

September 22nd, 2005

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, MD 20857

Citizen Petition

The undersigned submits this petition under Sec. 10.30 of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to issue permission to Donna Ricks to continue using Palladone for severe chronic pain due to Stage 4 Metastatic Breast Cancer which has spread to lungs, bones, and liver.

Palladone (hydromorphone hydrochloride, extended release capsules) was suspended in July 2005 (FDA Regulation 21 CFR 208) because of the potential for severe side effects if Palladone is taken with alcohol.

FDA ALERT (07/2005): Alcohol-Palladone interaction

FDA has issued a public health advisory to inform patients and health care providers that the sponsor of Palladone, Purdue Pharma, has agreed to suspend sales and marketing of Palladone (hydromorphone hydrochloride, extended release capsules), a potent narcotic painkiller, because of the potential for severe side effects if Palladone is taken with alcohol. Pharmacokinetic data indicate that the co-ingestion of Palladone and alcohol results in dangerous increases in the peak plasma concentrations of hydromorphone. These levels may be lethal, even in opioid tolerant patients.

FDA approved Palladone (hydromorphone hydrochloride extended-release) Capsules for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock opioid analgesia with a high potency opioid for an extended period of time generally weeks to months or longer.

I, Donna Ricks was diagnosed with breast cancer in May, 2003. In May, 2004 the breast cancer metastasized to both lungs. The cancer has since metastasized to my bones (L-5 vertebrae, ribs, and left temporal) and also my liver. I began taking Palladone in January 2005 for severe pain in my spine. During this time I was able to lead a fairly normal life without pain. In July 2005 after Palladone was suspended from the market my oncologist (Dr. Ungaro) has prescribed several different medications (Oxycodone and Duragesic patches) which have

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not relieved the severe pain that I have. I am in constant pain and am not able to function normally. I believe that I still have some good quality of life remaining if I could get this pain under control. I can only do this if you will grant me permission to continue to have access to Palladone. Please consider this as an urgent matter and approve this petition as soon as possible.

Attached you will find a written request from my Oncologist, Dr. Peter Ungaro. Please take his statement into consideration when making your decision.

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Donna Ricks
(Signature)

Donna Ricks
(Name of Petitioner)

230 Watts Landing Rd.
Hampsted, NC 28443
(Mailing Address)

910-329-1690
(Phone)

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Addition to Citizen Petition for Donna Ricks

Environmental Impact

Claim for categorical exclusion under S25.30, S25.31, S25.32, S25.33, or S25.34, of this chapter or an environmental assessment under S25.40, of this chapter.

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DEA # AM 6656029

UPIN #D 27138

NAME Donna Ricks AGE _____
ADDRESS _____ DATE 9/21/05

Rx To whom it may concern.

Donna Ricks was on Palladone from
June 05 to Aug 05. She has metastatic
breast cancer & suffers from back pain.
When she was on Palladone, she had
the pain. Since Palladone was taken off
the market, her pain regimen was
changed. Since then, she has developed
severe pain which is not relieved with
Oxyadone + Duragesic patches. She
does not consume alcoholic beverages
& does not abuse pain medication.
Please assist her in any way possible.

times Thank you
Pete Ungaro

PRODUCT SELECTION PERMITTED
PH-092 (9/01)

DISPENSE AS WRITTEN

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