DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19627/ S-060

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Attention: Dale Carlson
Senior Director, Regulatory Affairs
Three Corporate Drive
Lake Zurich, Illinois 60047

Dear Mr. Carlson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 9, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diprivan® (propofol) Injectable Emulsion.

We acknowledge receipt of your amendments dated April 10, 2013 and June 28, 2013.

The June 28, 2013 amendment constituted a commitment to revise the container and carton labeling within 6 months.

This "Changes Being Effected in 30 Days" supplemental new drug application provides to change the packaging configuration for 20 X 50 mL and 10 X 100 mL Diprivan® bottles in a carton from horizontal placement to upright vertical placement in the carton.

We have completed our review of this supplemental new drug application. This supplement is approved.

This supplemental new drug application provides for revisions to the labeling for Diprivan® (propofol) Injectable Emulsion.

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on January 10, 2013, except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling 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.

REVISIONS

1. For the 20 mL vial, revise the expression of strength as the total drug content followed by the concentration in a smaller sized font in accordance with USP General Chapter <1> requirements, similar to the proposed labels for the 50 mL and 100 mL vials.
   For example:
   Diprivan
   (Propofol) Injectable Emulsion, USP
   200 mg per 20 mL
   (10 mg per mL)

2. For the 20 mL vial, revise the statement "FOR I.V. ADMINISTRATION" to read "FOR INTRAVENOUS ADMINISTRATION," similar to the proposed labels for the 50 mL and 100 mL vials.

Please submit these labels electronically according to the guidance for industry titled "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 heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 19627/S-060**." Approval of this submission by FDA is not required before the labeling is used.

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 LCDR Luz E Rivera, Regulatory Project Manager, at (301) 796-4013.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
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/

RAMESH RAGHAVACHARI
07/09/2013