NDA 17029/S156
NDA 17651/S066

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Attention: Jennifer Boysen
Regulatory Specialist
Three Corporate Drive
Lake Zurich, IL 60047

Dear Ms. Boysen:

Please refer to your supplemental new drug applications (sNDAs) dated and received December 20, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 17651 S-066 Heparin Sodium Injection and NDA 17029 S0156 for Heparin Sodium Injection. We note that both NDAs share the same labeling.

These Prior Approval supplemental new drug applications provide for revisions to the Package Inserts to comply with the Physicians Labelilng Rule (PLR) and the Pregnancy and Lactation Lableling Rule (PLLR) formats.

APPROVAL & LABELING

We have completed our review of these applications, as amended. The are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling text for the Prescribing Information (2), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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, call Judit Milstein, Chief, Project Management Staff at 301-796-0763.

Sincerely,

{See appended electronic signature page}

Albert Deisseroth, MD, PhD
Associate Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)
Center for Drug Evaluation and Research

ENCLOSURE: Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALBERT B DEISSEROTH
07/02/2020 11:38:15 AM