FDA IN BRIEF

FDA announces pilot program with World Health Organization to expedite efficiency of review of HIV drug applications

Description: The FDA is working with the World Health Organization (WHO) to pilot a process to share documents on HIV drug applications that have been approved or tentatively approved by the agency under the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR).

Short Title: FDA announces program to expedite review of HIV drug applications

For Immediate Release: Nov. 30, 2018
Media Inquiries: Alison Hunt, alison.hunt@fda.hhs.gov, 240-402-0764

FDA In Brief: FDA announces pilot program with World Health Organization to expedite review of HIV drug applications

“Since the President’s Emergency Plan for AIDS Relief (PEPFAR) was launched 15 years ago to battle the global HIV/AIDS epidemic, more than 17 million lives have been saved and currently over 14 million people living with HIV in the countries served by the program are being provided with safe, effective and low-cost antiretroviral therapy, including over 700,000 children. As we mark this year’s World AIDS Day on December 1, we reflect on the progress we have made in the global fight against HIV/AIDS as well as the men, women and children living with HIV who do not have access to prevention, care and treatment. As part of our public health mission, the FDA has played an important role in supporting PEPFAR and the agency remains committed to doing what we can to facilitate timely access to these essential medicines,” said Anna Abram, the FDA’s deputy commissioner for policy, planning, legislation and analysis. “Today we are announcing a pilot program with the World Health Organization (WHO) designed to expedite the review of HIV drug applications submitted to WHO’s Prequalification of Medicines Programme (PQP). The pilot will minimize duplication of efforts by the FDA and the WHO and help regulatory authorities in nations with limited resources make decisions faster on life-saving HIV drugs for patients with this devastating, but treatable disease.”

The U.S. Food and Drug Administration today announced a plan to work with the World Health Organization (WHO) to pilot a process to share documents on HIV drug applications that have been approved or tentatively approved by the agency under the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). In this initial pilot, to be called the Collaborative Registration Procedure-Lite (CRP-Lite),
the FDA will, with the applicants’ permission, provide the WHO/PQP with minimally-redacted reviews of one or two HIV drug applications. The WHO/PQP will then use the FDA’s reviews to expedite its own regulatory decision making, producing review dossiers which can in turn be shared with regulators in resource limited countries to speed up their own regulatory review processes—making lifesaving drugs available to patients who need them the most.

PEPFAR was launched in 2003 to address the global HIV/AIDS crisis by using U.S. funds to purchase, at low cost, antiretroviral therapies, including new combinations and formulations of medicines, for treatment in countries with limited resources that were hard-hit by the epidemic. Although there is no cure for HIV/AIDS, antiretroviral treatment, which usually involves a combination of three drugs, can dramatically reduce the severity of illnesses associated with HIV infection. It can also improve the duration and quality of life, as well as help reduce risk of transmission to uninfected individuals—including mother-to-child transmission, the leading cause of HIV infection in children. Since 2004, the FDA has approved or tentatively approved 211 antiretroviral drug applications for use in PEPFAR partner countries and 193 of those are still available for treatment. The FDA-reviewed products are currently being used to treat over 14 million patients with HIV globally (or about 38 percent of the total global population living with HIV). In addition, because of PEPFAR’s ARV-supported programs to prevent mother-to-child transmission, more than 2.4 million babies have been born HIV-free who could have otherwise been infected.

# # #

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.