Gilead and Tibotec’s Combo HIV Drug Is Back on Track

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Gilead announced that it is back on track with the approval process for the combination antiretroviral (ARV) pill it is developing in partnership with Tibotec, having refiled its New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA). The FDA rejected the original NDA in a letter dated January 25 over concerns about impurities found during test-batches of the new pill.

Gilead initially filed for approval of the fixed-dose combination tablet—which combines Tibotec’s rilpivirine (TMC278) with Gilead’s Truvada (tenofovir plus emtricitabine)—in November 2010. However, the FDA sent Gilead a “refuse to file” notification in late January, asking the company to provide further information about how the company came to determine what constitutes acceptable levels of “degradents” of emtricitabine that occurred while manufacturing the new combo pill. Drugs sometimes contain trace impurities, and it is the manufacturer’s responsibility to prove to the FDA the maximum levels of the impurity that the drug can contain and still remain safe and effective for people who take it. These data were included in the new filing Gilead just sent to the FDA.

Gilead reported in January that the refusal to file meant that when it resubmitted the application the drug could still receive priority review, which can shave months off the approval process. The FDA now has two months to decide whether the application is sufficient to proceed with the approval process—and to set a target date for approval.