

President's Emergency Plan for AIDS Relief (PEPFAR) “The Basics”

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Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines
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Overview

- PEPFAR program and its impact
- The roles of Generic Drugs in PEPFAR
- FDA's Tentative Approval Process (TA) for the Abbreviated New Drug Application (ANDA)
- PEPFAR eligibility and its criteria
- PEPFAR Change Amendments
- Practice Pearls



THE IMPORTANCE OF THE PEPFAR PROGRAM AND ITS OVERVIEW

What is PEPFAR?

President's
Emergency Plan
for AIDS Relief

Initiative to
address global
HIV/AIDS epidemic

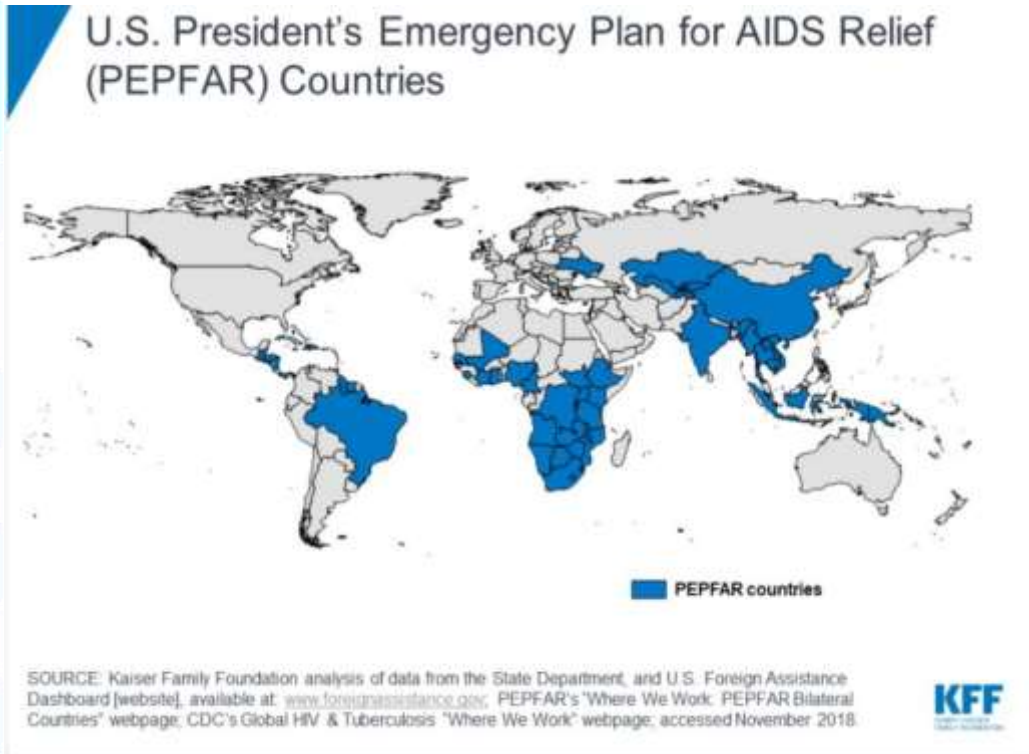
To date, PEPFAR
funding has
totaled more than
\$110 billion

To date, 239
PEPFAR
Applications with
303 products

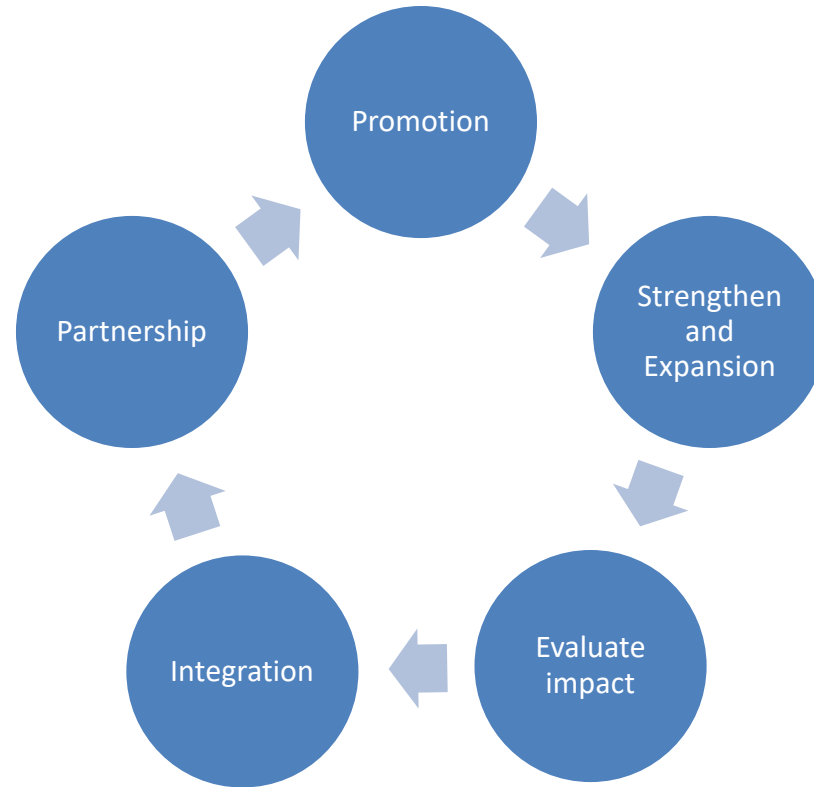
13 Priority Countries

Priority High Burden Countries

Haiti	Zambia
United Republic of Tanzania	Uganda
Zimbabwe	Malawi
Lesotho	Cote d'Ivoire
Botswana	Namibia
Swaziland	Kenya
Rwanda	



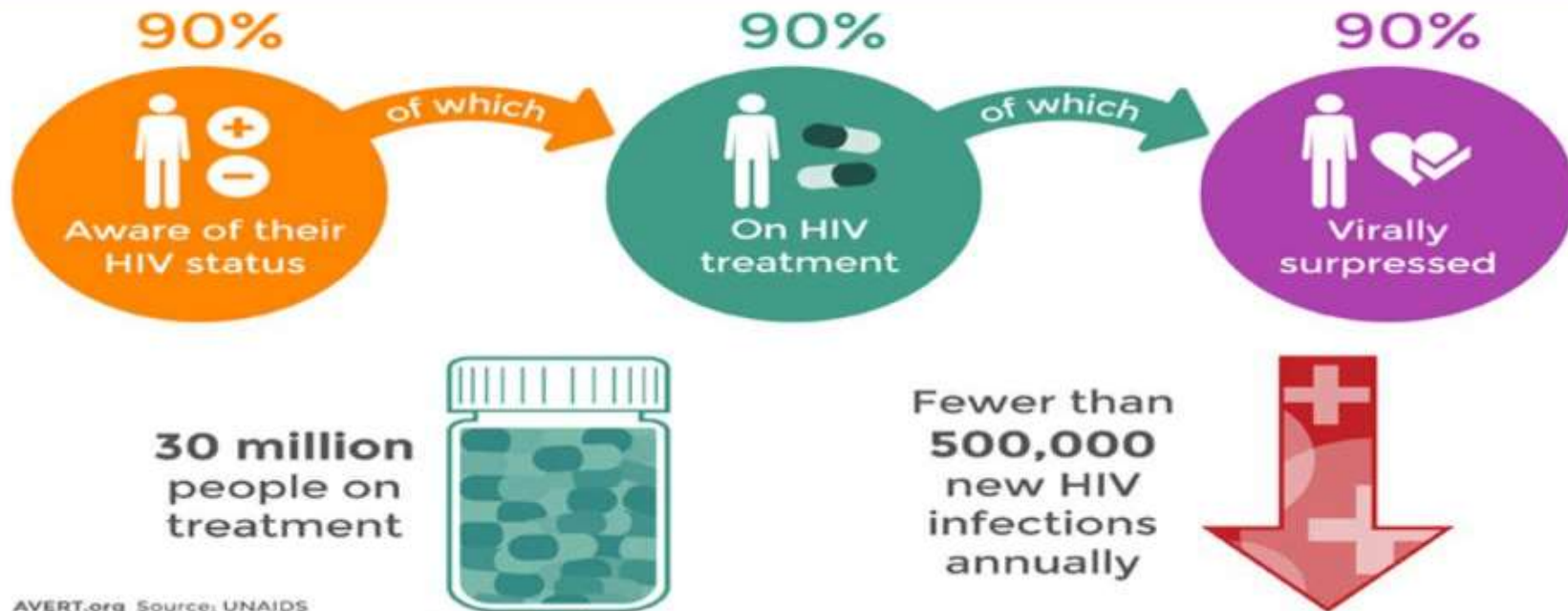
PEPFAR Program Goals



90-90-90 and 95-95-95 Treatment Target



KEY 2020 FAST TRACK TARGETS



Generic Drugs

Safe and effective

Commonly Encountered



Affordable

Global Savings

Role of Generic Drugs in PEPFAR

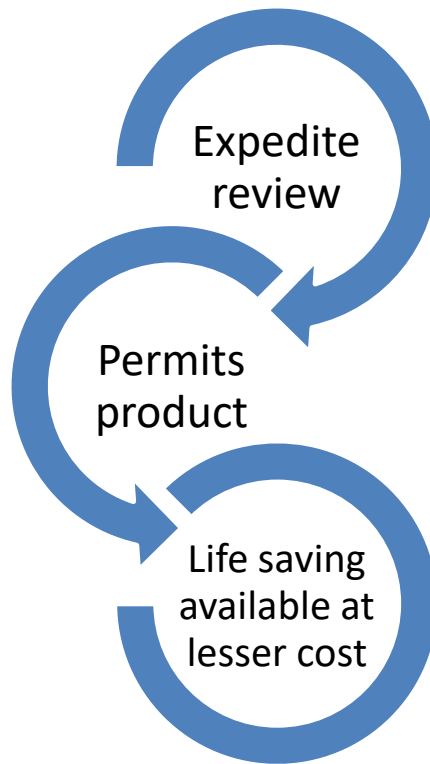


Review and Tentatively Approve antiretroviral (ARV) ANDAs for procurement under PEPFAR

Protects domestic patents of the Reference Listed Drug (RLD)

Saves \$ for the PEPFAR program, while ensuring the medications purchased are safe and effective

PEPFAR Tentative Approval (TA) Advantage



505(j) ANDA Pathway

Generic drug applicants do not repeat clinical or pre-clinical studies to establish safety or efficacy.

ANDAs can be approved if they establish that the drug is therapeutically equivalent to the innovator product

All ANDAs submitted pursuant to the PEPFAR program get a priority review

PEPFAR eligibility



Identified and validated by the
Division of Filing Review

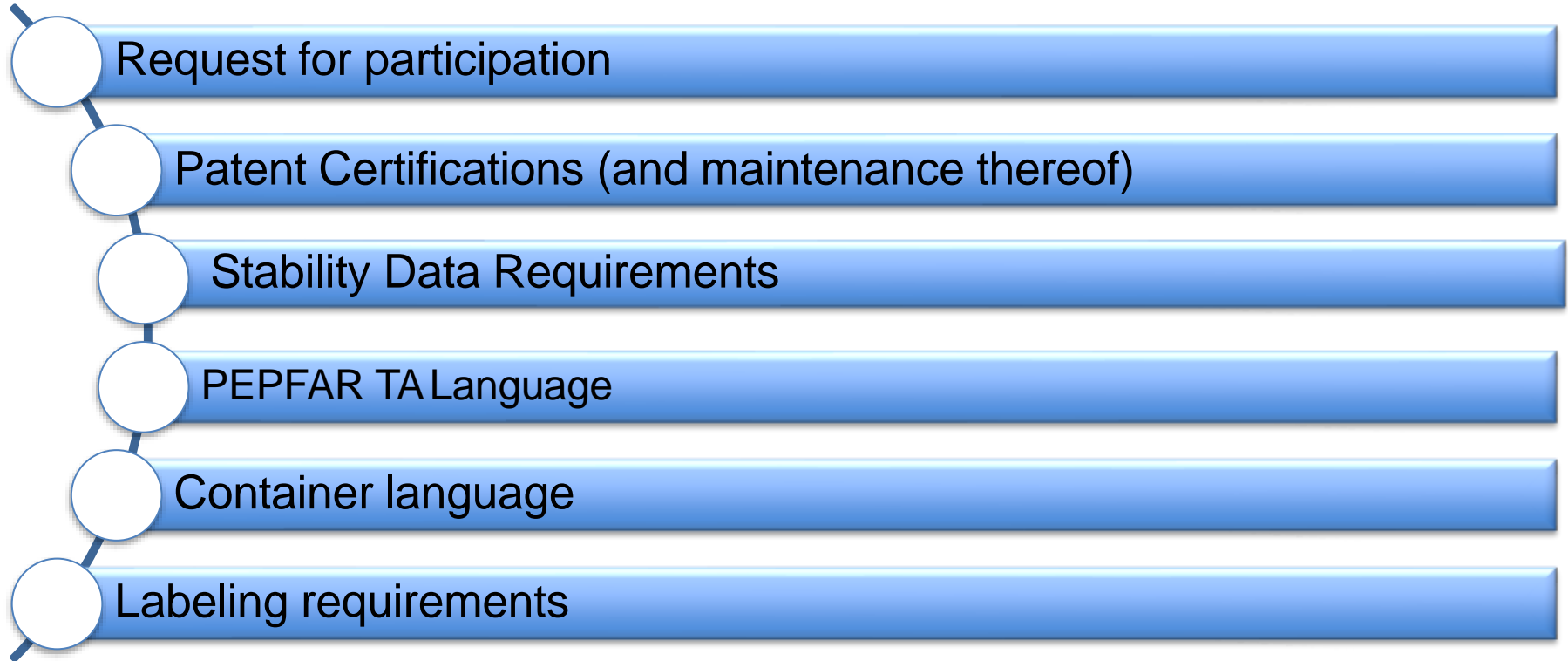


Meets Criteria

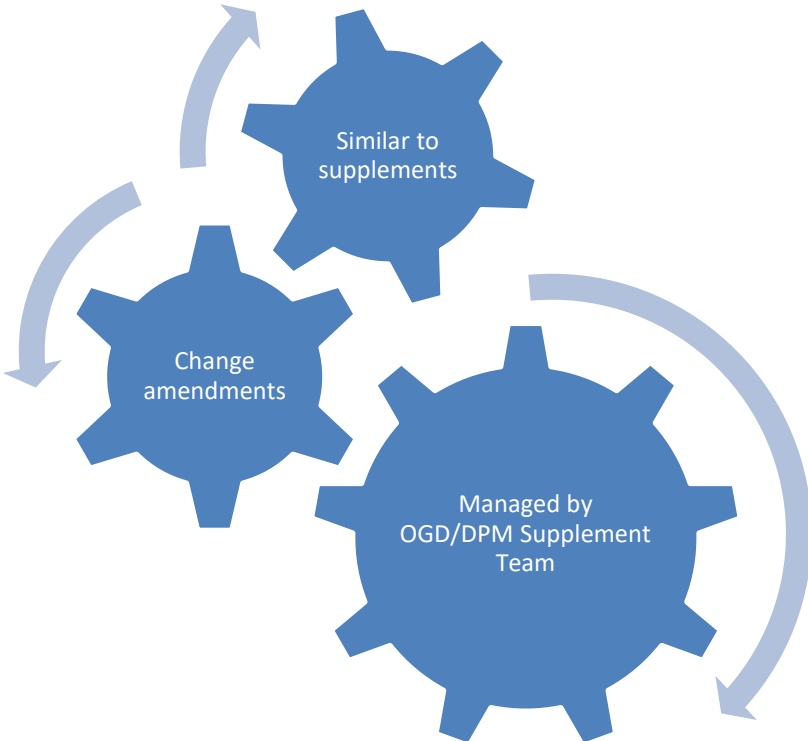


Other considerations

PEPFAR Information



PEPFAR Change Amendments



After Tentative Approval: FDA List

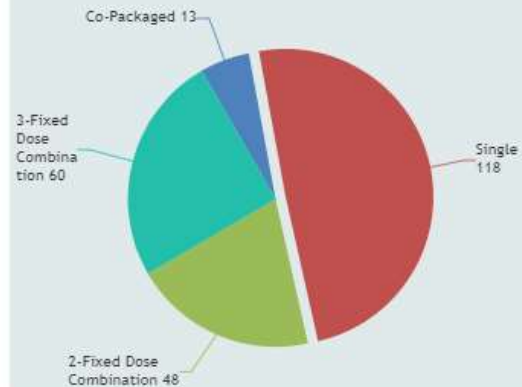


President's Emergency Plan for AIDS Relief (PEPFAR) Database

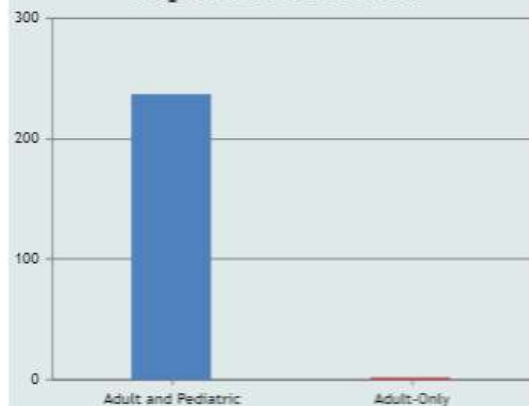
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PEPFAR Applications to Date = 239
Number of Products = 303

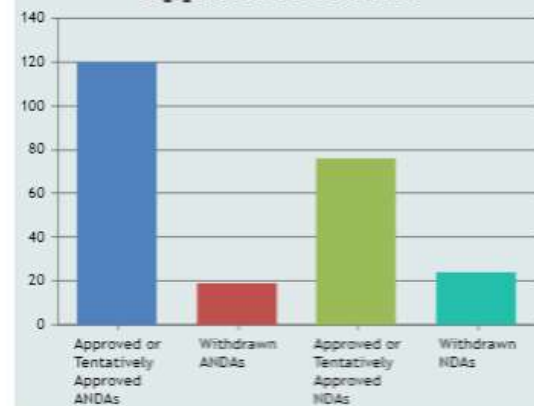
Single and Combination Products



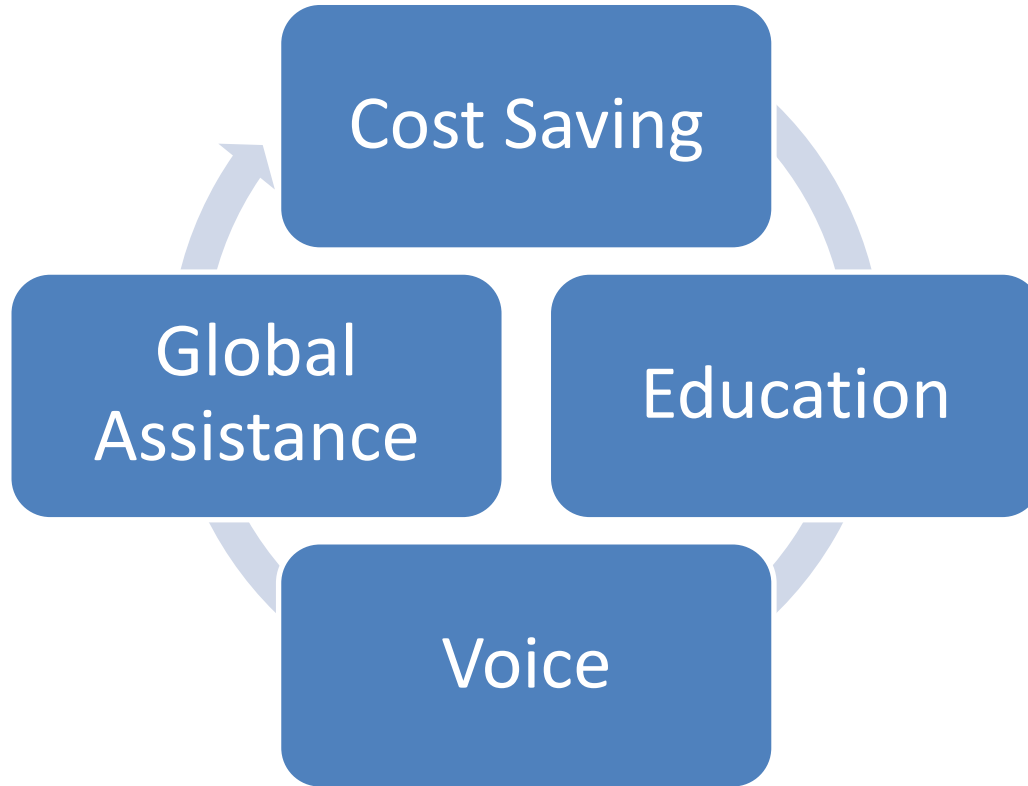
Populations for Use



Application Status



PEPFAR Impact



PEPFAR Pearls



- Priority Review
- Contact the Regulatory Project Manager
- Patent Certification
- Package label other than English: must submit English translation to the Agency for review

Questions?



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