

**Corrections to the FDA Clinical Briefing Document
December 15, 2005
Patricia Rohan, M.D.**

1. Table 5-1, page 13, success criteria for Substantial Interference with Activities of Daily Living included a p-value < 0.05.
2. The footnote for Table 9-3, page 21 contains an extraneous comment which should be removed to read as follows:

Table 9-3 Follow-Up by Vaccine Potency (ZOSTAVAX™ recipients)

	Group 1	Group 2	Group 3	Group 4
Vaccine recipients (N)	835	978	8720	8737
Dose (pfu/ 0.5ml dose)	50,000-62,000	34,000-42,000	26,000-33,000	21,000-26,000
Dates administered	11/98 - 11/99	04/99 – 11/99	07/99 – 12/00	07/00 – 09/01
Approx. Avg. F/U (days)	1400	1400	1200	900
See Table 4-1 for further information on Clinical Lots. #Accelerated aged lot groups				

2. Table 9-7, page 25 contains an error in the header row describing PHN incidence which should be PHN Incidence (not HZ Incidence):

Table 9-7 Durability of ZOSTAVAX™ Effect on Major Efficacy Endpoints (MITT)

Annual Incidence of PHN ¹									
	n	m	Follow-Up Time (Person-Years)	PHN Incidence (Per 1000 Person-Years)	n	m	Follow-Up Time (Person - Years)	PHN Incidence (Per 1000 Person-Years)	PHN Incidence

3. The description of Protocol 009 on page 51 is revised. The study was not placebo controlled:

10.2 Design

Protocol 009 is a randomized, double-blind, 18-center study comparing the safety profile of a higher potency zoster vaccine (~207,000 PFU/0.65-mL dose) with that of a lower potency (~58,000 PFU/0.65-mL dose) that had been assessed in prior clinical studies.