DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-928/S-012
NDA 21-928/S-013

Pfizer Inc.
235 E. 42nd Street
New York, NY 10017

Attention: Lilya Donohew, Ph.D.
Director, Worldwide Regulatory Affairs

Dear Dr. Donohew:

Please refer to your supplemental new drug applications dated January 16 and March 19, 2009, received January 16 and March 19, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Chantix (varenicline) tablets 0.5 mg and 1 mg.

We acknowledge receipt of your submissions dated June 4, 15, and 17, 2009 (to both supplements).

Reference is made to our Supplement Request letter dated December 22, 2008, requesting changes to the **MEDICATION GUIDE**, and **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the Package Insert.

Reference is also made to our letter dated February 19, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Chantix (varenicline). This information pertains to the risk of suicidality-related events in patients using Chantix (varenicline). The letter requested revisions to the **WARNINGS** and **ADVERSE REACTIONS** sections, and addition of a new **BOXED WARNING** to the package insert.

Supplement S-012, submitted in response to our December 22, 2008 letter, provides for revisions to the following sections of the package insert:

- **PRECAUTIONS: General:** ***Accidental Injuries***
- **PRECAUTIONS: General:** ***Angioedema and Hypersensitivity Reactions***
- **PRECAUTIONS: Information for Patients**
- **ADVERSE REACTIONS: Post-Marketing Experience**
- **MEDICATION GUIDE**

Supplement S-013 provides for revisions to the labeling for Chantix (varenicline), consistent with our letter dated February 19, 2009.

We also refer to the email correspondences between FDA and Pfizer dated May 21, June 10, 15, 16, and 17, 2009, in which agreement was reached on these safety labeling changes.

We have completed our review of these supplemental applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text for the package insert and the Medication Guide, and in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on June 17, 2009.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

PROMOTIONAL MATERIALS

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

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Ayanna Augustus, Regulatory Project Manager, at (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Drugs
Office of New Drugs II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

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