DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-721 / S-076, S-058

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 June 6, 2007 (serial #076), and received June 7, 2007 for Dalmane (flurazepam hydrochloride) capsules.

In addition we acknowledge receipt of your submission dated January 12, 2007 (serial #058).

This "Changes Being Effected" supplemental new drug application provides for changes to the package insert in response to the Agency's March 2, 2007 letter requesting a class labeling change for the sedative-hypnotic group.

We completed our review of this application, as amended. This application 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 package insert submitted on June 6, 2007).

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 of this submission "**FPL for approved supplement NDA 16-721, S-076**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit revised content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at the following website: http://www.fda.gov/oc/datacouncil/spl.html

We note that you provided a complete response to our October 21, 2002 approvable letter in supplemental application S-058 on November 14, 2006, and again on January 12, 2007. However, we note that all of the proposed changes included in the S-058 submission are approved in this action letter. Therefore, this supplemental application will be retained in our files with no further action.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, MD
Director
Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure: Approv Labeling 16721/ S-076

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

10/30/2007 04:29:57 PM