DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-400/S-012

Bayer Pharmaceuticals
Attention: Sharon Brown
Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Brown:

Please refer to your supplemental new drug application (NDA) dated February 12, 2008, received, February 13, 2008, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for LEVITRA® (vardenafil hydrochloride) tablets.

This Prior Approval supplement provides for the addition of the term "transient global amnesia" to the **POST-MARKETING EXPERIENCE** section, **Neurologic** subsection 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-012."

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 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

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
5/15/2008 10:17:38 AM