DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18902/S-027

**SUPPLEMENT APPROVAL**

Fresenius Kabi USA, LLC
Attention: Arabella Buesching
Associate Regulatory Specialist
Three Corporate Drive
Lake Zurich, IL 60047

Dear Ms. Buesching:

Please refer to your Supplemental New Drug Application (sNDA) dated August 21, 2015, received August 21, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Furosemide Injection, USP.

This Prior Approval supplemental new drug application provides for the following:

1. Update **Adverse Reactions** in accordance with other approved furosemide labeling.

2. Update **HOW SUPPLIED** section to include the full established name of the drug product.

3. Update **PRECAUTIONS/Drug Interactions** to describe an interaction between furosemide and levothyroxine in accordance with approved levothyroxine labeling. The language reads as follows:

   High doses (> 80 mg) of furosemide may inhibit the binding of thyroid hormones to carrier proteins and result in transient increase in free thyroid hormones, followed by an overall decrease in total thyroid hormone levels.

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 includes 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).

**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 Alexis Childers, RAC, SR. Regulatory Project Manager, at (301) 796-0442.

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

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/s/

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MARY R SOUTHWORTH
03/08/2016