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
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<td>SUPPL-15</td>
<td>PFIZER INC</td>
<td>CHANTIX</td>
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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/

LARISSA LAPTEVA
02/04/2010