



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-721/S-077

Valeant Pharmaceuticals, International
One Enterprise
Aliso Viejo, CA 92656

Attention: Arthur Rosenthal, RAC
Sr. Director, Corporate Regulatory Affairs

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated January 25, 2008, received January 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dalmane (flurazepam hydrochloride), 15 mg and 30 mg oral Capsules.

This supplemental new drug application provides for the implementation of a Medication Guide.

We completed our review of this application and it is approved, effective on the date of this letter for use as recommended in the attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the Medication Guide dated January 25, 2008).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 16-721/S-077**". Approval of this/these submission(s) by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Neurology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Cathleen Michaloski, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director, Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure: Medication Guide

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

/s/

Russell Katz
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