



pharmacists planning service, inc.

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January 9, 2013

Division of Dockets Management, FDA
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

0830

Re: Citizen's Petition to remove St John's Wort (SJW)/(hypericum perforatum) from Herbal Dietary Supplement to Behind Pharmacy Counter Status (BPCS)

Dear Divisions of Dockets Management,

Pharmacists Planning Services, Inc. (PPSI), a 501 C (3) nonprofit public health, consumer, pharmacy education organization submit's this Citizen's Petition to remove St. John's Wort (SJW)/(hypericum perforatum) from Herbal Dietary Supplement to behind pharmacy counter status (BPCS).

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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 remove sales of St. John's Wort (SJW) (hypericum perforatum) from Herbal Dietary Supplement to behind the pharmacy counter status 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 Herbal Dietary Supplement to behind pharmacy counter status drug to this new status immediately, similar to the most recent change of pseudoephedrine/Sudafed which became OTC/pharmacists-only from PPSI's earlier Citizen's petition.

STATEMENTS OF SCIENTIFIC BASIS FOR PETITION IS SPELLED OUT AS FOLLOWS:

1. US pharmacist article Nov 2012, "What is the Place of St. John's Wort", a 3-page article including patient information on who should use St. John's Wort (SJW)/(hypericum perforatum) and why, in the interest of public health and safety, the FDA should remove St. John's Wort (SJW)/(hypericum perforatum) from Herbal Dietary Supplement to behind the counter status. <http://www.uspharmacist.com/content/c/37742/>
2. This 3-page article also includes the safety issue of St. John's Wort (SJW)/(hypericum perforatum) from Herbal Dietary Supplement to Behind Pharmacy Counter Status (BPCS) and how St. John's Wort (SJW)/(hypericum perforatum) can cause trouble sleeping, vivid dreams, restlessness, anxiety, irritability, stomach upset, fatigue, dry mouth, dizziness, headache, skin rash, diarrhea, and tingling (see footnote 2).
3. St. John's Wort (SJW)/(hypericum perforatum) has the potential for many drug interactions with at least one (and interaction with cyclosporine) having caused a patient's death.
4. St. John's Wort (SJW)/(hypericum perforatum) has been totally banned for sale in France by the French Health Product Safety Agency (see footnote 2).
5. In Ireland, St. John's Wort (SJW)/(hypericum perforatum) was banned from non-prescription sales and OTC sales in January 2003.
6. The Irish Medicine Board also had concerns before banning St. John's Wort (SJW)/(hypericum perforatum) due to fatigue and photosensitivity as well as it's potential to cause dangerous patient drug interactions.

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7. Germany's regulatory agency for herbs known as *Commission E*, in a manner similar to Ireland's action restricted St. John's Wort (SJW)/(hypericum perforatum) to prescription only-status (see footnote 4). Other countries are re-thinking St. John's Wort (SJW)/(hypericum perforatum) to be used for non-prescription to prescription purposes behind pharmacy counters and requiring drug-herb warnings on all St. John's Wort (SJW)/(hypericum perforatum) packaging (see footnote 3)

8. In a marketing piece, "Thinking of Herbs? Check Carefully Before You Take Them With Medicines," put out by the California Board of Pharmacy and the University of San Francisco (UCSF) Center for Consumer Self-Care, there are 22 listed drug-interactions for St. John's Wort (SJW)/(hypericum perforatum) (see enclosed "Thinking of Herbs" with the 22 drug interactions).

9. Some of these serious drug interactions are listed below and are potentially dangerous drug-herbal interactions. Some of these drug interactions are additive and have not been well-studied for St. John's Wort (SJW)/(hypericum perforatum):

Atazanavir, Benzodiazepines, Carbamazepine, Chemotherapy, Cyclosporin, Digoxin, Fexofendadine, Fluvoamine, Fosamprenavir, Indinavir, Nefazodine, Omeprazole, Oral Contraceptives, Paroxetine, Phenelzine, Reserpine, Sertraline, Theophylline/Aminophylline, Trazodone, Tricyclic Antidepressants, Venlafaxine, Warfarin

10. In 2 new recent FDA approvals for Hepatitis C drugs which incorporates interferon with protease inhibitors (Boceprevir and Telaprevir) along with interferon and ribavirin combinations with St. John's Wort (SJW)/(hypericum perforatum) has specifically been spelled out in the patient package insert and the professional information given to health care providers.

11. The cumbersome information which is buried in the patient package insert is not being read by either patient consumers or health care professionals. Since more than 40% Americans take dietary supplements and many of these herbals and dietary supplements such as St. John's Wort (SJW)/(hypericum perforatum) are known to interact in dangerous ways with medicines, OTCs and other herbals and since mixing herbals supplements with your OTCs other herbals and your prescription medicines may put patients and consumers at great risks PPSI strongly recommends that this product is put behind the pharmacy counter and change label regulations with warnings by healthcare professionals.

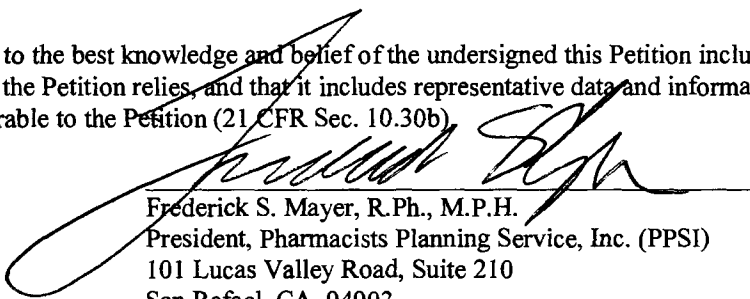
This Citizen's Petition requests the FDA commissioner to remove St John's Wort (SJW)/(hypericum perforatum) from Herbal Dietary Supplement status to Behind Pharmacy Counter Status (BPCS).

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

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 Petitioners:



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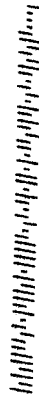


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