

Corrections to Errata in the FDA Clinical Briefing Document
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1. Page 8, Table 2.1: The criteria for the endpoints for each of the pertussis antigens have been corrected from 90% CI ratio to 95% CI ratio Tdap/Sweden $I \geq 0.67$, with the revision shown in **bold**.

Table 2.1. Summary of Study Td506 Endpoints

Antigen	Endpoint	Criteria
Diphtheria	% booster	95% CI $\delta < 10\%$
	% ≥ 0.1 IU/ml	95% CI $\delta < 10\%$
Tetanus	% booster	95% CI $\delta < 10\%$
	% ≥ 0.1 IU/mL	95% CI $\delta < 10\%$
PT	GMC	95% CI ratio Tdap/Sweden $I \geq 0.67$
	% booster*	95% CI $> 80.8\%$ (85 EU/ml)
FHA	GMC	95% CI ratio Tdap/Sweden $I \geq 0.67$
	% booster*	95% CI $> 79.5\%$ (170 EU/ml)
Pertactin	GMC	95% CI ratio Tdap/Sweden $I \geq 0.67$
	% booster*	95% CI $> 86.2\%$ (115 EU/ml)
Fim	GMC	95% CI ratio Tdap/Sweden $I \geq 0.67$
	% booster*	95% CI $> 81.7\%$ (285 EU/ml)
Safety	Erythema, swelling, pain and fever	95% CI $\delta < 10\%$

*Booster response = 4-fold rise for values below and 2-fold rise for values above the pre-defined cutoff levels (for diphtheria: cut-off value = 2.56 IU/ml and for tetanus cut-off value = 2.7 IU/ml)

2. Page 9, Laboratory Methods ¶, 3rd line: The sentence has been corrected as follows:
 - 2.1. Strike through: Seroneutralization assays were performed for dip antibodies (IUs/ml) and ELISA for tetanus antibodies with values in ~~EU/ml converted to~~ IUs/ml.
 - 2.2. Revised: Seroneutralization assays were performed for dip antibodies (IUs/ml) and ELISA for tetanus antibodies with values in IUs/ml.
3. Page 19, Section 4.3.6 Serious Adverse Events, 3rd ¶: The 1st sentence has been corrected as follows:
 - 3.1. Strike through: Three seizure events reported, two in adolescent male ~~Tdap recipients~~ with pre-existing histories of seizure disorders and one seizure event that occurred 22 days after Tdap in a 55 year old female with a history of migraines and hypertension.
 - 3.2. Revised: Three seizure events reported, two in adolescent males (one Tdap recipient and one Td recipient) with pre-existing histories of seizure disorders and one seizure event that occurred 22 days after Tdap in a 55 year old female with a history of migraines and hypertension.
4. Page 43, Section 25, 2nd ¶: The percent of subjects in the separate administration study group with sore/swollen joints has been revised from 12% to 18%, as follows:
 - 4.1. Strike through: Of note, reports of swollen and/or sore joints were frequent (~22% for concomitant vaccination and ~~~12~~18% for separate administration) and appeared more frequent in this trial compared to the others in the BLA.

4.2. Revised: Of note, reports of swollen and/or sore joints were frequent (~22% for concomitant vaccination and ~18% for separate administration) and appeared more frequent in this trial compared to the others in the BLA