



Press Release
For Immediate Release
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HHS/FDA Warnings: Ranbaxy Laboratories

Washington, DC – On September 16, 2008, the Food and Drug Administration within the U.S. Department of Health and Human Services (HHS/FDA) issued an “Import Alert” for drugs manufactured at, or containing materials from, two Ranbaxy facilities in India, located in the cities of Dewas and Paonta Sahib.

There are three Ranbaxy-manufactured products that HHS/FDA has tentatively approved or fully approved and thus have been eligible for purchase by programs supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR): Zidovudine, Lamivudine, and Nevirapine. In fiscal year 2007, PEPFAR supported the procurement of \$8.9 million in antiretroviral drugs from Ranbaxy. All three products are manufactured at one of the two identified Ranbaxy facilities cited in the HHS/FDA warnings.

The warnings issued by HHS/FDA are only applicable to the U.S. market. However, it is a principle of PEPFAR to purchase only antiretroviral drugs that meet standards equal to those established for patients in the United States. Thus, for the three PEPFAR-eligible antiretroviral drugs manufactured at the two plants, PEPFAR country teams have been instructed to notify implementing partners that PEPFAR funds may only be used to procure drugs that are produced by alternative manufacturers and tentatively or fully HHS/FDA-approved. HHS/FDA-approved and tentatively approved drugs are available from alternative manufacturers for each of the three affected products.

Since at this time, there is no evidence of deficiencies in existing products and HHS/FDA is not recalling existing stocks of these drugs in the U.S., PEPFAR does not recommend that governments or implementing partners withdraw existing drug stocks produced by or containing active ingredients produced by Ranbaxy at the two affected plants at this time. PEPFAR country teams have been instructed that patients should continue taking their medications manufactured by Ranbaxy and should not disrupt their drug therapy without consulting their doctor.

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The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) was launched in 2003 by President George W. Bush to combat global HIV/AIDS, and is the largest commitment by any nation to combat a single disease in history. Through PEPFAR, the U.S. Government has already provided \$18.8 billion in HIV/AIDS funding, with a reauthorization of up to \$48 billion for HIV/AIDS, tuberculosis and malaria over the next five years.