



September 23, 2011

S.A.N.E. Vax, Inc.
Attention: Norma Erickson
President
154 Cecil Drive
Troy, MT 59935

Dear Ms. Erickson:

Thank you for your most recent inquiry to Dr. Margaret Hamburg, the Commissioner of Food and Drugs, concerning Gardasil. Your inquiry was forwarded to the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) for reply. CBER is responsible for regulatory oversight of vaccines. Assuring the safety and effectiveness of vaccines is one of FDA's top priorities.

In your letter, you express concerns regarding the possible contamination of Gardasil by human papillomavirus (HPV) DNA, because you report finding recombinant HPV L1-specific DNA sequences in 13 vials of Gardasil from different lots distributed in various countries, including the United States. We are aware that your letter to FDA has been made available to the public by posting it on your website at <http://sanevax.org/sane-vax-to-fda-recombinant-hpv-dna-found-in-multiple-samples-of-gardasil/>.

We have evaluated the concerns conveyed to us in your letter. We have determined that Gardasil is not contaminated with HPV DNA and remains a safe and effective vaccine. We also reviewed all reports of the Vaccine Adverse Event Reporting System (VAERS) for the lots that you tested and reported as HPV DNA positive and did not identify any unusual adverse events.

Recombinant technology has been utilized for many years to manufacture medical products. Gardasil does contain recombinant HPV L1-specific DNA fragments. This is expected, since DNA encoding the HPV L1 gene is used in the vaccine manufacturing process to produce the virus-like particles. The presence of these expected DNA fragments, which are inevitable in vaccine production, is not a risk to vaccine recipients, is not harmful, and this DNA is not a contaminant.

Since the early development of Gardasil, FDA and the manufacturer (Merck and Co., Inc.) have known that after purification of the vaccine, small quantities of residual recombinant HPV L1-specific DNA fragments remain in the vaccine. However, Gardasil does not contain DNA from other HPV genes or any full-length infectious HPV genomes; Gardasil is a safe and effective vaccine.

Information concerning the presence of HPV DNA has never been in the U.S. labeling for Gardasil, therefore, it was not suddenly removed in April 2011. The presence of residual DNA is not a safety factor as defined by U.S. regulations, and is not required to be included in Gardasil's labeling.

Although not specifically conveyed in your most recent letter, we understand that you are concerned that there may be a link between Gardasil and juvenile rheumatoid arthritis. Please be assured that there is no scientific evidence linking juvenile rheumatoid arthritis and vaccination with Gardasil. FDA recently evaluated the results of a postmarketing study, which included 189,629 females ages 9 to 26 years, 51% of whom were 9 to 15 years of age. The results of this study showed that there is no elevated risk for juvenile rheumatoid arthritis or rheumatoid arthritis associated with use of Gardasil. We also separately reviewed all VAERS reports of juvenile rheumatoid arthritis after vaccination with Gardasil, and there is no evidence of unusual clinical patterns or high reporting rates.

Thank you for sharing your concerns with us. Please be assured that the scientific data available to the FDA supports the continued use of Gardasil as a safe and effective vaccine, and we find that its benefits continue to outweigh its risks.

We hope that you will post this letter on your website so that your readers can also be assured that Gardasil remains a safe and effective vaccine.

Sincerely,

A handwritten signature in black ink, appearing to read "Walter J. Gardner", with a long horizontal flourish extending to the right.

Walter J. Gardner
Chief, Consumer Affairs Branch
Office of Communication, Outreach
and Development
Center for Biologics Evaluation and Research