FDA Rejects Gardasil for Older Women

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The pharmaceutical company, Merck & Co. Inc., won approval in 2006 from the US Food and Drug Administration (FDA) to market Gardasil, the first vaccine ever approved for the prevention of infection from human papillomavirus (HPV), which often causes cervical cancer. Gardasil is approved for use only in young females, those between the ages of 9 and 26.

Merck recently applied for FDA approval to use the vaccine on women aged 27 to 45 but the government agency denied approval of the vaccine for women in that age group, saying there are unresolved issues that prevent approval at this time. The FDA rejected Merck's application for approval because they did not expect the unresolved issues to be addressed thoroughly within the time allocated for review.

GARDASIL®

A Merck official says the company expects to have a complete response to the FDA's concerns ready in July.

The company is approaching the FDA's current decision as a delay, not a final outcome, and is continuing with its plans to apply for approval to market Gardasil to men by the end of 2008. Men contract HPV and risk spreading it to their sexual partners. By vaccinating both males and females, the spread of the virus can be dramatically reduced.

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