



pharmacists planning service, inc.

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2014 OCT -3 P. 1: 22

September 24, 2014

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 to place Viagra (Sildenafil Citrate) in both
Prescription and Pharmacists Category of Drugs Behind the
Pharmacy Counter (BPC) with Patient Counseling.

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 place Viagra (Sildenafil Citrate) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) with Patient Counseling.

This Petition requests the FDA Commissioner to issue a Federal Regulation to place Viagra (Sildenafil Citrate) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) with Patient Counseling.

Pharmacist Planning Services, Inc. (PPSI) is a 501(C)3 public health, consumer pharmacy non-profit educational foundation which has instigated over 55 education and awareness campaigns including the Great American SmokeOut (GAS), poison prevention campaigns, safety caps on prescription vials, the pregnant man posters, National Condom Week, and 50 other national and international public health campaigns See www.ppsinc.org

2014-7871

Some of the scientific facts, which require immediate action on this petition, are as follows

- 1. Viagra (Sildenafil Citrate) is currently being used in the treatment of erectile dysfunction.**
- 2. Viagra (Sildenafil Citrate) does not directly cause penile erections, but affects the response to sexual stimulation. The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. NO then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation and inflow of blood to the corpus cavernosum.**
- 3. Viagra (Sildenafil Citrate) recommended dose is 25 mg- 100mg taken as needed 30 mins - 4 hours before sexual activity.**
- 4. Viagra (Sildenafil Citrate) is contraindicated in patients using nitric oxide donors such as organic nitrates or organic nitrites in any form.**
- 5. Viagra (Sildenafil Citrate) has been shown to potentiate the hypotensive effect of nitrates.**
- 6. Viagra (Sildenafil Citrate) single oral dose administered to healthy volunteers produced decreases in sitting blood pressure (mean maximum decrease in systolic/ diastolic blood pressure of 8.3/5.3 mmHg)**
- 7. When Viagra (Sildenafil Citrate) 100 mg oral was co-administered with amlodipine, 5 mg or 10 mg oral, to hypertensive patients, the mean additional reduction on supine blood pressure was 8 mmHg systolic and 7 mmHg diastolic.**
- 8. CYP3A4 inhibitors such as ritonavir, ketoconazole, itraconazole, erythromycin can increase Viagra (Sildenafil Citrate) exposure.**
- 9. When a single 100 mg dose of Viagra (Sildenafil Citrate) was administered with erythromycin, a moderate CYP3A4 inhibitor,**

at steady state (500 mg bid for 5 days), there was a 160% increase in sildenafil C_{max} and a 182% increase in sildenafil AUC.

10. In a study performed in healthy male volunteers, co-administration of the HIV protease inhibitor saquinavir, also a CYP3A4 inhibitor, at steady state (1200 mg tid) with Viagra (100 mg single dose) resulted in a 140% increase in sildenafil C_{max} and a 210% increase in sildenafil AUC.
11. Viagra (Sildenafil Citrate) should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.
12. Viagra (Sildenafil Citrate) can potentiate the hypotensive effects of nitrates, alpha blockers, and anti-hypertensives.
13. Viagra (Sildenafil Citrate) can cause sudden loss of vision occurs in one or both eyes, which could be a sign of non arteritic anterior ischemic optic neuropathy (NAION)
14. Counseling Patients About Sexually Transmitted Diseases The use of Viagra (Sildenafil Citrate) offers no protection against sexually transmitted diseases. Counseling of patients about the protective measures necessary to guard against sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV), may be considered.
15. Historically, the FDA has approved the conversion of a number of prescription drugs to over-the-counter (OTC) status for example heartburn drugs like the histamine receptor antagonist (H₂RA) like Zantac/Ranitidine and the proton pump inhibitor (PPI) like Prilosec/Omeprazole are readily available. The same can be said for anti-allergy medications such as Claritin-D/Loratidine-D, Zyrtec-D/Cetirizine-D, and Mucinex-D/Guaifenesin-D that are sold as a pharmacist only class behind the counter.
16. In general, these prescription-to-BPC pharmacists only switches are for drugs that have been used extensively, have a well

understood side-effect profile, and are deemed by the FDA as being relatively safe with monitoring by a health care professional.

- 17. In one of the most successful FDA switches from Prescription to over-the-counter (OTC) to Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) is pseudoephedrine (Sudafed) 30 mg, 60 mg, and 120 mg LA (Long Acting).**
- 18. Besides pseudoephedrine hydrochloride, FDA has also put into the pharmacists only class of drugs such as all forms of insulin (long acting, shorting acting, and rapid acting), OTCs epinephrine hydrochloride injectable, ipecac, needles, syringes, naloxone injectable, Mucinex-D (Guiafenesisin), Primatene and other asthma medications, and all antihistamines with pseudoephedrine decongestants and all cough syrups combinations with pseudoephedrine along with many other products that are labeled USP.**
- 19. PPSI is asking the FDA to place Viagra (Sildenafil Citrate) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) to be sold only under a pharmacist's supervision with Patient Counseling.**
- 20. This petition only applies to pharmacists licensed by their corresponding States who have been certified by the State or national pharmacy organization or pharmacy educational body who can certify and train pharmacists for screening, testing, and can have protocols, for dispensing Viagra (Sildenafil Citrate) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) with Patient Counseling**
- 21. Pharmacies are available, accessible and acceptable, twenty-four (24) hours per day in all locations and are the 2nd only profession to the nursing profession as far as honesty and trustworthiness.**
- 22. PPSI believes there is ample amount of scientific evidence and information available regarding to place Viagra (Sildenafil**

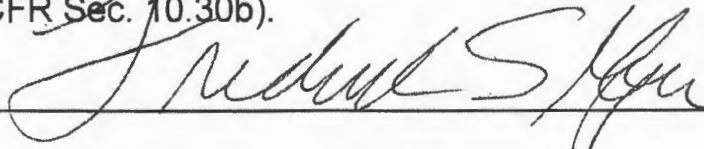
**Citrate) in both Prescription and Pharmacists Category of Drugs
Behind the Pharmacy Counter (BPC) with Patient Counseling.**

Petition and we wish to be excluded under 21 CFR Sec. 25.24. We wish to be excluded as a 501(C)3 public health, consumer, pharmacy non-profit public education organization.

There is no economic impact involved with this Citizen's Petition and according to recent studies there would be hundred and twenty-three billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits along annual costs incurred by all communities in the United States by pharmacists intervention in discovering the 20 million Americans who continue to smoke tobacco products.

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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2014 APR 18 P 2:45

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

April 9, 2014

**Re: Citizen's Petition to place Lipitor/Atorvastatin Calcium 10 mg in both
Prescription and Pharmacists Category of Drugs Behind the Counter.**

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 place Lipitor/Atorvastatin Calcium 10 mg in both Prescription and Pharmacists Category of Drugs Behind the Counter.

This Petition requests the FDA Commissioner to issue a Federal Regulation to place Lipitor/Atorvastatin Calcium 10 mg in both Prescription and Pharmacists Category of Drugs Behind the Counter.

Pharmacist Planning Services, Inc. (PPSI) is a 501(C)3 public health, consumer pharmacy non-profit educational foundation which has instigated over 55 education and awareness campaigns including the Great American SmokeOut (GAS), poison prevention campaigns, safety caps on prescription vials, the pregnant man posters, National Condom Week, and 50 other national and international public health campaigns.

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

1. Lipitor/Atorvastatin Calcium 10 mg is currently being used as the low-density lipoprotein (LDL) and the cholesterol lowering statin and the drug of choice in the United States for this indication.
2. Lipitor/Atorvastatin Calcium is the biggest selling drug of all time with annual sales of almost \$13 billion and has been used in the United States as the drug of choice for lowering cholesterol in patients.
3. Lipitor/Atorvastatin Calcium has been studied in over 1480 clinical trials involving tens of thousands of patients dosed for multiple years.

4. These studies have demonstrated the importance of this drug in the treatment of cardiovascular diseases (CVD) and as a result has become the cornerstone of any CVD treatment regimen.
5. Currently, over 23 million Americans have cardiovascular diseases including high blood pressure, obesity, diabetes, and high cholesterol and do not know they have it as they are undiagnosed and untreated.
6. In the United Kingdom for the past 10 years, Zocor/Simvastatin 10 mg, a drug in a similar class, is available as a pharmacists category of drug behind the counter.
7. Lipitor/Atorvastatin Calcium has been far more extensively studied than Zocor/Simvastatin in the United States and the world.
8. Historically, the FDA has approved the conversion of a number of prescription drugs to over-the-counter (OTC) status for example heartburn drugs like the histamine receptor antagonist (H2RA) like Zantac/Ranitidine and the proton pump inhibitor (PPI) like Prilosec/Omeprazole are readily available. The same can be said for anti-allergy medications such as Claritin-D/Loratidine-D, Zyrtec-D/Cetirizine-D, and Mucinex-D/Guaifenesin-D that are sold as a pharmacist only class behind the counter.
9. In general, these prescription-to-OTC pharmacists only switches are for drugs that have been used extensively, have a well understood side-effect profile, and are deemed by the FDA as being relatively safe.
10. In one of the most successful FDA switches from Prescription to over-the-counter (OTC) to Pharmacists Category of Drugs Behind the Counter is pseudoephedrine (Sudafed) 30 mg, 60 mg, and 120 mg LA (Long Acting).
11. Besides pseudoephedrine hydrochloride, FDA has also put into the pharmacists only class of drugs OTCs epinephrine hydrochloride injectable, ipecac, needles, syringes, naloxone injectable, Mucinex-D (Guaifenesin), Primatene and other asthma medications, and all antihistamines with pseudoephedrine decongestants along with many other products that are labeled USP.
12. PPSI is asking the FDA to list to place Lipitor/Atorvastatin Calcium 10 mg in both Prescription and Pharmacists Category of Drugs Behind the Counter to be sold only under a pharmacist's supervision.
13. This petition only applies to pharmacists licensed by their corresponding States who have been certified by the State or national pharmacy organization or pharmacy educational body who can certify and train pharmacists for screening, testing, and can have protocols for dispensing Lipitor/Atorvastatin Calcium 10 mg

in both Prescription and Pharmacists Category of Drugs Behind the Counter.

14. Pharmacists can ensure patients will regularly get blood tests to show that patients taking Lipitor/Atorvastatin Calcium are taking it correctly and the drug is efficacious in lowering their cholesterol and to provide needed benefits. Pharmacists would have the ability to refer patients onto physicians that require higher doses or were screened for early high blood pressure, cholesterol, diabetes, or other metabolic disorders.

15. Pharmacies are available, accessible and acceptable, twenty-four (24) hours per day in all locations and are the 2nd only profession to the nursing profession as far as honesty and trustworthiness.

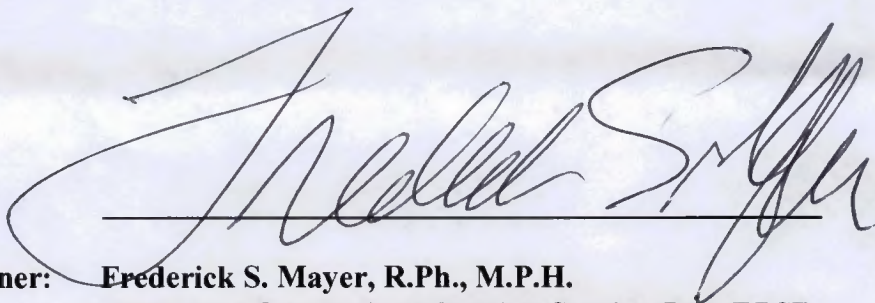
PPSI believes there is ample amount of scientific evidence and information available regarding to place Lipitor/Atorvastatin Calcium 10 mg in both Prescription and Pharmacists Category of Drugs Behind the Counter.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24. We wish to be excluded as a 501(C)3 public health, consumer, pharmacy non-profit public education organization.

There is no economic impact involved with this Citizen's Petition and according to recent studies there would be a forty-three billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits along annual costs incurred by all communities in the United States by pharmacists intervention in discovering the 23 million Americans with cardiovascular disease (CVD).

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 large, stylized handwritten signature in black ink, appearing to read 'Frederick S. Mayer', is written over a horizontal line.

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2014 JUL 23 A b: 17

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

July 18, 2014

Re: Citizen's Petition to place Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC).

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 place Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC).

This Petition requests the FDA Commissioner to issue a Federal Regulation to place Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC).

Pharmacist Planning Services, Inc. (PPSI) is a 501(C)3 public health, consumer pharmacy non-profit educational foundation which has instigated over 55 education and awareness campaigns including the Great American SmokeOut (GAS), poison prevention campaigns, safety caps on prescription vials, the pregnant man posters, National Condom Week, and 50 other national and international public health campaigns.

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

1. Chantix (Varenicline Hydrochloride) is currently being used as a non-nicotine prescription medicine specifically developed to help adults 18 and over quit smoking.
2. Chantix (Varenicline Hydrochloride) works in two ways. It targets nicotine receptors in the brain, attaches to them, and blocks nicotine from reaching them. It is believed that Chantix also activates these receptors, causing a reduced release of dopamine compared to nicotine.
3. Chantix (Varenicline Hydrochloride) is easy to use and is recommended that you begin your Chantix treatment a week before quitting smoking. This gives Chantix a chance to build up in your body. You may smoke during the first week of your Chantix treatment, but you should stop smoking completely on Day 8 of your treatment.

FDA-2014-P-1057

4. Chantix (Varenicline Hydrochloride) has been studied in over 280 clinical trials involving tens of thousands of patients dosed for multiple years both here in the U.S.A. and the abroad.

5. Currently, almost 90% of adult smokers start smoking by 18 years of age, and 98% start by the age of 26. 5.6 million younger than 18 years of age who are alive today are projected to die prematurely from smoking related diseases.

6. According to data from the Centers for Disease Control, tobacco use causes more than 480,000 deaths annually in the United States. Smoking is the leading known cause of preventable disease and death.

7. Chantix (Varenicline Hydrochloride) has been far more extensively studied both in the United States and around world. Over 20,000 pharmacists are currently trained and certified as smoking cessation counselors and are available to help patients choose a product, understand how it works, possible adverse effects, and provide on-going coaching to enhance treatment successes.

8. Historically, the FDA has approved the conversion of a number of prescription drugs to over-the-counter (OTC) status for example heartburn drugs like the histamine receptor antagonist (H2RA) like Zantac/Ranitidine and the proton pump inhibitor (PPI) like Prilosec/Omeprazole are readily available. The same can be said for anti-allergy medications such as Claritin-D/Loratidine-D, Zyrtec-D/Cetirizine-D, and Mucinex-D/Guaifenesin-D that are sold as a pharmacist only class behind the counter.

9. In general, these prescription-to-BPC pharmacists only switches are for drugs that have been used extensively, have a well understood side-effect profile, and are deemed by the FDA as being relatively safe with monitoring by a health care professional.

10. In one of the most successful FDA switches from Prescription to over-the-counter (OTC) to Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) is pseudo ephedrine (Sudafed) 30 mg, 60 mg, and 120 mg LA (Long Acting).

11. Besides pseudoephedrine hydrochloride, FDA has also put into the pharmacists only class of drugs such as all forms of insulin (long acting, shorting acting, and rapid acting), OTCs epinephrine hydrochloride injectable, ipecac, needles, syringes, naloxone injectable, Mucinex-D (Guaifenesin), Primatene and other asthma medications, and all antihistamines with pseudoephedrine decongestants along with many other products that are labeled USP.

12. PPSI is asking the FDA to list to place Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC) to be sold only under a pharmacist's supervision.

13. This petition only applies to pharmacists licensed by their corresponding States who have been certified by the State or national pharmacy organization or pharmacy

educational body who can certify and train pharmacists for screening, testing, and can have protocols for smoking cessation therapy, for dispensing Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC).

14. Pharmacists with training can assure that patients with CNS depression, hypersensitivity reactions, nausea, and neuropsychiatry effects (U.S. Boxed Warning) can cause patients with serious neuropsychiatry events (including depression, suicidal thoughts, and suicide). This is similar to black box warning currently giving by pharmacists for non-steroidals anti-inflammatory prescription and OTC products such as Ibuprofen, Motrin, Naproxen, and similar behind the counter warnings such as pseudo ephedrine which is now solely prescription and Behind the Pharmacy Counter (BPC).

15. Pharmacies are available, accessible and acceptable, twenty-four (24) hours per day in all locations and are the 2nd only profession to the nursing profession as far as honesty and trustworthiness.

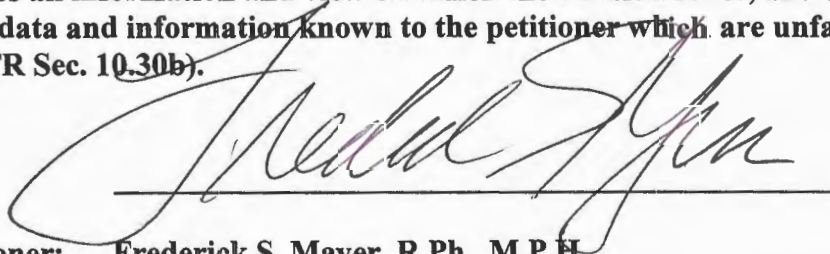
PPSI believes there is ample amount of scientific evidence and information available regarding to place Chantix (Varenicline Hydrochloride) in both Prescription and Pharmacists Category of Drugs Behind the Pharmacy Counter (BPC).

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24. We wish to be excluded as a 501(C)3 public health, consumer, pharmacy non-profit public education organization.

There is no economic impact involved with this Citizen's Petition and according to recent studies there would be hundred and twenty-three billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits along annual costs incurred by all communities in the United States by pharmacists intervention in discovering the 20 million Americans who continue to smoke tobacco products.

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

2014 May 27, 2014 2:38

Re: Citizen's Petition to Place Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use

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 place Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use.

This Petition requests the FDA Commissioner to issue a Federal Regulation to place Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use.

Pharmacist Planning Services, Inc. (PPSI) is a 501(C)3 public health, consumer pharmacy non-profit educational foundation which has instigated over 55 education and awareness campaigns including the Great American Smoke Out (GAS), poison prevention campaigns, safety caps on prescription vials, the pregnant man posters, National Condom Week, and 50 other national and international public health campaigns.

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

1. Across the country, lawmakers and officials are widening access to naloxone, a prescription drug that can be injected or given nasally to reverse an Opioid, heroin, or painkiller overdose. Some federal data suggests that heroin use has doubled across the country, bringing fatal overdoses due to the switch from painkiller abusers to cheaper illicit, drugs, increasing deaths, and emergency room visits.
2. Medical first responders have traditionally administered naloxone, which is non addictive and only has an effect if a person has opioids in her or his system.
3. However, people with little or no training can easily administer the life-saving drug as well.

FDA-2014-P-0752

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4. APHA (American Public Health Association) adopted a policy statement in 2013 in support of widening access to Naloxone.
5. As of this year, policymakers in 17 states and Washington, D.C., had amended laws to make it easier to prescribe and dispense naloxone, according to the Network for Public Health Law.
6. The legal changes are in line with emerging science on the topic as well. For example, a study published in January in the *British Medical Journal* examined naloxone distribution and bystander training programs in Massachusetts found that such programs are associated with a decrease in opioid overdose deaths.
7. Last year, in response to a rise in heroin-related overdose deaths, Vermont leaders amended its law to allow health care professionals to dispense and prescribe naloxone to people at risk of overdose, as well as to family and friends of those at risk.
8. Naloxone rescue kits, which include two doses of naloxone, as well as instructions on how to administer the drug nasally, after pharmacists training for at-risk patients of an opioid overdose. . . This truly is a public health problem and pharmacists are part of the solution. **Pharmacies are available, accessible and acceptable, twenty-four (24) hours per day in all locations and are the 2nd only profession to the nursing profession as far as honesty and trustworthiness.**
- 9.. **In general, these prescription-to-OTC pharmacists only switches are for drugs that have been used extensively, have a well understood side-effect profile, and are deemed by the FDA as being relatively safe.**
10. **According to the National Institute of drug Abuse, heroin has been on the rise since 2007. In 2012, about 670,000 American reported using heroin in the past year, with the greatest increase among young people, ages 18-25. Heroin overdose deaths have risen 45% between 2006-2010.**
11. **In 2010, National drug surveys found that more than 12 million people reported using prescription painkillers for non medical reasons.**
12. **In one of the most successful FDA switches from Prescription to over-the-counter (OTC) to Pharmacists Category of Drugs Behind the Counter is pseudoephedrine (Sudafed) 30 mg, 60 mg, and 120 mg LA (Long Acting).**
13. **Besides pseudoephedrine hydrochloride, FDA has also put into the pharmacists only class of drugs OTCs -epinephrine hydrochloride injectable, ipecac, needles, syringes, Mucinex-D (Guiafenesin), Primatene and other asthma medications, and all antihistamines with pseudoephedrine decongestants, along with many others**

14. PPSI is asking the FDA to list to place Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use to be sold only under a pharmacist's supervision, after training and counseling.

15. This petition only applies to pharmacists licensed by their corresponding States who have been certified by the State or national pharmacy organization or pharmacy educational body who can certify and train pharmacists for screening, testing, and can have protocols for dispensing Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use.

16. Pharmacists would have the ability to steer patients onto physicians or health care clinics that require treatment for addiction.

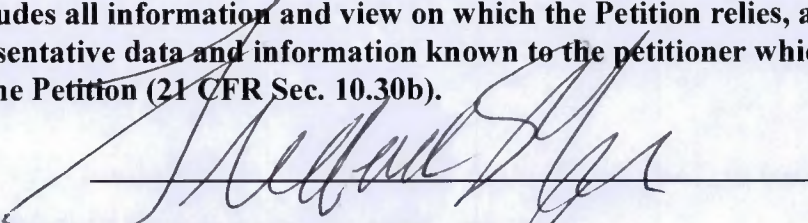
17. PPSI believes there is ample amount of scientific evidence and information available regarding to place Naloxone Injected or Given Nasally To Reverse an Opioid Overdose Behind the Pharmacy Counter in addition to Prescription Use.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24. We wish to be excluded as a 501(C)3 public health, consumer, pharmacy non-profit public education organization.

There is no economic impact involved with this Citizen's Petition and according to recent studies there would be a sixty two billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits, making Naloxone available, accessible and acceptable will prevent overdoses, fatalities which are a leading cause of accidental death in the United States, killing 38,000 people in 2010, according to CDC. CDC credited Naloxone with successfully reversing 10,000 drug overdoses over fifteen years.

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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Pharmacists Planning Service, Inc.
101 Lucas Valley Road #240
San Rafael, CA 94903

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Change Service Requested

~~Information~~ Information Inside

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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



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pharmacists planning service, inc.

Frederick S. Mayer

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President

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