



NDA 20-714/S-016

Pharmacia & Upjohn Company
235 East 42nd Street
New York, NY 10017

Attention: Amanda Radola, MS
Associate Director
Worldwide Regulatory Strategy

Dear Ms. Radola:

Please refer to your supplemental new drug application dated December 17, 2008, received December 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol[®] Inhaler (nicotine inhalation system).

We acknowledge receipt of your submission dated January 23, 2009.

This "Changes Being Effected" supplemental new drug application provides the following change to the package insert:

OVERDOSE: Overdose from Inhalation- Changing the current emergency number (1-800-498-8666), a Pfizer maintained number, to the National Capital Poison Center (1-800-222-1222).

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 attached content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on December 17, 2008. We will transmit this version to the National Library of Medicine for public dissemination.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
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 Margarita Tossa, Regulatory Project Manager, at (301) 796-4053.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Bob Rappaport
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