



FDA Accepts New Applications for Cobicistat and Elvitegravir

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As of April 21, the U.S. Food and Drug Administration (FDA) has accepted Gilead Sciences' resubmitted applications for the approval of cobicistat and elvitegravir to treat HIV. The company seeks the FDA's imprimatur to market cobicistat as a pharmacoenhancing, or boosting, agent that raises the blood levels of the protease inhibitors Reyataz (atazanavir) and Prezista (darunavir) as well as the integrase inhibitor elvitegravir, allowing them to be dosed just once daily. In addition, Gilead seeks approval for elvitegravir's use in treatment-experienced adults.

The company had submitted new drug applications for the antiretrovirals in mid-2012, but the FDA responded nearly a year later that it could not sign off on them because of shortcomings in Gilead's provided documentation supporting the drugs. Gilead states that it has since worked with the FDA to address these problems.

The FDA's decisions for the applications are expected on October 3 and 4.

Janssen, which developed Prezista, [filed an application](#) with the FDA on April 1 for approval of a once-daily fixed-dose combination tablet of that drug and cobicistat. And on April 22 Bristol-Myers Squibb [filed for approval](#) of a fixed-dose tablet of the company's Reyataz (atazanavir) and cobicistat.

To read the Gilead press release, [click here](#).

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