

**MEMORANDUM    DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION**

**DATE:** November 18, 2008

**FROM:** Dianne Murphy, MD, FAAP  
Director, Office of Pediatric Therapeutics  
Office of the Commissioner

**SUBJECT:** Zyvox (linezolid) Follow-up Report Requested by the Committee

**TO:** Members of the Pediatric Advisory Committee (PAC)

The Office of Pediatric Therapeutics (OPT) is pleased to provide a follow-up report on Zyvox (linezolid) comprised of (1) the OSE Safety Review dated December 21, 2006 and (2) the OSE Follow-up Safety Review dated August 11, 2008, requested at the November 16, 2006 PAC meeting. At the conclusion of the Zyvox (linezolid) 1-year adverse event discussion, the committee requested a report upon completion of the pending review of cardiac events for all age populations. This report is being provided in the background materials as a document only, and there will be no presentation at the November 18, 2008 PAC.