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

QUESTIONS TO THE COMMITTEE

January 30, 2009

The committees will discuss the safety and efficacy of propoxyphene and propoxyphene-combination products for the treatment of mild to moderate acute pain.

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1. Based on the data that have been presented regarding the efficacy of propoxyphene-containing products:

    a. Discuss whether you agree or disagree that there is evidence of efficacy for propoxyphene as monotherapy.

    b. Discuss whether you agree or disagree that there is evidence that propoxyphene contributes to the efficacy of propoxyphene and acetaminophen combination products.

2. Based on the data that have been presented regarding the nonclinical cardiac effects of propoxyphene and the postmarketing reports of deaths in which propoxyphene was identified,

    a. Discuss whether there is evidence that propoxyphene is cardiotoxic in the therapeutic range.

    b. Discuss whether additional data are needed to adequately assess the potential for cardiac effects, and if so, what data.

3. Propoxyphene-containing products are the second most frequently prescribed opioid analgesic in the U.S. Discuss the potential risks associated with the replacement of propoxyphene-containing products by the alternative products listed below should propoxyphene-containing products be removed from the market.

    Propoxyphene-containing products are listed under Schedule IV of the Controlled Substances Act. Alternatives to propoxyphene-containing products include NSAIDs, tramadol (unscheduled), butorphanol (Schedule IV), codeine/ acetaminophen combination products (Schedule IV), and hydrocodone/ acetaminophen combination products (Schedule III).

4. Based on the data presented, does the balance of risk and benefit support continued marketing of propoxyphene-containing products for the management of mild to moderate pain?*(vote)*

    a. If you conclude that the balance of risk and benefit is unfavorable and these products should no longer be marketed, could additional information about safety or efficacy change your conclusion?

    b. If you conclude that the balance of risk and benefit is favorable enough to support continued marketing, are there changes that should be made to the labeling?