FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Advisory Committee for Reproductive Health Drugs

June 18, 2010

Hilton Washington DC North/Gaithersburg, The Ballrooms
620 Perry Parkway, Gaithersburg, MD

DRAFT Questions to the Committee

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1. Considering that the two primary US efficacy studies did not demonstrate efficacy for the prespecified co-primary endpoint of sexual desire as measured by the daily eDiary,
    a. Do you agree with the Applicant that the impact of flibanserin on sexual desire is better evaluated with the desire domain of the FSFI using 28-day recall?
    (Vote)
    b. Is it appropriate to alter the prespecified method of assessing sexual desire?
    (Vote)

2. Has the Applicant provided sufficient evidence of overall efficacy for flibanserin compared to placebo?
    (Vote)

3. Considering the available data on efficacy and safety, has the Applicant demonstrated that the overall risk/benefit profile of flibanserin in premenopausal women for the treatment of hypoactive sexual desire disorder (HSDD) is acceptable for the proposed indication?
    (Vote)