Cervical cancer vaccines manufactured by both Merck and GlaxoSmithKline (GSK) hit speed bumps recently with U.S. regulators.

Merck's Gardasil® is currently approved for the prevention of cervical precancers and cancers in females ages 9-26 years. Earlier this year the Food 

and Drug Administration (FDA) granted a speedy priority review to the company's application requesting that women up to age 45 be included in the vaccine's indication. In late June, however, FDA notified Merck that questions about the new indication couldn't be resolved in the time allotted for the review and a decision would have to be tabled until later.

Merck had also asked FDA to approve Gardasil as offering "cross protection" against a number of HPV types not included in the vaccine but the agency declined, saying the data submitted do not support such an indication. Gardasil is a quadrivalent vaccine that provides significant protection against cervical, vaginal and vulvar disease associated with the four types included in the vaccine: two "high risk" HPV types (HPV 16/18) found in the majority of cervical cancers, and two "low risk" types (HPV 6/11) associated with about 90% of genital warts.

GSK's Cervirix®, a bivalent vaccine that protects against HPV 16/18, is approved in many countries around the world (including Australia and the European Union). A decision on GSK's application to market Cervarix in the U.S. was delayed last December when FDA asked the company to provide additional information. The company recently announced it also plans to give FDA data from a clinical trial that won't conclude until late 2008, meaning a decision likely won't come until 2009