FDA NEWS RELEASE

FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old

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The U.S. Food and Drug Administration today approved a supplemental application for Gardasil 9 (Human Papillomavirus (HPV) 9-valent Vaccine, Recombinant) expanding the approved use of the vaccine to include women and men aged 27 through 45 years. Gardasil 9 prevents certain cancers and diseases caused by the nine HPV types covered by the vaccine.

“Today’s approval represents an important opportunity to help prevent HPV-related diseases and cancers in a broader age range,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. ”The Centers for Disease Control and Prevention has stated that HPV vaccination prior to becoming infected with the HPV types covered by the vaccine has the potential to prevent more than 90 percent of these cancers, or 31,200 cases every year, from ever developing.”

According to the CDC, every year about 14 million Americans become infected with HPV; about 12,000 women are diagnosed with and about 4,000 women die from cervical cancer caused by certain HPV viruses. Additionally, HPV viruses are associated with several other forms of cancer affecting men and women.

Gardasil, a vaccine approved by the FDA in 2006 to prevent certain cancers and diseases caused by four HPV types, is no longer distributed in the U.S. In 2014, the FDA approved Gardasil 9, which covers the same four HPV types as Gardasil, as well as an additional five HPV types. Gardasil 9 was approved for use in males and females aged 9 through 26 years.

The effectiveness of Gardasil is relevant to Gardasil 9 since the vaccines are manufactured similarly and cover four of the same HPV types. In a study in approximately 3,200 women 27 through 45 years of age, followed for an average of 3.5 years, Gardasil was 88 percent effective in the prevention of a combined endpoint of persistent infection, genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and cervical cancer related to HPV types covered by the vaccine. The FDA’s approval of Gardasil 9 in women 27 through 45 years of age is based on these results and new data on long term follow-up from this study.

Effectiveness of Gardasil 9 in men 27 through 45 years of age is inferred from the data described above in women 27 through 45 years of age, as well as efficacy data from Gardasil in younger men (16 through 26 years of age) and immunogenicity data from a clinical trial in which 150 men, 27 through 45 years of age, received a 3-dose regimen of Gardasil over 6 months.

The safety of Gardasil 9 was evaluated in about a total of 13,000 males and females. The most commonly reported adverse reactions were injection site pain, swelling, redness and headaches.

The FDA granted the Gardasil 9 application priority review status. This program facilitates and expedites the review of medical products that address a serious or life-threatening condition.

The FDA granted approval of this supplement to the Gardasil 9 Biologics License Application to Merck, Sharp & Dohme Corp. a subsidiary of Merck & Co., Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

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- Gardasil 9
- Gardasil
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