Crofelemer for HIV Diarrhea Delayed Again by FDA

September 6, 2012

The U.S. Food and Drug Administration (FDA) has again postponed a decision on approving crofelemer, a compound made from the sap of the Peruvian Dragon's Blood tree for the treatment of diarrhea in people living with HIV receiving antiretroviral therapy, according an announcement by Salix Pharmaceuticals. Originally scheduled to be approved on June 5, 2012, the FDA informed Salix in April that it required more time to review the company's new drug application (NDA) for the 125 mg tablets. On September 5, the revised approval date, Salix announced that the agency required more time to review the NDA. "The primary topic is the production and control of the crofelemer active pharmaceutical ingredient, a complex mixture that is the first botanical product to be reviewed by the Agency for oral use," the September 5 Salix announcement explained. The company now anticipates an action by the FDA by the end of the March 2013.

To read the September 5 Salix news announcement, click here.

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