DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205109/S-006

SUPPLEMENT APPROVAL

Vifor Fresenius Medical Care Renal Pharma France
c/o Fresenius Medical Care North America (FMCNA)
Attention: Haifa Amra
Senior Manager, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Dear Ms. Amra:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 18, 2017, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Velphoro® (Sucroferric Oxyhydroxide) 25 mg, 50 mg, 100 mg, and 200 mg Chewable Tablets

This Prior Approval supplemental new drug application proposes for revisions to the following sections of the approved label:

- HIGHLIGHTS
- DOSAGE AND ADMINISTRATION updated to include revised information regarding chewing or crushing the tablets.
- ADVERSE REACTIONS updated to include percentage of Velphoro treated patients experiencing diarrhea during a dose-finding study
- DRUG INTERACTIONS updated to revise Table 1
- CLINICAL PHARMACOLOGY updated to include new information regarding drug interactions with acetylsalicylic acid and cephalexin
- NONCLINICAL TOXICOLOGY updated to include revised information in the 2 year carcinogenicity study
- CLINCIAL STUDIES updated to replace Figure 1, and add information regarding the proportion of adherence
- PATIENT COUNSELING INFORMATION updated to include revised information on chewing or crushing the tablets, and revising the information about discoloration of stools
- The word “chewable” was added throughout the label to describe Velphoro
- Updates were made to the carton and container labels

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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), with the addition of any labeling changes in pending

"Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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 titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 205109/S-006**." Approval of this submission by FDA is not required before the labeling is used.

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:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Health Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

MARY R SOUTHWORTH
04/25/2018