



NDA 020648/S-013

**SUPPLEMENT APPROVAL**

Valeant Pharmaceuticals North America, LLC (VPNA)  
400 Somerset Corporate Blvd.  
Bridgewater, New Jersey 08807  
Attention: Libette Luce, MA  
Director, U.S Regulatory Affairs

Dear Ms. Luce:

Please refer to your Supplemental New Drug Application (sNDA) dated August 5, 2016, received August 5, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diastat (diazepam rectal gel)/ Diastat AcuDial (diazepam rectal gel) Rectal Delivery System.

This “Changes Being Effected” supplemental new drug application provides for the following revised statement on the Pharmacy Instruction Cards (PIC):

Original Statement:

ADJUST SYRINGES PRIOR TO DISPENSING

Revised Statement:

DIAL AND LOCK DOSE FOR SYRINGES PRIOR TO DISPENSING

**APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels (e.g., the pharmacy instruction cards) submitted on August 5, 2016, 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 heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 020648/S-013.**” 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.

## **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, contact E. Andrew Papanastasiou, Regulatory Project Manager, via email at [emilios.papanastasiou@fda.hhs.gov](mailto:emilios.papanastasiou@fda.hhs.gov) or by phone at (301) 796-1930.

Sincerely,

*{See appended electronic signature page}*

Alice Hughes, MD  
Deputy Director for Safety  
Division of Neurology Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Pharmacy Instruction Cards

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ALICE HUGHES  
10/27/2016