

From: Edward.M.Yuhas@gsk.com
To: [Sullivan, Helen M.](#)
Subject: Cervarix: Partial Response to Email of Sep 20, 2007
Date: Tuesday, October 23, 2007 2:50:24 PM

Helen,

Reference is made to your email of Sep 20, 2007 wherein you requested additional information regarding 7 patients with various adverse events.

On Oct 2, 2007 we provided FDA (via email) with a table that indicated the treatment assignments.

On Oct 15, we provided FDA (via email) with brief narratives for these patients.

The remaining information to be provided to FDA was "if safety reports for these subjects have been previously submitted to IND (b)(4) or to BLA 125259, please indicate the location of these reports and submit to the BLA".

The information I have received on this latter point is as follows:

Of the seven subjects identified, only two were considered to have had an serious adverse event (PIDs 123422 and 294498). As neither event was considered to be related to drug treatment, no safety reports were submitted to the IND.

The event for PID 123422 (that was considered a SAE (c. section due to arrested phase labor) occurred after the safety database freeze used in the safety reporting for the BLA (cut-off date was Sep 30 2006 and the event was reported Oct 20, 2006). As such, no information regarding this SAE is in the original BLA. It should be noted that this patient also had an adverse event (not considered drug related; history of rheumatoid arthritis) that was noted during the study and information on this adverse event was described in the BLA (and noted in your email to GSK on Sep 20th).

The SAE for patient 294498 occurred prior to database freeze and was noted in the BLA. Please refer to module 5.3.5.4-Other Study Reports-HPV-009, p.241.

With this email, GSK has responded to all information requested in the Sep 20, 2007 email. We will submit the aforementioned information in a formal submission to the BLA shortly.

Finally, please note that in my email to you of Oct 15th, I made mention of some safety information I received that was in Spanish. This information was the original CRF safety information that is now (upon internal examination) considered NOT to be relevant to your request (albeit referenced, in part, in the narratives provided). This information will not be provided to the FDA unless you explicitly request it.

Regards

"EMF <fda.hhs.gov>" made the following annotations.

This message was sent by GlaxoSmith Kline across the Internet in encrypted format
and was successfully decrypted, unless otherwise noted. Glaxo Wellcome
=====