MYLAN TECHNOLOGIES INC.

August 9, 2006

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20857

DOCKET NO. 2006P-0123: SUPPLEMENT TO CITIZEN PETITION

On June 29, 2006, the innovator, Ortho-McNeil, Inc.[1], submitted a comment to the docket supporting Mylan Technologies Inc.'s ("Mylan") request that the Agency require applicants for fentanyl transdermal systems to conduct a study to determine the effect of an overlay with their respective patches. *See* Comment to Citizen Petition, Docket No. 2006P-0123/C4 (June 29, 2006) ("Mandating such data will enhance patient safety and reduce the potential for serious adverse consequences should a patient use a product capable of releasing higher rates of fentanyl when an overlay dressing is applied to support adhesion in situations where an occlusive overlay is needed."). In fact, Ortho-McNeil in its comment noted that it was the Agency who expressed concerns over the use of an overlay dressing and therefore requested the company to conduct such a study. *Id.*

Mylan originally conducted a study using the Bioclusive™ overlay system (which the innovator makes available upon request for Duragesic®) and provided evidence to FDA on May 25, 2006 from its clinical study that demonstrated the use of a Bioclusive™ overlay system does not alter the rate and extent of absorption of Mylan's fentanyl transdermal system. Mylan has just now completed another study using an overlay system manufactured by its medical products division, which it proposes to provide to patients for its product. Mylan is currently analyzing the clinical data from this new study and will be imminently providing evidence to FDA as part of its application that this overlay system can be safely used with its product. In addition, in light of the potential adverse consequences to patients of using an untested overlay system with a fentanyl transdermal system, Mylan will be proposing that additional safety information be included as part of the labeling for fentanyl transdermal systems and that all fentanyl transdermal systems should be packaged with a tested and proven overlay system to ensure patient safety[2].

As raised in Mylan's original petition, and noted by FDA, patient complaints about the "poor adhesion of the patches to the skin" continue to occur. *See* FDA Alert for

[1] The comment was filed by PriCara, a unit of Ortho-McNeil, Inc.
[2] As noted in Ortho-McNeil's comment, the current labeling does not speak to the use of an overlay system.

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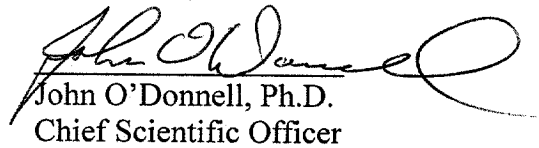
Healthcare Professionals, Fentanyl Transdermal Patch (marketed as Duragesic), Narcotic Overdose and Death, July 2005. While Mylan's "wear study" demonstrated equivalence to Ortho-McNeil's product, nevertheless a certain percentage of patients will experience disadhesion from any transdermally delivered product. And, as pointed out by Ortho-McNeil, the type of device used to "fix" adhesion cannot be generalized to all fentanyl transdermal patches. For example, different types of devices (i.e., occlusive versus non-occlusive) may impact the pharmacokinetic characteristics of a particular fentanyl transdermal system. With fentanyl being designated as a Schedule II under the Controlled Substance Act coupled with the labeling of fentanyl transdermal systems requiring close monitoring of the use of the product, any change in the release characteristics could potentially put patient safety at undue risk.

Accordingly, Mylan in this Petition Supplement, submitted under 21 C.F.R. § 10.30(g), reiterates its request that FDA require all applicants prior to approval and holders of approved applications for fentanyl transdermal systems to conduct a study to support the safe and appropriate use of an overlay system with their respective patch. In addition to the December 16, 2005 labeling enhancements for the safety of patients that were provided by Mylan in a controlled correspondence to FDA, Mylan will be proposing and requesting that the Agency and the innovator insert additional safety information regarding the use of an overlay system in the approved labeling for fentanyl transdermal systems and requesting that all fentanyl transdermal systems should be packaged with a tested and proven overlay system. Furthermore, Mylan requests that FDA publicly address this Petition before the Agency decides to grant final approval of any additional abbreviated new drug applications (ANDAs) for fentanyl transdermal systems.

Sincerely,



John O'Donnell, Ph.D.
Chief Scientific Officer