FDA reviews first rapid, take-home test for HIV

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The Food and Drug Administration is considering approval of the first over-the-counter HIV test that would allow consumers to quickly test themselves for the virus at home, without medical supervision.

FDA reviewers said Friday the OraQuick In-Home HIV test could play a significant role in slowing the spread of HIV, according to briefing documents posted online. But they also raised concerns about the test's accuracy.

Public health experts estimate one-fifth, or about 240,000 people, of the 1.2 million HIV carriers in the U.S. are not aware of their status. Testing is one of the chief means of slowing new infections, which have held steady at about 50,000 per year for two decades.

In a trial conducted by the company OraSure Technologies Inc., the test correctly detected HIV in those carrying the virus 93 percent of the time. The FDA estimates the test would miss about 3,800 HIV-positive people per year, if approved for U.S. consumers.

The test was more accurate at correctly clearing patients who do not have the disease. In company studies, OraQuick correctly identified HIV-negative users 99 percent of the time.

On Tuesday, the FDA will ask a panel of experts whether the test should be approved for over-the-counter sales in U.S. The agency is not required to follow the group's advice, though it usually does.

In their briefing documents, agency scientists noted both the benefits and risks of expanding HIV testing with the take-home diagnostic kit, a mouth swab which returns results in about 20 minutes.

"There is considerable personal and public health value in informing infected, but otherwise untested, persons of their true positive HIV status ," the reviewers state. "However, this benefit is offset in some measure by HIV-positive individuals who receive an incorrect message that they are not infected."

The FDA has already approved HIV test kits that people take home. However, those kits, which require a blood sample, must be sent to a laboratory for development.