

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

QUESTIONS TO THE ADVISORY COMMITTEE

OCTOBER 23, 2008

1. To what extent, if any, would an indication for the use of an *in vivo* diagnostic radiopharmaceutical agent for the "detection of cerebral amyloid" provide useful clinical information?
2. If an *in vivo* diagnostic radiopharmaceutical is clinically useful in the "detection of cerebral amyloid," what should be a "standard of truth" in phase 3 clinical studies?
3. Please comment on the strengths and weaknesses of the phase 3 study outlines supplied by the companies.