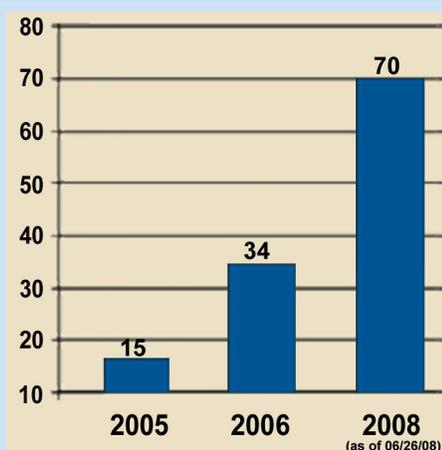




## *Increasing the Availability of Safe, Effective, Low-Cost Generic Medications*

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supports the increased availability of safe, effective, low-cost, and generic antiretroviral drugs (ARVs) in the developing world, extending its impact on treatment access beyond PEPFAR-supported programs. To meet the need for such ARVs, the Food and Drug Administration within the U.S. Department of Health and Human Services (HHS/FDA) introduced an expedited "tentative approval" process whereby ARVs from anywhere in the world, produced by any manufacturer, could be rapidly reviewed to assess quality standards and subsequently cleared for purchase under PEPFAR.

### Cumulative HHS/FDA Approvals/Tentative Approvals of Generic ARVs



As of June 26, 2008, **70 generic ARV formulations** have been approved or tentatively approved by HHS/FDA under the expedited review. These include:

- **Ten** fixed-dose combination products that contain two drugs in the same tablet or capsule
- **Four** fixed-dose combination products that contain three drugs in the same tablet or capsule
- **Sixteen** products intended primarily for pediatric use

### **Why is this process important?**

PEPFAR is committed to procuring drugs – generic or branded – from any source, as long as they are proven safe, effective and of high quality and their purchase is consistent with international law. Requiring ARVs to be approved through the expedited HHS/FDA process (meaning they must meet safety standards equal to those established for drugs in the United States) ensures antiretroviral drugs purchased for use in PEPFAR programs abroad meet standards for drugs available to U.S. patients.

### **How does the U.S. Government work with multilateral partners to improve access to safe ARVs?**

HHS/FDA has signed a confidentiality agreement with the World Health Organization (WHO) Prequalification Unit to hasten the inclusion on WHO's pre-qualification list of generic ARVs approved by HHS/FDA, and the WHO Secretariat has begun to add such ARVs to the drug list maintained by its pre-qualification project based solely on the HHS/FDA assessment.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) recognizes HHS/FDA approval as approval by a "stringent regulatory authority," which means Global Fund resources may be used to purchase generic ARVs that have received HHS/FDA approval.

### **Where can I see the list of approved and tentatively approved drugs?**

For additional information, please visit <http://www.fda.gov/oia/pepfar.htm>.

President George W. Bush's Emergency Plan for AIDS Relief is the largest commitment ever by any nation for an international health initiative dedicated to a single disease -- a five-year, \$15 billion, comprehensive approach to combating the disease around the world.

*U.S. Department of State*

*U.S. Agency for International Development*

*U.S. Department of Defense*

*U.S. Department of Commerce*

*U.S. Department of Labor*

*U.S. Department of Health and Human Services*

*Peace Corps*

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