DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021928/SLR-014, SLR-017 **SUPPLEMENT APPROVAL**

Pfizer, Inc.
235 East 42nd Street
Mailstop 605 6 31
New York, NY 10017

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

Dear Dr. Donohew:

Please refer to your supplemental new drug applications dated July 20, 2009, and January 14, 2010, received July 20, 2009, and January 14, 2010, 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 February 17, 2010 (S-017) and February 25, 2010 (S-014).

Supplement NDA 021928/S-014 proposes conversion of the content of the currently approved package insert into the Physicians Labeling Rule (PLR) format as set forth under 21 CFR 201.56 and 21 CFR 201.57.

We also refer to the email correspondences between FDA and Pfizer dated March 16, 2010, in which agreement was reached on content of the package insert in the PLR format.

Supplement NDA 021928/S-017 provides for a proposed modification to the approved risk evaluation and mitigation strategy (REMS) and includes your REMS assessment.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text for the package insert, Medication Guide and modified REMS.

CONTENT OF LABELING

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)(1)(i)] 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 Medication Guide). For administrative purposes, please designate this submission, "SPL for approved NDA 21928/S-014 and S-017.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Chantix (varenicline) was originally approved on October 19, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. The proposed modified REMS contains a revised Medication Guide that includes a new section "Who should not take Chantix".

Your proposed modified REMS, submitted on January 14, 2010, and appended to this letter, is approved. The REMS consists of the Medication Guide and the timetable for submission of assessments.

The timetable for submission of assessments will remain the same as that approved on October 19, 2009.

There are no changes to the REMS assessment plan described in our October 19, 2009 letter.

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to 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 following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see 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.

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 at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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, contact Ayanna Augustus, Regulatory Project Manager, at ayanna.augustus@fda.hhs.gov or (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, MD, MHS
Deputy Director for Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

1. Package Insert
2. Medication Guide
3. REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21928	SUPPL-17	PFIZER INC	CHANTIX
NDA-21928	SUPPL-14	PFIZER INC	CHANTIX

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

/s/

LARISSA LAPTEVA
04/22/2010