



NDA 20-385/S-005

Pharmacia Consumer Healthcare
100 Route 206 North
Peapack, New Jersey 07977

Attention: Stephanie Barba
Associate Director, Regulatory Affairs

Dear Ms. Barba:

Please refer to your supplemental new drug application dated March 11, 2002, received March 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol NS (nicotine nasal spray).

The supplement provides for a revised **HOW SUPPLIED** section and a revised carton label.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-385/S-005." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (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.

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

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, 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
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/s/

Cynthia McCormick
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