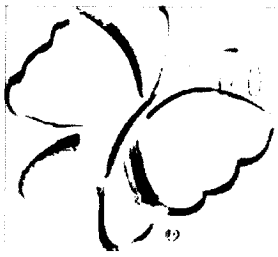

Pain Therapeutics, Inc.

February 23 2007

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2007N–0005; Comments Regarding the Prescription Drug User Fee Act

Dear Sir or Madam:

Thank you for the opportunity to submit comments on the Food and Drug Administration's (FDA) proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years 2008 to 2012.

Pain Therapeutics, Inc. ("PTI") is a biopharmaceutical company that develops novel opioid analgesic drug products for pain management. We are currently developing a new generation of opioid analgesics that we believe will provide a significant advancement over opioid analgesic drugs in clinical use today and help address the enormous public health problem of prescription drug abuse and misuse. These investigational products include Remoxy™, an abuse-resistant form of long acting oxycodone and Oxytrex™, a next-generation pain medication that potentially causes less physical dependence than currently marketed opioid analgesics.

FDA's proposed recommendations for PDUFA IV build upon the program's success and incorporate a number of appropriate enhancements. PTI agrees that user fees are critical to support FDA's premarket review program and to ensure that patient access to innovative new treatments is not delayed. We also agree that the agency's activities under PDUFA IV should expand to further support risk management, including technological solutions to prevent abuse and diversion.

2007N-0005

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In the past, FDA has recognized the serious risks associated with certain opioids and worked closely with manufacturers to educate physicians, other health care professionals, and patients about the serious and potentially fatal risks associated with abuse or misuse of oxycodone products.[1] Unfortunately, despite such efforts, the Office of National Drug Control Policy reports this month that nonmedical use of opioid analgesics and other prescription drugs has become the second leading form of illicit drug abuse in the United States as measured by prevalence.[2]

Under PDUFA IV, FDA should expand such efforts and devote user fee funding to working with industry to promote the development and approval of the next generation of abuse and misuse resistant/deterrent opioid analgesic products, including appropriate communication of such attributes in labeling. Since encouraging the adoption of technologies that mitigate prescription drug abuse and misuse can be a critical component of risk management, the formulation or reformulation of prescription drugs to limit or reduce their abuse or misuse liability also should be among the first risk mitigation tools the effectiveness of which FDA proposes to systematically review under PDUFA IV.

We applaud the recent statement of Dr. Sandra Kweder, Deputy Director of the Office of New Drugs, Center for Drug Evaluation and Research, that reviews of abuse resistant forms of currently prescribed opioid drugs would be given priority review.[3] This is clearly a congressional priority as well. In the report accompanying the FY2006 Agriculture Appropriations legislation, Congress provided that "FDA may use available funds to support review and action on new drug applications and supplements seeking approval for replacement or alternative abuse-resistant formulations of currently-available drug products that include an active ingredient that is a listed chemical under the Controlled Substances Act. Further, it is the understanding of the conferees that these applications may be considered under the expedited, priority review process at FDA."[4]

PTI also applauds FDA's PDUFA IV proposal to publish additional premarket guidance to improve understanding of the agency's thinking and prevent wasting scarce resources. Efficient use of resources is also critically important for smaller pharmaceutical companies. In 2006, FDA announced that it planned to develop guidances titled "Assessment of Abuse Potential of Drugs," and "Development of Analgesic

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[1] Statement of John K. Jenkins, Director, Office of New Drugs, CDER, FDA, *OxyContin: Balancing Risks and Benefits: Hearings Before the Senate Committee on Health, Education, Labor, and Pensions* (Feb. 12, 2002), *available at* http://www.fda.gov/ola/2002/oxycontin0212.html; *see also*, FDA OxyContin Information Page, *available at* http://www.fda.gov/cder/drug/infopage/oxycontin/.

[2] Office of National Drug Control Policy, *National Drug Control Strategy*, at 31 (February 2007), *available at* http://www.whitehousedrugpolicy.gov/publications/policy/ndcs07/index.html.

[3] *Prescription Drug Abuse: What is Being Done to Address this New Drug Epidemic?: Hearing Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, House Committee on Government Reform*, (testimony of Sandra Kweder) (July 26, 2006).

[4] Conference Report 109-255. H.R. 2744, Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, FY 2006, at 102 (2005).

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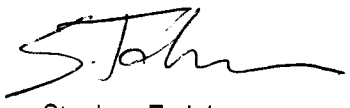
Products for Treatment of Pain."[5] However, while we certainly appreciate guidance from the agency, we also must ensure that publication of these guidances does not delay any activities related to supporting the prompt review and approval of pain treatments incorporating technologies that reduce abuse or misuse potential.

We appreciate the opportunity to provide these comments, and we look forward to working with you in the future. We hope that our suggestions will assist FDA in its mission to provide patients with access to safer therapies.

Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,



Stephen E. Johnson
Pain Therapeutics, Inc.

[5] FDA, *Guidance Agenda: Guidance CDER is Planning to Develop During Calendar Year 2006*, at 3, *available at* http://www.fda.gov/cder/guidance/CY06.pdf.