DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-720/S-016

Valeant Pharmaceuticals International
3300 Hyland Avenue
Costa Mesa, CA 92626

Attention: Arthur L. Rosenthal, RAC
Director of Regulatory Affairs

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated May 18, 2001, received May 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levo-Dromoran (levorphanol tartrate) 2 mg Tablets.

We acknowledge receipt of your submission dated May 14, 2004.

Your submission of May 14, 2004, constituted a complete response to our December 28, 2001, action letter.

This supplemental new drug application proposes a (b)(4)----------
(b)(4)----------, a change in manufacturing process for drug product, a new location for packaging and distribution of finished drug product, a new location for release testing for drug product and stability testing site, an additional known impurity in specification for drug product, implementation of an HPLC procedure for dissolution testing, and revisions to the package insert and immediate carton and container labels.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and immediate container and carton labels submitted May 14, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 8-720/S-016." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you of your telephone conversation with Lisa Basham-Cruz, Regulatory Project Manager, on September 3, 2004, in which you agreed to the following:

1. Tighten the following acceptance criteria for the impurities (b)(4)--- in the drug product.

   (b)(4)----------

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2. The limits for the particle size distribution (b)(4)---------- (b)(4)----- are acceptable as being tentative. Based on the analysis of five additional batches of the drug substance, establish the limits for % retained for the (b)(4)---------- and report the final specification in the annual report.

3. Provide the revised specification sheet for the drug product.

We also remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Ravi Harapanhalli, PhD
Chemistry Team Leader
Division of Anesthetic, Critical Care, and
Addiction Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Ravi Harapanhalli
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AP with reminder