FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Meeting of the Anesthetic and Life Support Drugs Advisory Committee

May 7, 2008

The committee will discuss new drug application (NDA) 22-244, fospropofol disodium injection (35 mg/mL) (proposed tradename Aquavan), MGI Pharma, Inc., for the proposed indication of sedation in adult patients undergoing diagnostic or therapeutic prodcedures.

Draft Discussion Points for the Committee

1. In the ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, retention of purposeful responsiveness is used to demarcate levels of sedation and their associated risk. These guidelines suggest that practitioners should be able to safely manage patients who become more deeply sedated than intended and are therefore at risk for airway complications. Do the clinical trial data support that retention of purposeful responsiveness is a reliable indicator of depth of sedation so as to allow practitioners to make appropriate and safe decisions regarding supplemental dosing of fospropofol disodium?

2. Adverse events, particularly respiratory adverse events were observed with higher frequency among geriatric patients, patients with cardiopulmonary morbidities and/or patients having a low body weight. Are additional data needed for these patient populations in order to provide appropriate dosing guidelines?

3. Do these data suggest that fospropofol disodium sedation can be safely managed by health care providers without training in general anesthesia?