DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011287/S-022 **APPROVAL LETTER**

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 May 20, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kayexalate (sodium polystyrene sulfonate, USP) Powder.

This supplemental new drug application provides for labeling revised as follows:

1. Under WARNINGS, the following information has been added:

   Colonic Necrosis: Cases of colonic necrosis and other serious gastrointestinal adverse events (bleeding, ischemic colitis, perforation) have been reported in association with KAYEXALATE use. The majority of these cases reported the concomitant use of sorbitol. Risk factors for gastrointestinal adverse events were present in many of the cases including prematurity, history of intestinal disease or surgery, hypovolemia, and renal insufficiency and failure. Concomitant administration of sorbitol is not recommended (see PRECAUTIONS, Drug Interactions).

2. Under PRECAUTIONS/Drug Interactions/Sorbitol, a cross-reference to the new colonic necrosis warning has been added.

3. Under DOSAGE AND ADMINISTRATION, the phrase “such as sorbitol” has been removed from the sixth paragraph.

4. Under DOSAGE AND ADMINISTRATION, the last sentence of the seventh paragraph has been changed from:

   Particular attention should be paid to this cleansing enema when sorbitol has been used.

   To:

   While the use of sorbitol is not recommended, particular attention should be paid to this cleansing enema if sorbitol has been used.

5. The revision number has been updated.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling. 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 NDA 011287/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 the requirements for an approved NDA set forth under 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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
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/

MARY R SOUTHWORTH
09/02/2009