Truvada HIV PrEP Approval Decision Delayed Three Months

June 11, 2012

The U.S. Food and Drug Administration has extended its review of Gilead Sciences' approval application for Truvada (tenofovir plus emtricitabine) as pre-exposure prophylaxis (PrEP), according to a June 6 announcement by the company. Whereas an approval decision was originally expected by this Friday, June 15, the agency now has until September 14 to make its final determination.

"The FDA has indicated that this extension relates to the agency's standard administrative procedures for reviewing Gilead's proposed Risk Evaluation and Mitigation Strategy (REMS) for Truvada as PrEP," Gilead's Gregg Alton specified in the announcement sent to HIV treatment and prevention advocates. "As was discussed at the FDA Advisory Committee Meeting last month, there are many components of a REMS, including a Medication Guide, educational training and an implementation system, all of which may require additional time for adequate FDA review."

If Gilead's PrEP request is approved by the FDA, Truvada can be used by those not infected with HIV but are at risk of infection with the virus. In one clinical trial involving men who have sex men, Truvada was approximately 90 percent effective at preventing infection among those who consistently and correctly used the medication on a daily basis.