U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Vaccines, Blood & Biologics

FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk

October 21, 2011

The FDA has recently received inquiries regarding the presence of human papillomavirus (HPV) DNA fragments in Gardasil and is aware that information related to this issue is on the internet. A concern that the presence of these fragments could represent contamination of the vaccine arises from an unpublished report that recombinant HPV L1-specific DNA sequences were present in 13 vials of Gardasil from different lots.

The presence of DNA fragments is expected in Gardasil and not evidence of contamination. Based on the scientific information available to FDA, Gardasil continues to be safe and effective, and its benefits continue to outweigh its risks.

Key Facts:

- Gardasil does contain recombinant HPV L1-specific DNA fragments, but these are not contaminants. DNA encoding the HPV L1 gene is used in the vaccine manufacturing process to produce the virus-like particles that make up the vaccine. The presence of these DNA fragments is expected, is not a risk to vaccine recipients, and is not a safety factor. DNA is the "blueprint" for the majority of living organisms and carries the genetic instructions for how cells function and grow.
- The vaccine manufacturing process is highly regulated under FDA's current good manufacturing practice requirements, including inspections conducted by FDA of the manufacturing processes and facilities.
- 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. Gardasil does not contain DNA from other HPV genes or any full-length infectious HPV genomes.
- As it does with all vaccines, FDA continues to monitor the safety of Gardasil. For example, 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 to assess the risk for onset of new autoimmune diseases after vaccination with Gardasil. Examples of these types of diseases include juvenile rheumatoid arthritis, lupus, multiple sclerosis, etc. The results of this study showed that there is no elevated risk for onset of new autoimmune disease associated with the use of Gardasil.
- FDA also continually reviews all reports of the Vaccine Adverse Event Reporting System after vaccination with Gardasil, and there is no evidence of unusual clinical patterns or high reporting rates of adverse events, including autoimmune diseases.

One of FDA's highest priorities is the protection of public health through safe and effective vaccines. As it does with all vaccines, FDA will continue to monitor the safety of Gardasil.

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