DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-677/S-011

Valeant Pharmaceuticals International
Attn: Arthur Rosenthal
Director, Corporate Regulatory Affairs
3300 Hyland Avenue
Costa Mesa, CA 92626

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated November 4, 2004, received November 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cesamet™ (nabilone) Capsules, 1mg.

We acknowledge receipt of your submissions dated December 14, 2005, February 8, April 10, April 19, and May 8, 2006. Your April 10 and 19, 2006 submissions constituted a complete response to our December 23, 2005 action letter.

This supplemental new drug application provides for revisions to your package insert to comply with current labeling regulations.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

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 18-67/S-011**." Approval of this submission 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 product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Gastroenterology Products, and two copies of both the promotional materials and the package inserts 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). Due to the reintroduction of this product into the market, please submit a periodic safety report on a quarterly basis for the first year [21 CFR 314.80(c)(2)(i)].

If you have any questions, call Giuseppe Randazzo, Regulatory Project Manager, at (301) 796 - 0980.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D. Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (Agreed upon label)

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

/s/

Brian Harvey
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