DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020246/S-036 **SUPPLEMENT APPROVAL**

Pfizer, Inc.
Attention: Clara Arrocain
Associate Director, Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Arrocain:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on December 17, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Depo-Provera Contraceptive Injection (medroxyprogesterone acetate) injectable suspension, for intramuscular use.

We acknowledge receipt of your amendments dated January 7, February 9, April 8, and 27, July 15, and October 14, 2010.

This supplemental new drug application provides for revisions to the Package Insert that include the following:

1. Changes to the WARNINGS AND PRECAUTIONS section related to the loss and recovery of bone mineral density in adolescent girls during and following the use of Depo-Provera Contraceptive Injection.
2. Updated information in the CLINICAL STUDIES section related to the loss and recovery of bone mineral density in adolescent girls during and following the use of Depo-Provera Contraceptive Injection. These revisions are based upon the results of the Final Report for Study A6791022: "DEPO PROVERA: Evaluation of Bone Mineral Density and Total Body Calcium in Adolescent DP150CI Users and Non Hormonal Contraceptive Users."
3. A minor revision of the wording for the third bullet in the Boxed Warning as shown below (strike-through of deleted words and underline of added words):

   Depo-Provera Contraceptive Injection should not be used as a long-term birth control method (~~e.g.,~~ i.e., longer than 2 years) ~~only if~~ unless other birth control methods are considered inadequate.
4. Changes to the WARNINGS AND PRECAUTIONS section related to Breast Cancer Risk.
5. Changes to Patient Labeling for consistency with revisions made to Physician Labeling.
6. Conversion of the Package Insert to the Physician Labeling Rule format for labeling.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials

should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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, call Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

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(S):
Content of Labeling

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

/s/

SCOTT E MONROE
10/15/2010