DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-928/S-007

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 and received on January 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chantix (varenicline).

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

- Modification of the **WARNINGS** section to include a new paragraph that addresses neuropsychiatric symptoms, as described in reported adverse events.

- Modification of the package insert's **PRECAUTIONS, Information for Patients** section to address these same neuropsychiatric symptoms.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL), submitted on January 17, 2008 (copy enclosed).

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 2099-0002

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the WARNINGS and PRECAUTIONS sections that appear in the revised package insert

labeling. Please submit a written response to this request on or before February 15, 2008, stating whether you intend to comply with this request 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

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 labeling

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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