



NDA 11-287/S-017

Sanofi-Synthelabo  
Attention: Ms. Andrea K. Czeizinger  
90 Park Avenue  
New York, NY 10016

Dear Ms. Czeizinger:

Please refer to your supplemental new drug application dated November 11, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kayexalate (sodium polystyrene sulfonate, USP) 100 mg sodium/gm Powder.

This "Changes Being Effected" supplemental new drug application provides for FPL revised by adding the following dosage information to the immediate container label:

“Average adult dose: 15 g (approximately 4 level teaspoons) one to four times daily in water.  
See complete prescribing information.”

In addition, we note the following changes in the current package insert, dated September 1999, submitted with this supplemental new drug application:

1. Under DESCRIPTION, the first sentence following the structural formula was changed from:

The drug is a sterile, light brown to brown finely ground powdered form of sodium polystyrene sulfonate, a cation-exchange resin prepared in the sodium phase with an *in vitro* exchange capacity of approximately 3.1 mEq (*in vivo* approximately 1 mEq) of potassium per gram.

To:

The drug is a cream to light brown finely ground, powdered form of sodium polystyrene sulfonate, a cation-exchange resin prepared in the sodium phase with an *in vitro* exchange capacity of approximately 3.1 mEq (*in vivo* approximately 1 mEq) of potassium per gram.

2. Under WARNINGS/Hypokalemia, the text was separated into two paragraphs.
3. The sentence “ KAYEXALATE should not be heated for to do so may alter the exchange properties of the resin.” was moved from the HOW SUPPLIED section to the end of the DOSAGE AND ADMINISTRATION section.

4. Under the HOW SUPPLIED section:

- The phrase “cream to light brown, finely ground” was added to the first sentence to read: “KAYEXALATE is available as a cream to light brown, finely ground powder in jars of 1 pound (453.6 G), NDC 0024-1075-01.”
- The phrase “Store at room temperature.” was replaced with “Store at 25°C (77° F); excursions permitted to 15° - 30° C (59°- 86° F) [see USP Controlled Room Temperature]”
- The sponsor was changed from Winthrop Pharmaceuticals to Sanofi-Synthelabo.
- The copyright and revised dates were updated.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted November 11, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, we note the manufacturer information at the end of the package insert and the container label are incorrect; Kayexalate is not manufactured for Sanofi-Synthelabo by the Bayer Corporation. Please revise the manufacturer information at the time of the next printing.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
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:

Mr. Daryl Allis  
Regulatory Health Project Manager  
(301) 594-5309

Sincerely,

*{See appended electronic signature page}*

Douglas C. Throckmorton M.D.  
Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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/s/

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Doug Throckmorton  
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