**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-886/S-022

Pfizer, Inc.
Attention: Lisha Cole
Regulatory Liaison Director
235 East 42nd Street
New York, NY 10017

Dear Ms. Cole:

Please refer to your supplemental new drug application dated October 12, 2005, received October 13, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SYNAREL® (nafarelin acetate) Nasal Spray Solution.

This supplemental new drug application provides for the use of SYNAREL® (nafarelin acetate) Nasal Spray Solution for the treatment of endometriosis.

We completed our review of this application, as amended per our request dated May 11, 2005, to add the language regarding pituitary apoplexy, which was further revised and conveyed to you on August 18, 2005. 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 submitted labeling text for the package insert and the patient package insert submitted October 12, 2005.

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 19-886/S-022**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-2130.

Sincerely,

*{See appended electronic signature page}*

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Scott Monroe

4/12/2006 10:57:00 AM