DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-677/S-013

Valeant Pharmaceuticals International
Attention: Arthur Rosenthal, R.A.C.
Sr. Director, Corporate Regulatory Affairs
One Enterprise
Aliso Viejo, CA 92656

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated December 13, 2007, received December 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cesamet (nabilone) capsules, 1 mg.

We acknowledge receipt of your submissions dated April 28, 2008; July 7, 2008; July 18, 2008; November 25, 2008; and December 1, 2008.

This supplemental new drug application provides for:

- a formulation change – reduction in the amount of an excipient, Starch USP
- a color change in the imprint ink, the capsule cap, a company name change on the capsule cap from ICN to Valeant, and a change in the four digit code on the white body
- a change in the bottle count from 20 to 50, and a change in the NDC number
- changes in the manufacturing process from **(b) (4)**

We have 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 agreed-upon labeling text and with the revisions listed below. We acknowledge your submissions dated November 25, 2008 and December 1, 2008 in which you agreed to the following revisions.

Package Insert

- In the "DOSAGE AND ADMINISTRATION" section of the insert labeling, there is inconsistency in the presentation of the dosing frequency statements. For consistency and to minimize the potential for confusion due to the use of abbreviations, present the dosing frequency as 2 or 3 times a day, 2 times a day, or 3 times a day to optimize clarity.

Carton and Container Labeling

- Revise the established name to include the dosage form (i.e. Nabilone Capsules) on both the container label and carton labeling. Additionally, increase the prominence of

the established name so that it is at least one-half the size of the proprietary name in accordance with 21 CFR 201.10 (g)(2).

- Increase the prominence of the NDC number by increasing the size of the NDC number.
- Remove your company logo from the larger block on the principal display panel. Placing your company name in this block increases the prominence of the company name. The proprietary name, established name and strength should be the most prominent information on your labels.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed, the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted July 18, 2008. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplemental NDA 18-677/S-013**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels dated July 18, 2008, except with the revisions listed above, 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. 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 supplemental NDA 18-677/S-013**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug

LETTERS TO HEALTH CARE PROFESSIONALS

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

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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures: Package Insert Label

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

/s/

Donna Griebel

12/5/2008 04:22:43 PM