Three Big HIV Days in May at the FDA

April 19, 2012 By Tim Horn

The U.S. Food and Drug Administration (FDA) has three important advisory committees planned in May to review new strategies in prevention, treatment and diagnostic testing, according to an AIDS.gov blog post by Richard Klein, who heads the agency's Office of Special Health Issues.

On May 10, the FDA's Antiviral Drugs Advisory Committee (ADAC) will meet to discuss Gilead Sciences' application seeking approval of Truvada (tenofovir plus emtricitabine) as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquiring HIV.

The next day, on May 11, ADAC will reconvene to review Gilead's application requesting marketing clearance for its "Quad" fixed-dose combination (FDC) tablet containing tenofovir and emtricitabine plus two still-unapproved agents: the integrase inhibitor elvitegravir and the novel boosting agent cobicistat. The advisory committee will vote on the quality of the FDC's safety and efficacy data in clinical trials involving people living with HIV starting therapy for the first time or without known HIV genetic mutations associated with resistance to any of the four drugs in the tablet.

Finally, on May 15, the FDA's Blood Products Advisory Committee will meet to evaluate data supporting the approval of OraQuick's In-Home HIV antibody test. This is the first time a complete home-use rapid HIV test has been submitted to the agency for approval.

All advisory committee meetings are open to the public. They begin at 8 A.M. and are set to conclude around 5 P.M. on all three days.

The May 10 PrEP advisory committee meeting will be held in Room 1503 of the FDA's White Oak Campus (10903 New Hampshire Avenue, Building 31 Conference Center) in Silver Spring, Maryland.

The May 11 Quad advisory committee meeting will be held at the Hilton DoubleTree Hotel (8727 Colesville Road) in Silver Spring.

The May 15 advisory committee meeting on home HIV testing will take place at the Hilton Washington DC/North (620 Perry Parkway) in Gaithersburg, Maryland.

The public is also invited to provide oral and/or written testimony on these topics, though the deadline for requesting time to speak at the May 10 meeting has passed and the deadline for

submitting a request to speak at the May 11 meeting is today (April 19). Individuals interested in making formal oral presentations at the May 15 meeting have until April 30 to notify the FDA.

All pertinent information regarding the meetings, including instructions for submitting oral and written testimony, can be found using the links above.

While the FDA is not required to follow its advisory committees' recommendations, it usually does so. Final approval decisions from the agency are expected to follow in the weeks following the advisory committee meetings.

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