DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-385/S-005
NDA 20-714/S-011

Pharmacia 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 September 29, 2003, received October 1, 2003, 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).

We also acknowledge receipt of your correspondence dated October 22, 2003.

The supplements provide for a revised **Patient Package Insert** for each product.

As stated in your correspondence dated October 22, 2003, the **HOW SUPPLIED** section of the Package Insert will remain the same as previously approved under NDA 20-385/S-005 and 20-714/S-010. There will be no changes made to the packaging configuration of any products.

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

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to each 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 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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