U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

The Drug Enforcement Administration (DEA) has had an opportunity to review the citizen petition dated July 25, 2012, that was filed with the Food and Drug Administration (FDA) by the Physicians for Responsible Opioid Prescribing. This citizen petition requested FDA to exercise its regulatory responsibility and change the product labeling for opioid analgesic products.

Although DEA supports legitimate and beneficial uses of opioid analgesics, such drugs unfortunately also have a long history of abuse. The diversion and abuse of prescription opioids have increased markedly over the past decade, resulting in numerous instances of addiction and death. According to the National Forensic Laboratory Information System, a laboratory data collection system of illicit and licit drug exhibits analyzed in state and local forensic laboratories throughout the United States, opioid analgesics, especially hydrocodone and oxycodone, continue to be encountered in increasing numbers. Hydrocodone and oxycodone are among the top ten most frequently encountered drugs.

Because opioid pharmaceuticals are not typically produced clandestinely, diverted pharmaceuticals are the primary source of the drug for abuse purposes. Doctor shopping, altered or fraudulent written prescriptions, fraudulent oral prescriptions, unlawful distribution by some physicians and pharmacists, and theft are some of the common sources of diversion. Our field offices continue to investigate numerous cases of opioid pharmaceutical diversion.

The Drug Abuse Warning Network data shows that there is a continuing increase in emergency room admissions related to the abuse of opioid pharmaceuticals. According to the National Vital Statistics System of the National Center for Health Statistics of the Centers for Disease Control and Prevention, in 2009 there were over 15,000 poisoning deaths involving opioid analgesics and these were markedly higher than the deaths involving cocaine and heroin combined (about 7,000 deaths).

The DEA is concerned about the potential public health risks resulting from abuse of opioid drug products. Additional regulatory measures are necessary for opioid formulations to adequately safeguard the American public. DEA previously requested FDA to consider additional

regulatory measures such as restrictions on prescribing, marketing practices, and clinical indications for these opioid products.

The clinical use of opioid analgesics must be accompanied by appropriate measures to minimize the adverse health impact associated with the diversion and abuse of these products. The DEA hopes that FDA will implement suitable measures, such as labeling revisions, to help mitigate the adverse impact on the public health resulting from abuse of these products.

Thank you for your attention to this important matter.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
8701 MORRISSETTE DRIVE
SPRINGFIELD, VA 22152-1080

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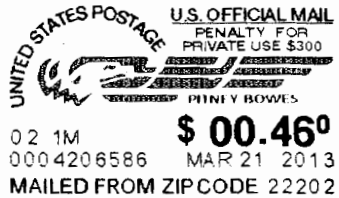

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