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2529 '03 MAY -8 P1:23

April 28, 2003

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20852

Re: Amended Citizen's Petition for Switching Nicotrol Inhaler from Rx to OTC

The undersigned submits this amended petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drug to request the Commission of Food and Drug to 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.

Currently FDA allows a third class of drugs category which includes injectable needles, syringes, insulin, pseudoephedrine, ephedrine products, etc.

Nicotrol Inhaler (Nicotine Inhalation System) should be added to this category and should be dispensed or sold unless counseling and supervision including "not to be sold under eighteen years of age (to minors)" is instituted by a registered pharmacist or healthcare provider.

PPSI encourages FDA to institute this switch as soon as possible. There is no environmental impact associated with this amended Citizen's Petition. We wish to be excluded under 21 CFR Section 25.24. There is no economic impact associated with this amended Citizen's Petition. According to recent studies there would be a ten billion dollar savings or more in hospital costs, lung cancers, emphysema, emergency room and doctor's visits.

The undersigned certified that to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

Signature _____

Name of Petitioner: **Frederick S. Mayer, R.Ph., M.P.H**
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April 9, 2003

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20852

Re: Citizen's Petition for Switching Nicotrol Inhaler from Rx to OTC

The undersigned submits this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the Commissioner of FDA to switch Nicotrol Inhaler (Nicotine Inhalation System) from prescription drug only to over-the-counter (OTC) status.

This Petition requests the FDA Commissioner to issue a Federal Regulation to augment this switch from prescription drug to OTC status immediately.

Some of the scientific facts which require immediate action on this Petition are as follows:

1. Although 48 million Americans have stopped smoking, there are still 50 million in the US who still smoke.

2. Besides one prescription product in the marketplace, Zyban, there are three nicotine replacement therapies (NRTs) available over-the-counter with no new products being produced in the last ten years.

3. The need for increasing the number of products that would reduce smoking in the USA is sorely needed by healthcare professionals.

4. Nicotrol inhaler is the first inhaled-based buccal delivery system in the USA.

5. The average American smoker puts a cigarette to his/her lips 200 times per day - which adds up to 73,000 times a year.

6. If a smoker decides to give up cigarettes, he/she might want something that deals with something more than just cravings, such as something that may help address the smoking ritual and oral fixation.

7. The importance of hand to mouth delivery and cigarette feeling in smoking cessation is a common technique that can be very useful.

8. The inhaler system is unique because it provides smokers the comfort of the hand to mouth ritual during the treatment.

9. The Nicotrol Inhaler is the only nicotine replacement therapy that helps to address the pharmacological behavioral and sensory stimuli aspects of smoking.

10. Virtually all of the nicotine derived from the Nicotrol Inhaler is absorbed through the lining of the mouth.

11. Unlike cigarettes which deliver a variety of carcinogens, the Nicotrol Inhaler simply delivers nicotine and the Surgeon General states that nicotine does not appear to be carcinogenic.

12. The most common nicotine related adverse event is dyspepsia (18% active vs. 9% placebo) and Nicotrol Inhaler is well tolerated.

In an article written in Clinical Pharmacokinetic 2001: 40 (9) by Schneider et al. from the UCLA School of Medicine, I quote the following:

"Nicotine inhaled in smoke is the most rapid form of delivery of the drug. With smoking, arterial boli and high venous blood nicotine concentrations are produced within seconds and minutes, respectively. The potency of nicotine as the primary reinforcement in tobacco addiction is attributed to this rapid rate of delivery. By design, nicotine treatments reduce the rate and extent of drug delivery for wearing from nicotine during smoking cessation. Theoretically, they prevent relapse by reducing withdrawal and craving associated with the abrupt cessation of cigarettes.

"The nicotine inhaler treats the complexity of smoking through weaning both from the drug and from the sensory/ritual components associated with smoking. The inhaler is 'puffed' but not lit and there is considerable 'puffing' required to achieve slower rising and lower nicotine concentrations. These factors allow it to be used as a nicotine reduction treatment.

"One inhaler contains 10 mg. of nicotine (and 1 mg. of menthol) of which 4 mg. of nicotine can be extracted and 2 mg. are systemically available. Shallow or deep 'puffing' results in similar nicotine absorption. Nicotine is delivered mainly to the oral cavity, throat and upper respiratory tract with a minor fraction reaching the lungs. This was confirmed with positron emission tomography and by assessment of arterial concentrations. A single inhaler can be used for one twenty minute period of continuous puffing or periodic use of up to 400 puffs per inhaler.

"With controlled puffing in laboratory testing, venous plasma nicotine concentrations from a single inhaler puffed eighty times over twenty minutes averaged 8.1 ug/L at thirty minutes. Lower concentrations of 6.4 to 6.9 ug/L have been reported for self-administration under clinical conditions. The time to peak

plasma concentrations varies but is always significantly longer than with cigarette delivery. Estimates of nicotine intake from cotinine concentrations were higher than expected (60 to 70% of baseline smoking concentrations). This elevation may be due to the swallowing of nicotine and subsequent first-pass biotransformation to continue. In general, venous blood nicotine concentrations are considerably lower than with smoking and are within the range observed for other nicotine reduction therapies.

"Efficacy trials show consistent superiority of the inhaler over placebo. Despite the 'cigarette-like' appearance of the inhaler and the associated sensory/ritual elements, little treatment dependence or abuse has been reported. This is attributed to the slow rise time and low nicotine blood concentrations. The inhaler is a valuable addition to treatment of tobacco dependence and can be used alone or with other treatments."

PPSI believes there is ample amount of scientific evidence and information available regarding switching Nicotrol Inhaler from Rx to OTC.

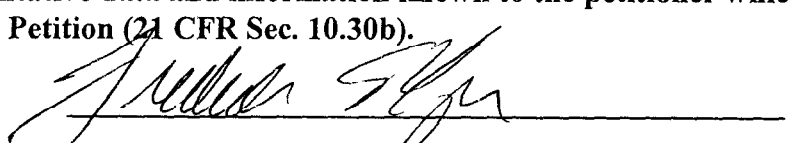
PPSI believes that switching from prescription drug to OTC status will benefit the 50 million Americans who smoke and will decrease morbidity, mortality, hospital visits and that this is in the best interest of public health and safety of Americans.

PPSI encourages FDA to institute this switch of oral Nicotrol Inhaler from prescription to OTC as soon as possible.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

There is no economic impact involved with this Citizen's Petition and according to recent studies there would be a ten billion dollar savings or more in hospital costs, lung cancers, emphysema, emergency room and doctor's visits.

The undersigned certified, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

Signature 

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