

To: Mr. Matt Whitman  
File: STN 125259/0 - CERVARIX  
RE: Unblinded Tables and Protocol HPV-009 Subjects  
Date: July 6, 2007

**APPROVED**

By Helen Sullivan Gemignani at 8:11 pm, Mar 11, 2008

We have the following comments pertaining to unblinded tables.

1. Please refer to Section 2.7.4 - Summary of Clinical Safety. It is noted that several tables contain blinded results. CBER requests that GSK provide the unblinded versions of these tables to the BLA. These include the following table and page numbers:

Table 49, p. 158  
Table 50, p. 159  
Table 51, p. 160  
Table 62, p. 178  
Table 83, pp. 204-205  
Table 84, pp. 206-207  
Table 85, p. 208  
Table 86, p. 210  
Table 87, p. 212  
Appendix Table 3, pp. 256-270  
Appendix Table 4, pp. 270-279  
Appendix Table 5, pp. 280-294  
Appendix Table 6, pp. 295-319  
Appendix Table 7, pp. 320-329  
Appendix Table 8, pp. 330-341  
Appendix Table 10, pp. 345-353  
Appendix Table 11, pp. 354-356  
Appendix Table 12, pp. 357-362  
Appendix Table 13, pp. 363-378  
Appendix Table 14, pp. 379-388  
Appendix Table 15, pp. 389-394

2. In addition, please respond to the following comments regarding Protocol HPV-009 (ongoing in Costa Rica):

- a. In the pre-BLA material, your March 31, 2006, submission to your IND (b)(4), the number of subjects in each of the two treatment groups was noted to be approximately 3731. Please provide the number of subjects in each treatment group.
- b. Please clarify whether subjects from HPV-009 were included in the total numbers of subjects who received CERVARIX and HAVRIX

720 in Table 9 of Section 2.7.4, Summary of Clinical Safety. CBER notes that Study HPV-009 is not included in Table 1, p. 21 of the Summary of Clinical Safety, nor is it included within the text on pp. 21-25 of the Summary of Clinical Safety as contributing to the overall safety database.

- c. In the pre-BLA material, your March 31, 2006, submission to your IND (b)(4) you indicated that subjects from HPV-009 would be included within the safety database for SAEs. All SAEs that occurred in HPV-009 are presented in Table 41 (pp. 121-123) in a blinded manner, and SAEs deemed related to study material that occurred in HPV-009 are provided in Table 42 (p. 125). Please clarify if the calculation of the overall proportions of subjects with SAEs (pp. 106-107) include subjects from HPV-009 (in the numerator and denominator).