



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-664/S-010

Pfizer, Inc.  
Attention: Clara Arroccain, M.D.  
Associate Director  
235 East 42<sup>nd</sup> Street 685/18/49  
New York, NY 10017

Dear Dr. Arroccain:

Please refer to your supplemental new drug application dated October 10, 2007, received October 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DOSTINEX<sup>®</sup> (cabergoline) Tablets.

We acknowledge receipt of your submissions dated November 27, December 6, 13, and 17, 2007.

This supplemental new drug application provides for the revision of the Package Insert, under Contraindications, Warnings, Precautions, Adverse Reactions, and Dosage and Administration sections to provide additional information concerning treatment with DOSTINEX<sup>®</sup> and the possible risk of valvular disease.

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.

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(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. 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 20-664/S-010." The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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.  
Director  
Division of Reproductive and Urologic Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Scott Monroe  
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