ANDA Program Public Stats and What They Mean - Office of Pharmaceutical Quality

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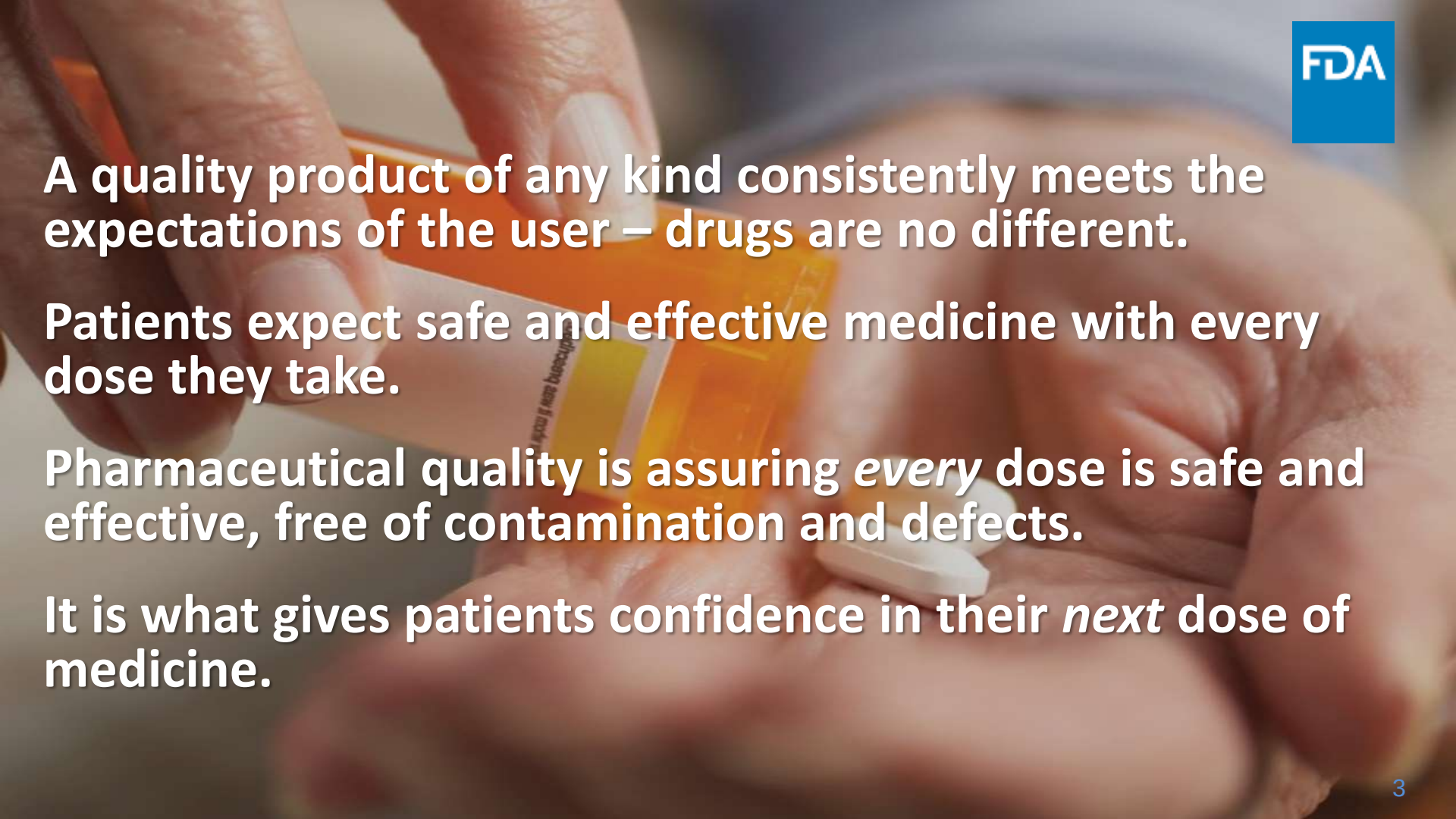
Generic Drug Forum – April 26, 2022

Learning Objectives

- Understand what Generic Drug information and stats are posted by Office of Pharmaceutical Quality (OPQ)
- Gain insight on what the 2021 Generic Drug stats mean from the pharmaceutical quality perspective
- Describe impact of the use of alternative tools for facility assessment inspection on Generic Drug program



A quality product of any kind consistently meets the expectations of the user – drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

OPQ 2021 Annual Report

- Discusses efforts to improve supply chain transparency and resiliency
- Highlights OPQ's assessment activities to support new approvals
- Describes achievements in overcoming COVID-19 inspection challenges
- Summarizes surveillance, research, and policy activities

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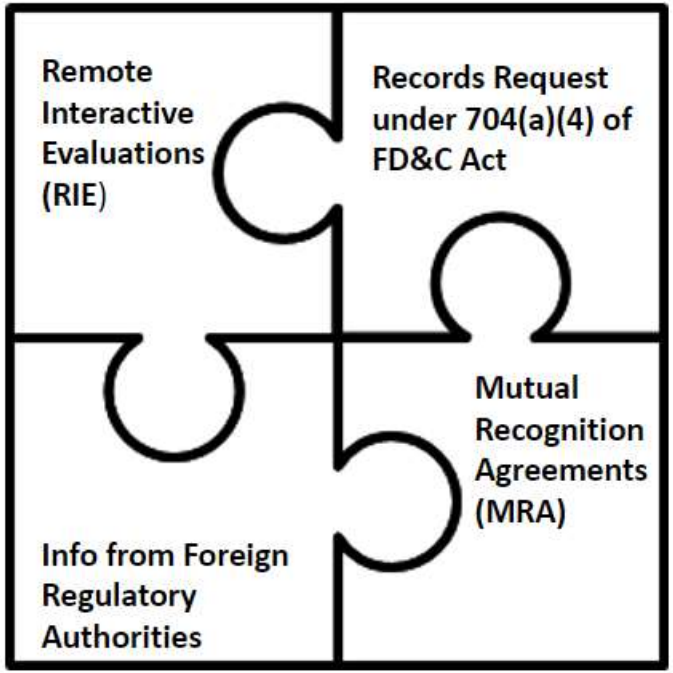
https://www.fda.gov/media/156272/download

OPQ Generic Drug Highlights

- Supported >750 ANDA and >8000 application supplement approvals
- Milestones reached:
  - 100 approved complex generics
  - 1000 approved drug submissions to assist in treating patients with COVID-19
- First FDA approved generic for ferumoxytol injection
- Marketing of first FDA approved generic for glucagon for injection

Overcoming Inspection Challenges



- ORA and CDER collaborated to develop inspection prioritization and use of alternative tools within different programs
- Pre-pandemic, Pre-Approval Inspections needed to support ~20% of submission assessments
- Throughout pandemic, reduced need to conduct Pre-Approval Inspection for ~50% of facilities named in submissions
- Data summarized across all UFA programs:
  - https://www.fda.gov/industry/fda-user-fee-programs/cders-work-meet-user-fee-goals-during-pandemic

CDER's Work to Meet User Fee Goals During the Pandemic – Facility Assessment

- >350 ANDA submissions assessed for ability to use alternative tools to PAI
- ~160 ANDA submissions acted upon in 2021 based on information from alternative tools for facility assessment
  - >120 facilities assessed using alternative tools for facility assessment
- >35 inspections completed by ORA impacting >60 ANDA submissions acted upon in 2021

CDER's Work to Meet User Fee Goals During the Pandemic – Facility Assessment

- 42% reduction in need for PAIs supporting ANDA submission assessment
- On-time application action >90% across all GDUFA submissions in 2021

Challenge Question #1

All of the following are alternative tools for facility assessment except:

A. Remote Interactive Evaluation

B. Records Requested through 704(a)(4)

C. Third-party, non-regulatory authority audit

D. Inspection information shared through the Mutual Recognition Agreement or other confidentiality agreement with trusted regulatory partners.

Summary

- OPQ Annual Report highlights activities and accomplishments in critical pharmaceutical quality initiatives and programs
- While inspections remain the gold standard, alternative tools for facility assessment allowed OPQ to overcome pandemic travel challenges
- On-time action >90% across all GDUFA submissions in 2021


Let’s keep working together…
Using the best available science…
To assure quality medicines are available for patients…
Through COVID-19 *and beyond*.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