DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDAs see attached list

SUPPLEMENT APPROVAL

Fresenius Kabi USA
Three Corporate Drive
Lake Zurich, IL 60047

Attention: Jenna Holm
Regulatory Specialist

Dear Ms. Holm:

Please refer to your Supplemental Abbreviated New Drug Applications (sANDAs) dated and received May 22, 2014 and May 23, 2014, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for see attached list

We also refer to our letter dated April 23, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for injectable corticosteroids. This information pertains to the risk of serious neurologic events, some resulting in death, reported with epidural injection of corticosteroids.

These supplemental abbreviated new drug applications provide for revisions to the labeling for Dexamethasone Sodium Phosphate Injection, consistent with our April 23, 2014 letter.

We have completed the review of these supplemental applications and they are approved. However, please make the following editorial change and submit in the next annual report provided the change is explained in full:

> The SAFETY LABELING CHANGE NOTIFICATION letter dated April 23, 2014 requested that the information appear in the first subsection of the Warnings Section

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files. If you have any questions, contact Stephanie Lim, Regulatory Project Manager, at (240) 240-402-8998 or stephanie.lim@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: List of ANDAs
Attachment: Content of Labeling

040491/S-008 Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL (Preservative Free)
040572/S-002 Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL (Preservative)
084916/S-066 Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL

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

/s/

ROBERT L WEST

07/03/2014

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.