DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-385/S-007
NDA 20-714/S-012

Pfizer Consumer Healthcare
201 Tabor Road
Morris Plains, New Jersey 07950

Attention: Diane D. McPherson
Associate Director, Global Regulatory Affairs

Dear Ms. McPherson:

Please refer to your supplemental new drug applications dated January 15, 2004, received January 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol NS (nicotine nasal spray) and Nicotrol Inhaler (nicotine inhalation system).

The supplements provide for a revised **HOW SUPPLIED** section of the package insert.

We have completed the review of these supplemental applications and they are approved effective on the date of this letter.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Pratibha Rana, Regulatory Health Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Bob Rappaport

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