DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDAs 078522/S-005 [0.1 mg (base)/mL]
078090/S-005 [4 mg (base)/4 mL]
078096/S-005 [1 mg (base)/mL]

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Attention: Kurt Pearl
Regulatory Specialist

Dear Mr. Pearl:

Please refer to your Supplemental Abbreviated New Drug Applications (sANDAs) dated and received August 8, 2014, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Granisetron Hydrochloride Injection, USP.

We acknowledge receipt of your amendments dated August 29, 2014.

We also refer to our letter dated July 10, 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 the 5-HT_3 receptor antagonist class. This information pertains to the risk of serotonin syndrome.

These supplemental abbreviated new drug applications provide for revisions to the labeling for granisetron hydrochloride injection.

The agreed upon changes to the language included in our August 19, 2014, email communication are considered minor and editorial and do not change the original safety message issued in our July 10, 2014, Safety Labeling Change Notification Letter.

We have completed the review of these supplemental applications, as amended. They are approved effective on the date of this letter. However, please further revise your labeling as described below and submit as a separate Supplement Changes Being Effected (CBE-0).

GENERAL COMMENT

The Pediatric Exclusivity (M-102: information from pediatric study report ML16633, intravenous granisetron (kytril) in the prevention of post-operative nausea and vomiting (ponv) in pediatric subjects undergoing tonsillectomy or adenotonsillectomy) for the innovator (NDA 020239) expired on April 19, 2014.

Please revise your labeling to include the pediatric information previously protected by exclusivity M-102.

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 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.

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.

Postmarketing reporting requirements for these ANDAs 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.

If you have any questions, contact Heidi Lee, Regulatory Project Manager, at (240) 402-8989 or heidi.lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

CAPT Jason J.Y. Woo, M.D., M.P.H.
Acting Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling