



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 21-928/SLR-015

**SUPPLEMENT APPROVAL**

Pfizer, Inc.  
235 East 42<sup>nd</sup> 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 application dated August 20, 2009 received August 20, 2009, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Chantix® (varenicline).

This “Changes Being Effected” supplemental new drug application provides for changes to the outer carton/container packaging for the Chantix.

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 final printed labeling text (FPL) submitted on December 12, 2009.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA 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, call Ayanna Augustus, Regulatory Project Manager, at (301) 796-3980.

Sincerely,

*{See appended electronic signature page}*

Larissa Lapteva, M.D.  
Deputy Director of Safety  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure  
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21928	SUPPL-15	PFIZER INC	CHANTIX

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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.**

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/s/

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LARISSA LAPTEVA  
02/04/2010