DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-287/S-021

sanofi-aventis U.S. LLC
Attention: Jo Beth Crimmins
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug application dated August 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kayexalate (sodium polystyrene sulfonate, USP) Powder.

We acknowledge receipt of your submissions dated March 4 and 30 (via email), 2009.

Your submission of March 4, 2009, constituted a complete response to our January 9, 2009, action letter.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the labeling:

1. The OVERDOSAGE section has been changed from:

   Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalemia, including: irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, which may progress to frank paralysis and/or apnea. Electrocardiographic changes may be consistent with hypokalemia or hypercalcemia; cardiac arrhythmias may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium), and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

   To:

   Overdosage may result in electrolyte disturbances including hypokalemia, hypocalcemia, and hypomagnesemia. Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalemia, including: irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, which may progress to frank paralysis and/or apnea. Tetany may occur. Electrocardiographic changes may be consistent with hypokalemia or hypocalcemia; cardiac arrhythmias may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium, magnesium), and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

2. Under DOSAGE AND ADMINISTRATION, the following sentence has been added to the end of the fourth paragraph:

   Healthcare professionals should follow full aspiration precautions when administering this product, such as placing and maintaining the patient in an upright position while the resin is being administered.

3. The revision date of the labeling has been updated.

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

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted electronic draft labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 19-439/S-022." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

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: Agreed-upon labeling text

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

/s/

Norman Stockbridge

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