DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-400/S-010

Bayer Pharmaceuticals
Attention: Mary Ellen Evanich
Assistant Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

Dear Ms. Evanich:

Please refer to your supplemental new drug application (NDA) dated August 31, 2007, received September 4, 2007, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for LEVITRA® (vardenafil hydrochloride) tablets.

We also acknowledge receipt of your submission of September 24, 2007 and your email correspondence dated October 12, 2007, conveying your agreement to the Division's recommended changes to the LEVITRA Package Insert (PI) and Patient Package Insert (PPI).

This Prior Approval supplement provides for revisions to LEVITRA labeling in response to the Division's request that the potential risk of sudden hearing loss be addressed in the product labeling for PDE5 inhibitors. Specifically, this supplement provides for labeling changes under the following sections of the LEVITRA labeling:

- **PRECAUTIONS, Information for Patients**
- **ADVERSE REACTIONS,** AUDITORY
- **POST-MARKETING EXPERIENCE, Otologic**
- **POSSIBLE SIDE EFFECTS** section of the PPI

Additionally, we also acknowledge your October 12, 2007, submission containing a proposal for a risk communication plan regarding these changes. We find the proposal reasonable and appropriate.

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-010."

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print.

Send one copy to the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert(s) 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

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}

Scott Monroe, M.D.
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/

Scott Monroe

10/18/2007 11:57:45 AM