

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

**Derek S. Smith, Ph.D.**

Deputy Director

Office of Pharmaceutical Manufacturing Assessment

Office of Pharmaceutical Quality

CDER | US FDA

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

FDA

- 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



Issued February 2022

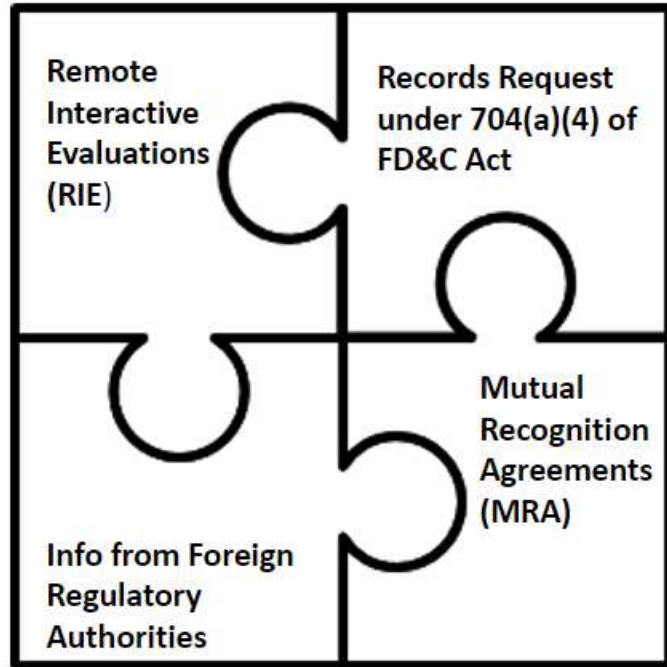
<https://www.fda.gov/media/156272/download>

# 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

A close-up photograph of a person's hands. One hand is holding an orange plastic pill bottle, tilted to pour several white, oval-shaped pills into the palm of the other hand. The background is blurred, focusing attention on the action of dispensing medication.

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

