MEMORANDUM

DATE: October 16, 2002

TO: Members, Peripheral and Central Nervous Systems Drugs and Nuclear Medicine Drugs Advisory Committees, and Invited Guests

FROM: Staff
Division of Neuropharmacological Drug Products

SUBJECT: Addendum to Background Document for Joint Advisory Committee Meeting of November 18, 2002: Issues Related to the Role of Brain Imaging as an Outcome Measure in Phase III Trials of Putative Drugs for Alzheimer’s Disease

LIST OF PERTINENT PUBLICATIONS

The following publications are being supplied to the members of the Committees and invited guests in full text.

Fleming TR, DeMets DL. Surrogate end points in clinical trials: are we being misled? Annals of Internal Medicine 1996;125(7):605-13

Fox NC, Cousens S, Scahill R, Harvey RJ, Rossor MN. Using serial registered brain magnetic resonance imaging to measure disease progression in Alzheimer disease: power calculations and estimates of sample size to detect treatment effects. Arch Neurol 2000;57(3):339-44


