DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-928/S-003

Pfizer Inc
235 East 42nd Street
New York City, NY 10017

Attention: Samantha McNamara
Director, US Regulatory Affairs

Dear Ms. McNamara:

Please refer to your supplemental new drug application dated May 9, 2007, received May 9, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chantix (varenicline) Tablets.

We acknowledge receipt of your email communications dated November 14 and 20, 2007.

This "Changes Being Effected" supplemental new drug application provides for the following package insert and patient package insert labeling changes:

- Modification of the patient package insert to address possible drug adverse effects related to sleep and dreaming disturbance, depression, agitation, suicidal thoughts, and problems with driving or operating machinery when beginning treatment with varenicline to attempt to quit smoking.

- Modification of the package insert's **PRECAUTIONS, Information for Patients** section to address possible adverse drug effects relating to driving or operating machinery when beginning treatment with varenicline to attempt to quit smoking.

- Modification to the **ADVERSE REACTIONS** section to address the potential for newly emergent psychiatric illness and the potential for exacerbation of underlying psychiatric illness that may occur following treatment with varenicline to attempt to quit smoking.

- Several minor editorial changes (correction of typographical errors).

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and for the patient package insert.

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert and patient package insert. 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 21-928/S-003 " 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
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, call Dominic Chiapperino, Regulatory Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved package insert and patient package insert labeling

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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.

/s/

Rigoberto Roca
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