



pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

05-27-24110:54 RCVD

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

May 12, 2004

Re: Citizen's Petition for Switching "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review

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 Plan B Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review.

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

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

1. The Food and Drug Administration on Thursday, May 6, 2004 rejected over-the-counter sales of the Emergency Contraception "Plan B".
2. In December, 2003 an expert advisory panel voted 23 to 4 in favor of the switch to OTC status, concluding that the drug could be safely used without a prescription.
3. Emergency Contraception is available in 101 countries outside the USA and does not require a prescription in 33 countries since ECs are sold by pharmacists-only with consultation and information. **THE USA IS THE ONLY CIVILIZED COUNTRY IN THE WORLD THAT DOES NOT RECOGNIZE AN FDA PHARMACISTS-ONLY THIRD CLASS OF DRUGS BUT THE USA DOES HAVE A THIRD CLASS OF DRUGS, PHARMACISTS-ONLY RECOGNIZED BY INDIVIDUAL STATES. THIS NEEDS TO BE CHANGED.**
4. Pharmacists currently have a "third class of drugs category" which includes injectable needles, syringes, insulin, pseudoephedrine (Oklahoma, Arkansas, and other states), ephedrine products, adrenaline and epinephrine products for asthma, poisons such as strychnine, arsenic (in rate poisons), codeine cough syrups (in some states, dextromethorpine (DM), etc.

2001P.0075

CP2

5. PPSI is asking the FDA to add "Plan B" Emergency Contraception be sold only under a pharmacist's supervision as a third 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 third class of drugs sold only by pharmacists; however, many states such as Oklahoma, Arkansas, California, New York currently have this pharmacists-only third 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 "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review with registration by the pharmacist is necessary for the protection of the public health by reason of the drugs toxicity and potentiality for harmful effects.

8. PPSI also believes since Switching "Plan B" Emergency Contraception from Rx 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 the "Plan B" would be safe and effective for self-medication.

9. The use of "Plan B" being sold by a pharmacist-only intervention, PPSI believes would not increase promiscuity among teenage women nor would it cause women to abandon their regular birth control method since pharmacists who have been trained and certified would be involved with counseling patients on these issues.

10. By switching this product "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review to pharmacists-only vs currently physicians-only status it would make emergency contraception more available and reduce the three million a year abortions and unwanted pregnancies in the USA.

11. Since pharmacists are the most available, accessible and acceptable of all healthcare professionals, and are available 24 hours per day, free of charge, with no appointment necessary, and since emergency contraception, which can be used for up to 72 hours after unprotected sex, to be effective, the pharmacist would be a natural to be included in the dispensing of this much needed product.

12. Since some of the organizations against OTC switching have concerns which are as follows:

- a. EC leads to reduce use of condoms and since PPSI is instrumental in the 27 year old education and awareness campaign, National Condom Week, February 14-21 yearly, PPSI encourages FDA and manufacturers of ECs to educate the public about the proper use of condoms along with Ecs.

- b. The concern of the increase of sexually transmitted disease (STDs) might occur with ECs going OTC, PPSI would also encourage the EC manufacturer to educate and make the public aware with STD Awareness Month in April (which PPSI has sponsored for over 35 years - including its "Pregnant Man" poster "Mr. Mom"**

- c. The concerns including the possibility of EC being "slipped" into women's drinks without their knowledge - holds true for any prescription or OTC drug but would make it more unlikely since the pharmacist would be registering purchasers and counseling them.**

PPSI believes there is ample amount of scientific evidence and information available regarding switching "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review.

PPSI believes that Switching "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review will benefit the 3 million American women who abortions and unprotected sex by increasing condom and STD information and use. and will decrease morbidity, mortality, hospital visits and that this is in the best interest of public health and safety of Americans.

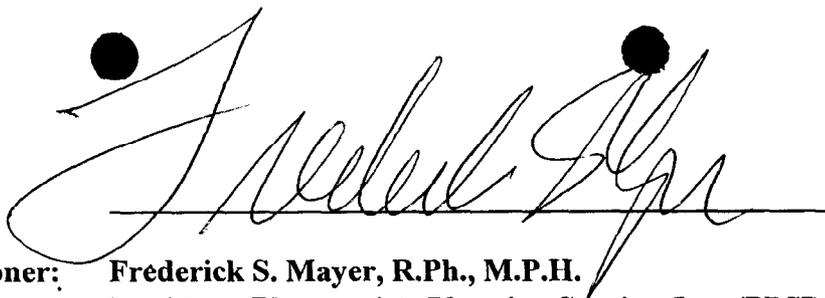
PPSI encourages FDA to institute this switching "Plan B" Emergency Contraception from Rx to Pharmacists-Only Class of Drugs with Mandatory Consultation & Patient History Review as soon as possible.

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 plus unwanted babies and the cost of rearing these unwanted children which is estimated at \$178,000 from birth to eighteen years of age or decreasing costs in hospital, 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

A handwritten signature in black ink, appearing to read "Frederick S. Mayer", written over a horizontal line. Two black circular marks are present above the signature, one on the left and one on the right.

Name of Petitioner: **Frederick S. Mayer, R.Ph., M.P.H.**
President, Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903
Telephone: 415 479-8628; Fax: 415 479-8608
Email: ppsi@aol.com; Website: www.ppsinc.org