

APPROVED

By Helen Sullivan Gemignani at 2:19 pm, Mar 11, 2008

To: Mr. Matthew Whitman
File: STN 125259/0 CERVARIX
RE: Unblinded Narratives HPV-009
Date: September 20, 2007

In regard to Serial 473 for IND (b)(4) (submitted 8/13/07), CBER has the following request:

It is noted that 4 subjects in study HPV-009 were diagnosed with rheumatoid arthritis, 2 with alopecia areata, and 1 with fibromyalgia. We realize that HPV-009 remains blinded. You have previously provided treatment group of subjects participating in study HPV-009 through the firewall group to maintain blinding (8/1/07 request, 8/14/07 response).

CBER requests that you provide unblinded treatment assignments and clinical narratives for the subjects listed in Case Group #2 (Appendix A of Amendment 472 (Serial 473) of IND (b)(4) p. 11) with the following diagnoses: 2 subjects with alopecia areata; 1 subject with fibromyalgia; and 4 subjects with rheumatoid arthritis. 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.