

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
August 17, 2022

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

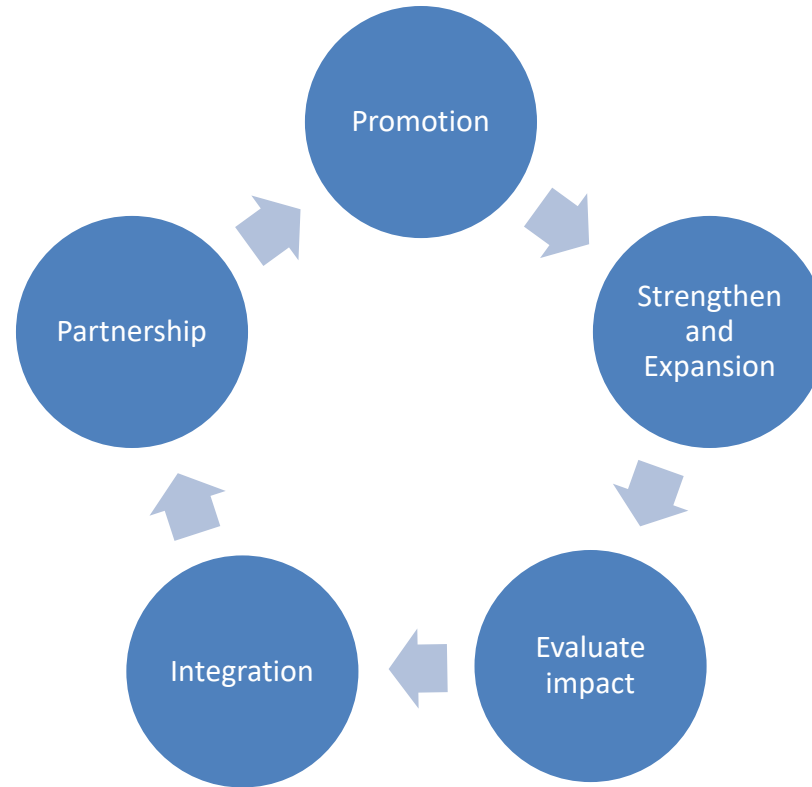
Haiti	Zambia
United Republic of Tanzania	Uganda
Zimbabwe	Malawi
Lesotho	Cote d'Ivoire
Botswana	Namibia
Swaziland	Kenya
Rwanda	

U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Countries



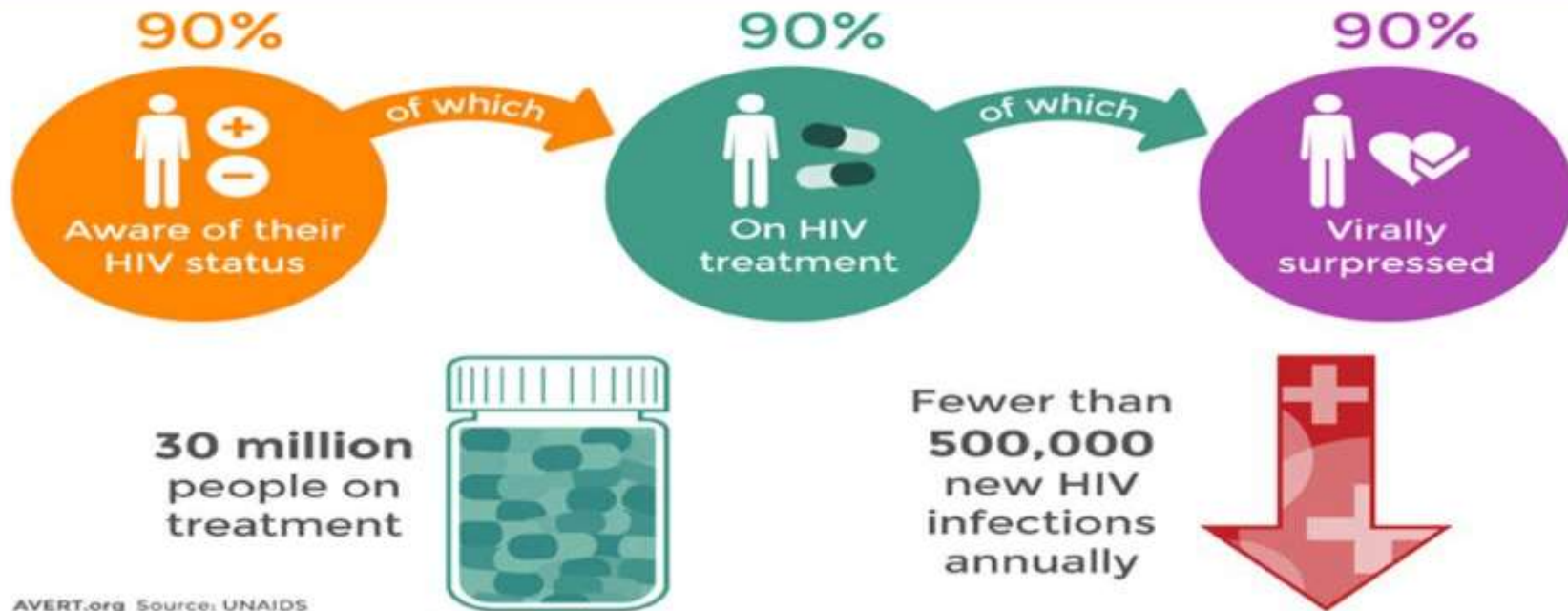
SOURCE: Kaiser Family Foundation analysis of data from the State Department, and U.S. Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov; PEPFAR's "Where We Work: PEPFAR Bilateral Countries" webpage; CDC's Global HIV & Tuberculosis "Where We Work" webpage; accessed November 2018.

PEPFAR Program Goals



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

KEY 2020 FAST TRACK TARGETS



Generic Drugs

Safe and
effective

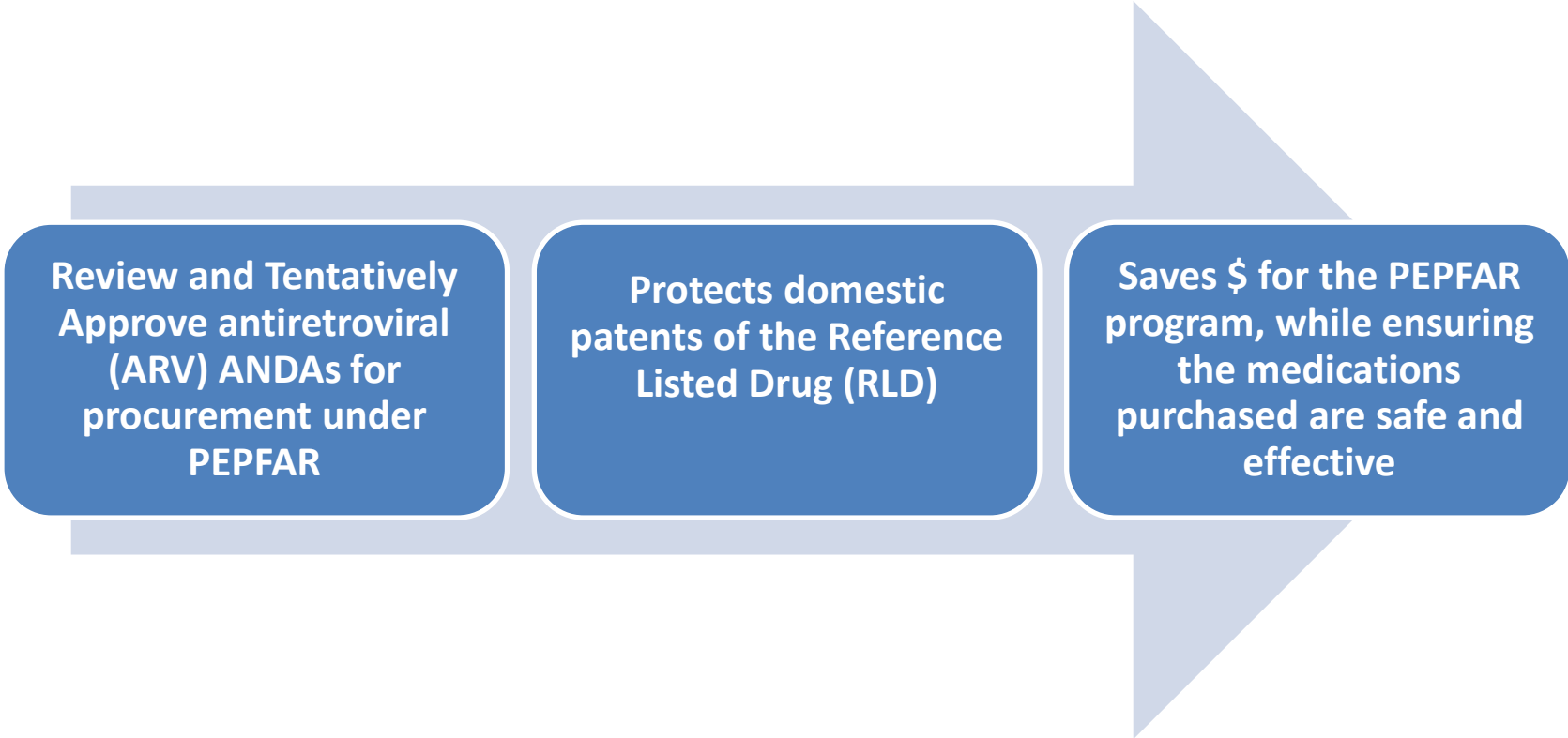
Commonly
Encountered



Affordable

Global Savings

Role of Generic Drugs in PEPFAR

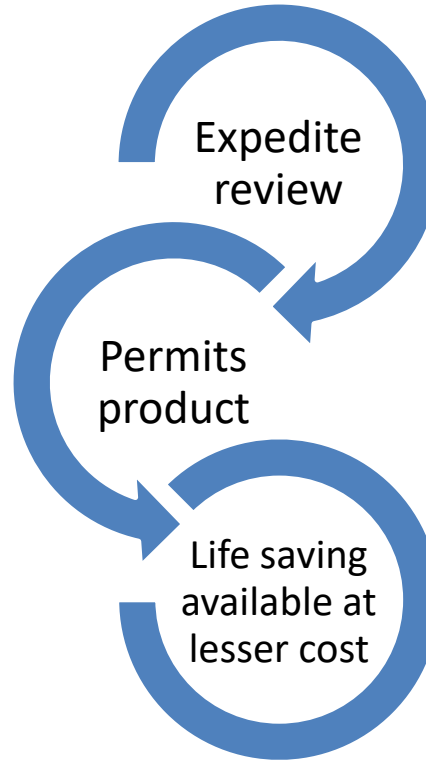
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**Review and Tentatively
Approve antiretroviral
(ARV) ANDAs for
procurement under
PEPFAR**

**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

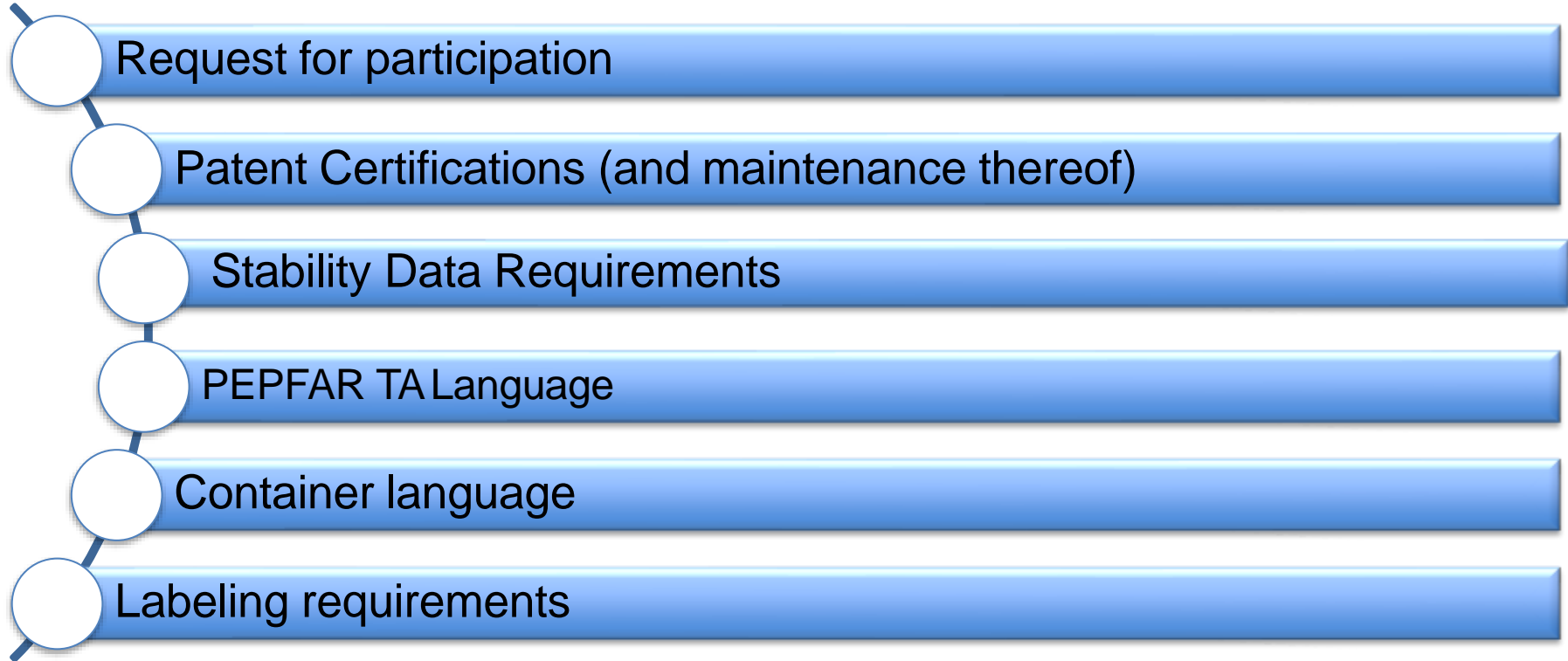


Meets Criteria

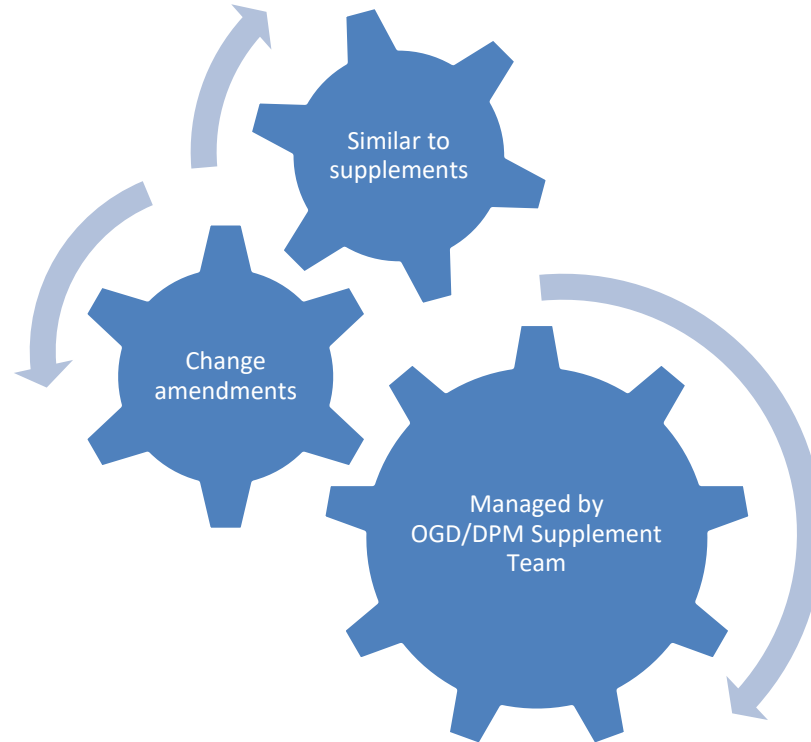


Other considerations

PEPFAR Information



PEPFAR Change Amendments



After Tentative Approval: FDA List

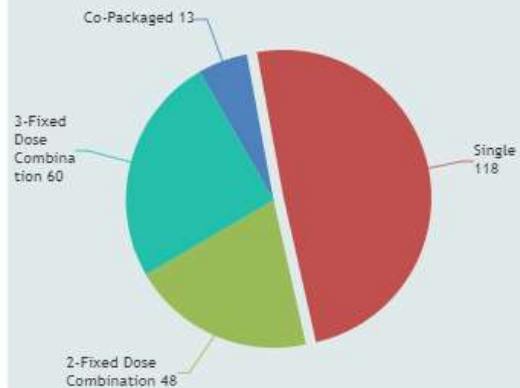


President's Emergency Plan for AIDS Relief (PEPFAR) Database

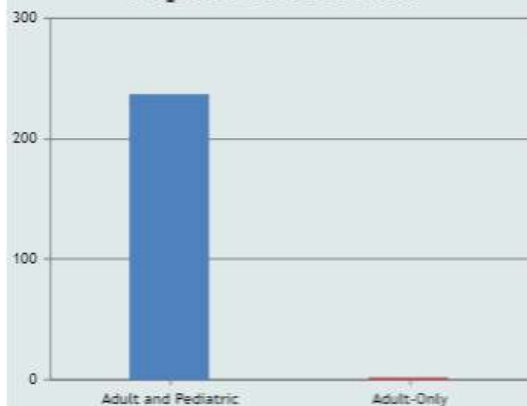
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PEPFAR Applications to Date = 239
Number of Products = 303

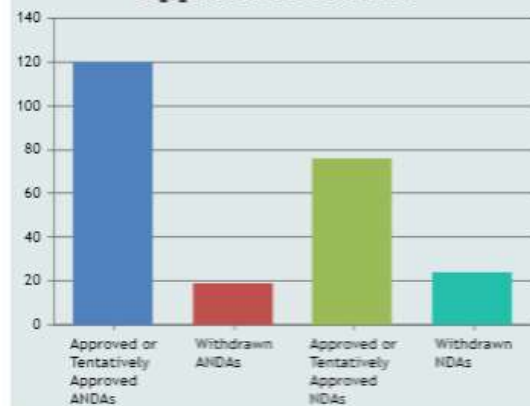
Single and Combination Products



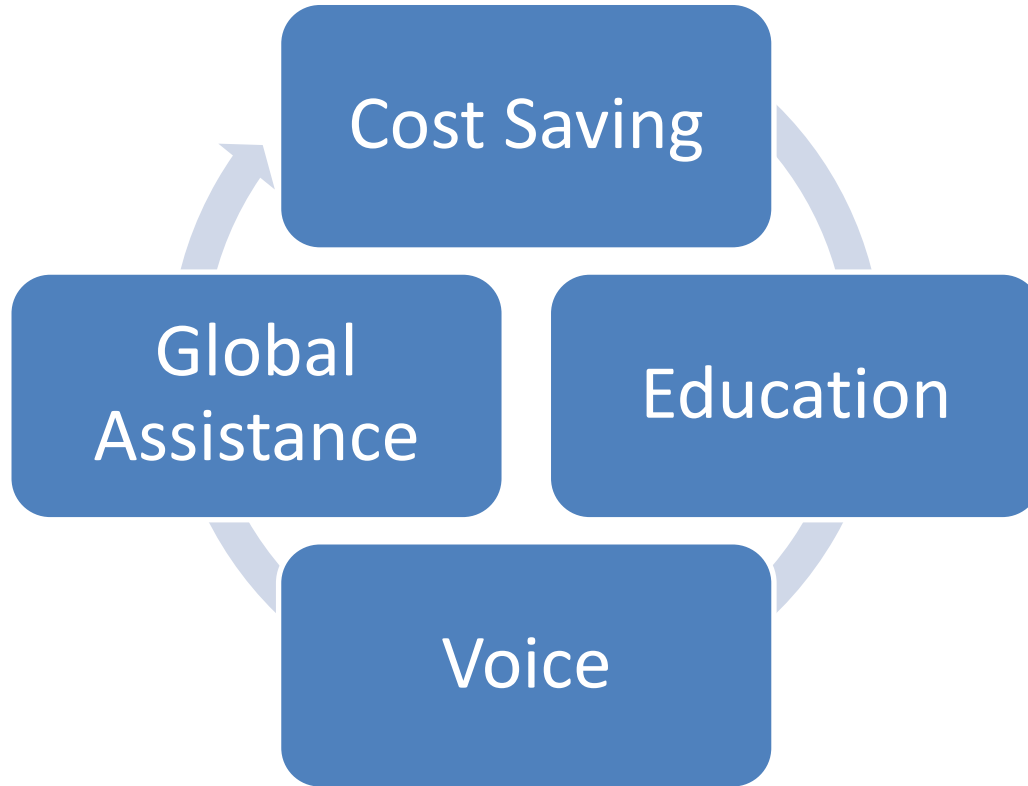
Populations for Use



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



U.S. FOOD & DRUG
ADMINISTRATION

Questions?



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