



NDA 020648/S-009

**SUPPLEMENT APPROVAL**

Valeant Pharmaceuticals North America  
Attention: Elizabeth L. Tan, Ph.D.  
Director, Regulatory Affairs  
700 Route 202/206 North  
Bridgewater, New Jersey 08807

Dear Dr. Tan:

Please refer to your Supplemental New Drug Application (sNDA) dated January 23, 2008, received January 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diastat AcuDial Rectal Gel (diazepam rectal gel) 2.5mg, 10mg, and 20mg.

Application	Drug Product	Submitted on:	Received on:
NDA 020648/S-009	Diastat AcuDial Rectal Gel (diazepam rectal gel) 2.5mg, 10mg, and 20mg.	01/23/2008 04/09/2013	01/24/2008 04/10/2013
<b>These “Changes Being Effectuated” supplements provide for:</b>			
<ul style="list-style-type: none"> <li>• A packaging labeling non-adhesive band and tab containing a conspicuous alert message to the pharmacist to dial and lock the Diastat syringes prior to dispensing.</li> <li>• A revised Pharmacist Instruction Card, common to the 10mg and 20mg delivery systems, containing a prominent STOP sign and message to dial and lock the Diastat syringes prior to dispensing.</li> <li>• A request to replac (b) (4) with the correct wrap band (Part Number (b) (4)), which protrudes from the side of the carton (also know as a sidersert).</li> </ul>			

We acknowledge receipt of your amendments dated February 7, 2013, March 31, 2013, April 1, 2013, April 2, 2013, April 5, 2013, April 9, 2013, and April 12, 2013.

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

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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-009.**” 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.

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## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Amundson Avenue  
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **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 Su-Lin Sun, Pharm.D, Regulatory Project Manager, at (301) 796-0036 or email [su-lin.sun@fda.hhs.gov](mailto:su-lin.sun@fda.hhs.gov) .

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, M.D.  
Acting Director  
Division of Neurology Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURES:

Revised 10mg Pharmacist Card  
Revised 20mg Pharmacist Card  
Sidesert for 10mg and 20mg  
Assembly Instruction Diagram (non-adhesive band/tab label)

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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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ERIC P BASTINGS  
08/29/2013