

To: Mr. Matt Whitman  
File: STN 125259/0 CERVARIX  
RE: Request for Patient Source Documents  
Date: July 23, 2007

APPROVED

By Helen Sullivan Generated at 7:47 pm, Mar 11, 2008

We have the following comments:

1. CBER is in the process of obtaining a neurology consult within FDA to further evaluate the identified cases of neuroinflammatory events that occurred in subjects participating in the clinical studies for Cervarix® and [REDACTED]. We are also further investigating the single case of transverse myelitis reported in a subject who received an [REDACTED] in a study under separate IND. The HPV vaccine recipients who experienced the neuroinflammatory adverse events include PID 704 in HPV-014, PID 1264 in HPV-014, PID 37 in HPV-012, and PID 11937 in HPV-008 (studies with Cervarix®). Additionally, a subject identified as case report B0404646A in IND [REDACTED] was also diagnosed with a neuroinflammatory adverse event (myelitis). We have located narratives and International Adverse Event reports within the BLA submission for these subjects. We request that you provide source documents (e.g., hospital records, doctor's notes at time of visits, laboratory tests etc.) for these five subjects so that we have all available information for our neurology consult's review. Please respond.
2. Please discuss whether you have obtained a neurology consult to evaluate the cases of neuroinflammatory adverse events reported for subjects who received your HPV vaccines (Cervarix and [REDACTED]). If you have not obtained a neurology consult, you may want to consider doing so to further evaluate these reported adverse events. Please respond.