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

June 23, 2004

Re: Citizen's Petition for Pseudoephedrine from Over the Counter (OTC) sales to Pharmacists-Only Class of Drugs with Mandatory Consultation, Patient History Review, Identification and Registration

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 Pseudoephedrine from Over the Counter (OTC) sales to Pharmacists-Only Class of Drugs with Mandatory Consultation, Patient History Review, Identification and Registration.

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

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

- 1. Pseudoephedrine products (Sudafed) are marketed to improve athletic performance; Pseudoephedrine is a powerful central nervous system stimulant and decongestant.**
- 2. Pseudoephedrine is structured similar to the amphetamine and increases heart rate and blood pressure.**
- 3. Pseudoephedrine is currently being used by drug addicts to make methamphetamine which is now epidemic in the United States especially in young people.**
- 4. Pharmacists currently have a "fifth class of drugs category" which includes injectable needles, syringes, insulin,**
- 5. Pseudoephedrine currently is a fifth class of drugs in Kansas, Oklahoma, Arkansas, and other states, along with ephedrine products, adrenaline and syrups (in some states, dexrometorphan, hydrobromide (DM), etc.**

5. PPSI is asking the FDA to list Pseudoephedrine to be sold only under a pharmacist's supervision as a fifth class of drugs.

6. PPSI realizes FDA's authority to classify a drug as prescription-only or OTC, and that currently there is not a fifth class of drugs sold only by pharmacists; however, many states such as Oklahoma, Arkansas, California, New York currently have this pharmacists-only fifth class of drugs with registration required by purchaser along with counseling and education.

7. PPSI believes that the FDA Commissioner will find that the Switching Pseudoephedrine from Over the Counter (OTC) sales to Pharmacists-Only Class of Drugs with Mandatory Consultation, Patient History Review, Identification and Registration by the pharmacist is necessary for the protection of the public health by reason of Pseudoephedrine's toxicity and potentiality for harmful effects especially the elicited manufacturing of methamphetamine.

8. PPSI also believes since Switching from OTC to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review is currently being done in 33 countries outside the USA and that under proper supervision of a pharmacist, Pseudoephedrine would be safe and effective for self-medication.

9. The switching by FDA measure would regulate any product containing Pseudoephedrine which is not in liquid, liquid capsule or gel capsule form.

10. Pharmacies will be required to keep these proposed schedule five drugs out of the reach of the general public, and will be required to report certain data to assist state bureaus of narcotics in tracking these sales to guard against the diversion into the manufacture of methamphetamine.

11. Pharmacies are available, accessible and acceptable, twenty-four (24) hours per day in all locations.

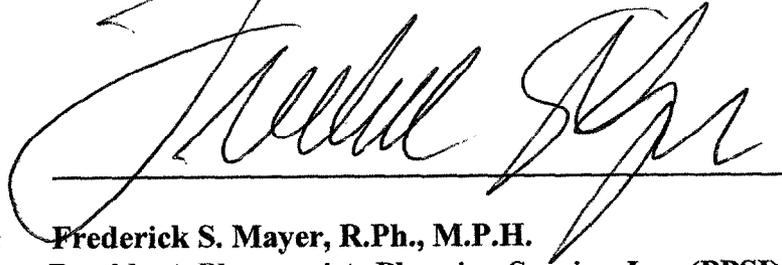
PPSI believes there is ample amount of scientific evidence and information available regarding switching Pseudoephedrine from Over the Counter (OTC) sales to Pharmacists-Only Class of Drugs with Mandatory Consultation, Patient History Review, Identification and Registration.

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 three billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits along with the untold lessening of drug abuse from the manufacturing of Pseudoephedrine into methamphetamine in the community.

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

A handwritten signature in black ink, appearing to read 'Frederick S. Mayer', is written over a horizontal line. The signature is fluid and cursive.

Name of Petitioner:

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