



NDA 21-400/S-011

Bayer Pharmaceuticals
Attention: Mary Ellen Evanich
Assistant Director, Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Evanich:

Please refer to your supplemental new drug application (NDA) dated September 19, 2007, received, September 24, 2007, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for LEVITRA[®] (vardenafil hydrochloride) tablets.

We further refer to your February 19, 2008, amendment, in response to the Division's proposed revisions to the LEVITRA Package Insert (PI) provided to you via email on February 6, 2008.

This Prior Approval supplement provides for 1) revisions to LEVITRA labeling in response to the Division's request dated January 11, 2007, that the terms "seizure" and "seizure recurrence" be added to the **POST-MARKETING EXPERIENCE** section, **Neurologic** subsection, and 2) addition to the **Pharmacodynamics: Effects on Vision** subsection of the **CLINICAL PHARMACOLOGY** section of the LEVITRA labeling.

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

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 the enclosed labeling (text for the package insert, text for the patient package insert). 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 NDA 21-400/S-011."

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

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If you have any questions, call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

George Benson
3/19/2008 02:54:35 PM