DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017029/S-135; NDA 017651/S-059

APPROVAL LETTER

Fresenius Kabi USA, LLC
Attention: Aditi Dron
Manager, Regulatory Affairs
1501 East Woodfield Road Suite 300 E
Schaumburg, IL 60173

Dear Ms. Dron:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 11, 2013, received March 11, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER	SUPPLEMENT NUMBER	PRODUCT NAME
017029	S-135	Heparin Sodium Injection, USP
017651	S-059	Heparin Sodium Injection, USP

We acknowledge receipt of your amendments dated July 19, 2013, September 20, 2013, and January 29, 2014.

The September 20, 2013, submission constituted a complete response to our September 11, 2013, action letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes to the heparin sodium injection product labels. The Dose Label will appear as the total drug content per total volume followed in close proximity the strength expressed as units per milliliter in parenthesis.

We have completed our review of these supplemental new drug applications, as amended. These supplements are approved.

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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on

Product Applications and Related Submissions Using the eCTD Specifications (June 2008). Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 017029/S-135 and NDA 017651/S-059.**" Approval of this submission by FDA is not required before the labeling is used. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, call Jewell Martin, Regulatory Project Manager, at (301) 796-2072.

Sincerely,

{See appended electronic signature page}

Ali H. Al Hakim, PhD
Branch Chief, Branch II
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

ALI H AL HAKIM
03/21/2014