DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021583/S-032

**SUPPLEMENT APPROVAL**

Pfizer, Inc.
Attention: Greg Carrier
Senior Director, Worldwide Safety and Regulatory
2350 East 42nd Street
New York, NY 10017

Dear Mr. Carrier:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 12, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for depo-SubQ provera 104 (medroxyprogesterone acetate).

This Prior Approval supplemental new drug application provides for revisions to the WARNINGS section, subsection Anaphylaxis and Anaphylactoid Reaction and ADVERSE REACTIONS section, subsection Postmarketing Experience to note the occurrence of such reactions (including angioedema) with depo-SubQ provera 104.

## APPROVAL & 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

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/s/

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CHRISTINE P NGUYEN
10/14/2016