FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and Drug Safety & Risk Management Advisory Committee

May 5, 2008

New drug application (NDA) 22-272, OXYCONTIN® (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma, L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The sustained-release characteristics of this formulation are purportedly less easily defeated than other formulations of OXYCONTIN.

Draft Discussion Points for the Committee

1. Discuss the adequacy of the tools we have to assess the impact of a novel opioid formulation on abuse, misuse and diversion of the product in the community. Do the available data suggest that this reformulation of OxyContin will likely reduce its abuse, misuse and diversion?

2. Currently, only the 10-mg, 20-mg, 30-mg and 40-mg strengths have been reformulated, although there are plans to reformulate the 60-mg and 80-mg strengths in the future. Could marketing and promotion of the lower, reformulated strength products as less abusable, prior to reformulation of the higher strength products, result in the misconception that the higher, non-reformulated strengths also provide a decreased risk of abuse? If so, are there ways to minimize this misconception? Given this concern, is this risk acceptable considering the potential benefit of the changes to the formulation for the lower strength products?

3. Many of the cases of addiction, overdose and death associated with OxyContin abuse have been due to ingestion of the product without manipulation of the extended-release properties. Could inclusion of data on the physiciochemical attributes of the new formulation into the product labeling potentially mislead prescribers or patients into thinking that this new formulation of OxyContin is less likely to be addictive or unlikely to be abused or result in addiction or overdose? If so, is this risk acceptable considering the potential benefits of the changes to the formulation?

4. If you concluded in Question 1 that the data suggest that this reformulation of OxyContin is likely to reduce its abuse, misuse and diversion, do you recommend inclusion of any of the data into the product labeling? If so, which specific data do you think should be incorporated into the labeling?

5. If you do recommend any of these data be placed into the product label, are there risk minimization strategies that need to be put in place to support the appropriate use of this product, e.g, additional language in labeling (please specify), educational information that will describe proper use and the potential for misuse and abuse of the product, special educational requirements/training for prescribers, limitations on which patients should be treated with the product, formal agreements between prescribers and patients for proper use, registries for prescribers?