DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-664/S-007

Pfizer, Inc.
Attention: Carol Haley, Ph.D.
Regulatory Strategist Director
235 East 42nd Street
New York, NY 10017

Dear Dr. Haley:

Please refer to your supplemental new drug application dated January 23, 2006, received January 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DOSTINEX® (cabergoline), 0.5 mg tablets.

This supplemental new drug application provides for the addition of a specification limit of not more than 1.0% for a cabergoline [redacted] impurity.

We acknowledge receipt of your submissions dated May 23 and 26, June 21, October 6, December 5 and 13, 2006. Your submission of October 6, 2006, constituted a complete response to our May 24, 2006, action letter.

We also refer to our February 7, 2007, teleconference between Corinne Gamper (Director/Team Leader) and Clara Arrocain, M.D. (Associate Director), both representing Worldwide Regulatory Strategy of Pfizer, Inc., and Jennifer Mercier (Chief, Project Management Staff) and Nenita Crisostomo, R.N. (Regulatory Health Project Manager), both representing the Division of Reproductive and Urologic Products of FDA to discuss the post-marketing adverse event reports that we, in conjunction with the Division of Drug Risk Evaluation have evaluated. During this teleconference, it was agreed to update the DOSTINEX® label to include language in the **ADVERSE REACTIONS** section, ***Post-Marketing Surveillance Data*** subsection to read as follows:

> ***Post-marketing Surveillance data:*** The following events have been reported in association with cabergoline: valvulopathy and fibrosis. (See PRECAUTIONS section ***Fibrosis/Vavulopathy***.) In addition, during post-marketing surveillance, cases of alopecia, aggression and psychotic disorder have been reported in patients taking DOSTINEX®. Some of these reports have been in patients who have had prior adverse reactions to dopamine agonist products.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-664/S-007**". Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Center for Drug Evaluation and Research
Office of Drug Evaluation III

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

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