

**Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Psychopharmacologic Drugs Advisory Committee**

March 23, 2006

Questions to the Committee

1. Has modafinil been shown to be effective for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents?

2. Has modafinil been shown to be acceptably safe in the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents?

In addition to your deliberations on the above two questions, we ask for comment on additional questions, assuming modafinil were to be considered for approval:

- What kind of a risk management plan should be implemented with regard to the

- signal for serious skin rashes with this drug in the ADHD program?

- How should the concern about serious skin rashes be addressed in product labeling (you have been provided our labeling proposal in the approvable letter and also the sponsor's currently proposed labeling)?

- Should there be a requirement for a post-marketing study(ies) to better understand the serious skin rashes, and what type of study(ies) might be considered?

