DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-400

Bayer Pharmaceuticals Corporation
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 dated October 9, 2006, received October 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levitra® (vardenafil hydrochloride), 2.5mg, 5.0mg, 10mg and 20mg.

This "Prior Approval" supplement was submitted in response to the Division's Supplement Request Letters dated March 15 and May 16, 2006, and it provides for:

1) Labeling revisions regarding the effect on the QT interval when vardenafil is taken with another drug of the same QT effect, and
2) labeling revisions regarding the potential for drug-drug interaction when vardenafil is taken with potent inhibitors of cytochrome p450 3A4.

We also refer to your submissions dated January 2, 2007, and email communications dated February 20 and March 8, and April 3, 2007, stating your agreement to the Division's recommended changes to the labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, please call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-2130.

Sincerely,

{See appended electronic signature page}

Mark Hirsch, 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/

Mark S. Hirsch

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