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 6, 2008

The committee will discuss supplemental new drug application (sNDA) 21-947/s-005, FENTORA (fentanyl buccal tablet), Cephalon, Inc., and its safety for the proposed indication of breakthrough pain in opioid tolerant non-cancer patients with chronic pain

Draft Discussion Points for the Committee

1. Do breakthrough pain episodes experienced by patients with chronic pain that is not related to cancer usually require treatment with potent opioids such as fentanyl, or can they be adequately managed with less potent opioid or non-opioid analgesics?

2. Can Fentora be prescribed to a broad, non-cancer, opioid-tolerant patient population cared for by a variety of specialists and primary care physicians, without a significant increase in morbidity and mortality related to misprescribing and misuse of the product?

3. Fentora has attributes that make it particularly attractive to abusers and attributes that make it particularly dangerous for those who do abuse it. In light of the increasing abuse of prescription opioids and the specific attributes of this particular product, would the widely increased availability of Fentora likely lead to widespread abuse and the public health consequences of that abuse?

4. If there is a substantial risk for increased abuse of this product due to greater availability, can this risk be effectively managed; and, if so, what specific risk management tools would be necessary to mitigate this risk while still ensuring reasonable access for patients who meet the conditions of labeling?

5. Considering your responses to the earlier questions, do you recommend approval of the expansion of the indication for Fentora to opioid-tolerant, non-cancer, chronic pain patients with breakthrough pain? Please vote yes or no.

    - If you voted yes, what means to mitigate abuse and diversion should FDA consider requiring? Do you recommend additional studies?

    - If you voted no, are there additional studies that the sponsor should conduct to address the reasons you think the drug should not be approved?