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/

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Bob Rappaport
1/31/2008 06:24:24 PM