Global Health R&D at FDA

What does FDA do for global health R&D?
The US Food and Drug Administration (FDA) regulates the safety and efficacy of drugs, vaccines, and other medical products marketed in the United States, which can include products also designed for use overseas. The FDA also works with international regulators in low- and middle-income countries (LMICs) to strengthen their regulatory capacity and provide technical assistance.

Why is FDA’s role in global health R&D important?
FDA approval of a product serves as a “gold standard” that can expedite regulatory review in LMICs. This effect, combined with the agency’s work in regulatory capacity strengthening, helps ensure new global health technologies are safe, effective, and accessible in low-resource settings.

Impact of investment

The FDA has approved more than 75 drugs, vaccines, and diagnostics for neglected diseases. The FDA has 208 formal arrangements for information sharing and technical assistance with regulatory authorities in 49 countries.

FDA R&D success stories: Saving lives, saving money

**CAPACITY STRENGTHENING**

Development of partnerships to strengthen regulatory capacity in LMICs, including collaborations with the World Health Organization (WHO) African Vaccine Regulatory Forum and the WHO Developing Country Vaccine Regulators Network to share expertise and provide training and mentoring.

**HIV/AIDS**

Creation of a “tentative approval” process allowing the President’s Emergency Plan for AIDS Relief (PEPFAR) to purchase generic antiretroviral (ARV) drugs for use outside the United States. Through the program, the FDA has approved more than 200 ARVs, which have helped support treatment for more than 15 million people worldwide.

**HEALTH EMERGENCIES**

Granted emergency use authorization for more than 350 medical products for COVID-19, 18 diagnostics for Zika, and 11 diagnostics for Ebola, facilitating their use during these crises.

**MENINGITIS**

Development of critical technology used in a low-cost meningitis A vaccine, which has been delivered to more than 340 million people in 24 countries, virtually eliminating meningitis A wherever it has been used.

**NTDs**

Release of guidance documents to aid organizations in developing drugs for neglected tropical diseases (NTDs) and issuance of 11 priority review vouchers (PRVs) as part of the NTD PRV program intended to stimulate private-sector investment in NTD R&D.

**TB**

Use of an accelerated approval pathway to speed review and approval of two new drugs to treat drug-resistant tuberculosis (TB).