DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-895/S-028 and S-029

Pfizer, Inc.
Attention: Naumann Chaudry, Pharm.D.
Associate Director, US Regulatory Affairs
235 East 42nd Street MS 235/3/4
New York, NY 10017

Dear Dr. Chaudry:

Please refer to your supplemental New Drug Applications (NDA) dated February 7, and July 16, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIAGRA® (sildenafil citrate) Tablets.

Prior Approval supplement (S-028) provides for labeling revisions in the Clinical Pharmacology section. The requested changes are based on the sponsor's review of Clinical Pharmacology and Pharmacokinetics studies submitted to support approval under the original NDA approved in 1998.

Prior Approval supplement (S-029) provides for a labeling revision, in response to the Division's Supplement Request Letters dated March 26, and June 23, 2008, to add the term "transient global amnesia" under the existing **Nervous** heading in the **Other Events** subsection of the **POST-MARKETING EXPERIENCE** subsection of the **ADVERSE REACTIONS** section of the VIAGRA labeling.

We have completed our review of these applications and they are 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 20-895/S-028 and 029."

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 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, please call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
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
8/6/2008 04:11:12 PM