28 days is very low.

We are also deferring submission of your pediatric study for ages one month to 17 years for this application because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act/FDCA are required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act/FDCA. This required study is listed below.

2103-1 Conduct a safety and efficacy trial in pediatrics aged 1month to 17 years.
Primary Objective(s):

- To evaluate the efficacy of PA21 in maintaining the serum phosphorus lowering effect in pediatric subjects with CKD in Stages 4-5 (defined by a glomerular filtration rate <30 mL/min/1.73 m2) or with CKD Stage 5D

receiving adequate maintenance HD or PD for at least 3 months prior to screening (versus placebo).

Secondary Objective(s):

- To evaluate the safety of PA21 in pediatric subjects with CKD.
- To evaluate the safety of Phoslyra™ in pediatric subjects with CKD.

Please consider the protocol recommendations provided in the preliminary comments dated September 5, 2013.

The timetable you submitted on October 24, 2013 via email states that you will conduct this study according to the following schedule:

Final Protocol Submission: 10/31/2014
Study/Trial Completion: 08/20/2018
Final Report Submission: 02/28/2019

Submit the protocol(s) to your IND 075610, with a cross-reference letter to this NDA.

Reports of this/these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Anna Park, Regulatory Project Manager, at (301)796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

cc: Fresenius Medical Care North America
Attention: Ms. Ruth Turner
U.S. Agent for Vifor Fresenius Medical Care Renal Pharma
Director, Regulatory Affairs Pharmaceuticals
920 Winter Street
Waltham, MA 02451

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

/s/

NORMAN L STOCKBRIDGE
11/27/2013