



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 29 2003

Food and Drug Administration
Rockville MD 20857

7807 '03 NOV -3 P1:22

Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903

Re: Docket No. 2003P-0196/CP1

Dear Mr. Mayer:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on May 28, 2003. Your petition requests that the Agency switch Nicotrol Inhaler (Nicotine Inhalation System) from prescription only to over-the-counter status to be sold only under a pharmacist's supervision as a third class of drugs.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0196

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