U.S. FOOD & DRUG ADMINISTRATION

Quality-Related Compliance Updates and Innovations

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- DISCLAIMER: The views and opinions expressed in this presentation are those of the authors and do not necessarily represent official policy or position of the Food and Drug Administration

Outline

- What OMQ Does
- FY 2021 Updates
- Use of Alternate Tools
- Regulatory Discretions
- Hand Sanitizers

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What We Do

CDER/OC Mission

To shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and ***risk-based*** enforcement action.

What OMQ Does

- We evaluate compliance with **C**urrent **G**ood **M**anufacturing **P**ractice (**CGMP**) for drugs based on inspection reports and evidence gathered by FDA investigators.
- We develop and implement compliance policy and take regulatory actions to protect the public from ***adulterated*** drugs in the U.S. market.

Source: FDA

Drug Adulteration Provisions

U.S. Federal Food, Drug, & Cosmetic Act

- 501(a)(2)(A): Insanitary conditions
- 501(a)(2)(B): Failure to conform with CGMP
- 501(b): Strength, quality, or purity differing from official compendium
- 501(c): Misrepresentation of strength, etc., where drug is unrecognized in compendium
- 501(d): Mixture with or substitution of another substance
- 501(j): Deemed adulterated if owner/operator delays, denies, refuses, or limits inspection

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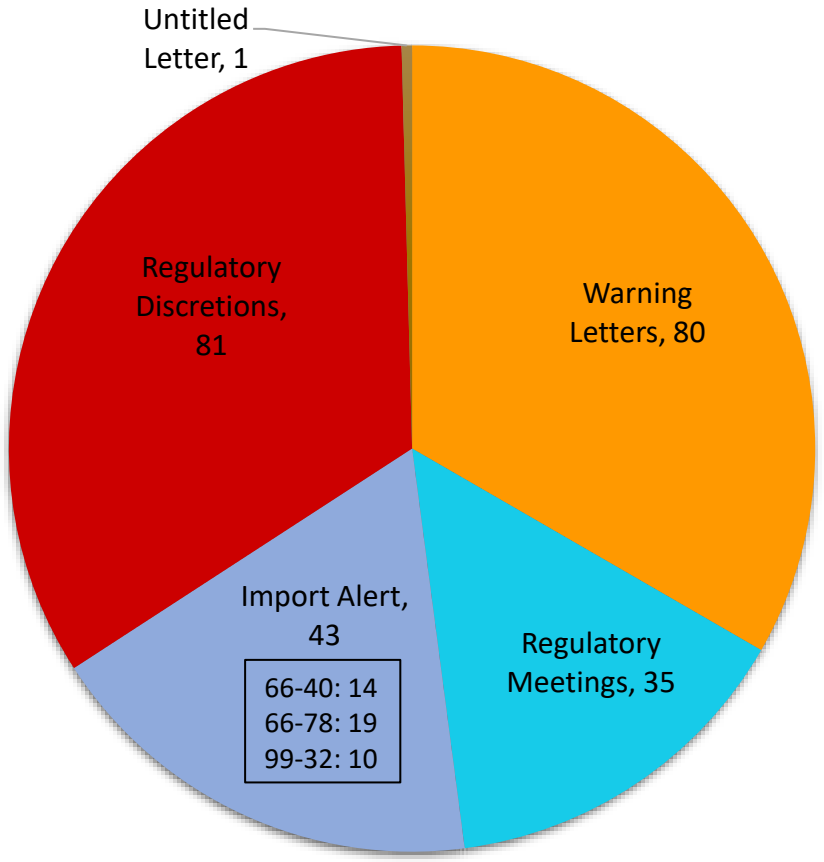
FY 2021 Actions

Enforcement and Advisory Tools

- Regulatory Meetings
- Injunctions
- Consent Decrees
- Import Alerts
- Seizures
- Warning Letters
- Untitled Letters
- Administrative Detention

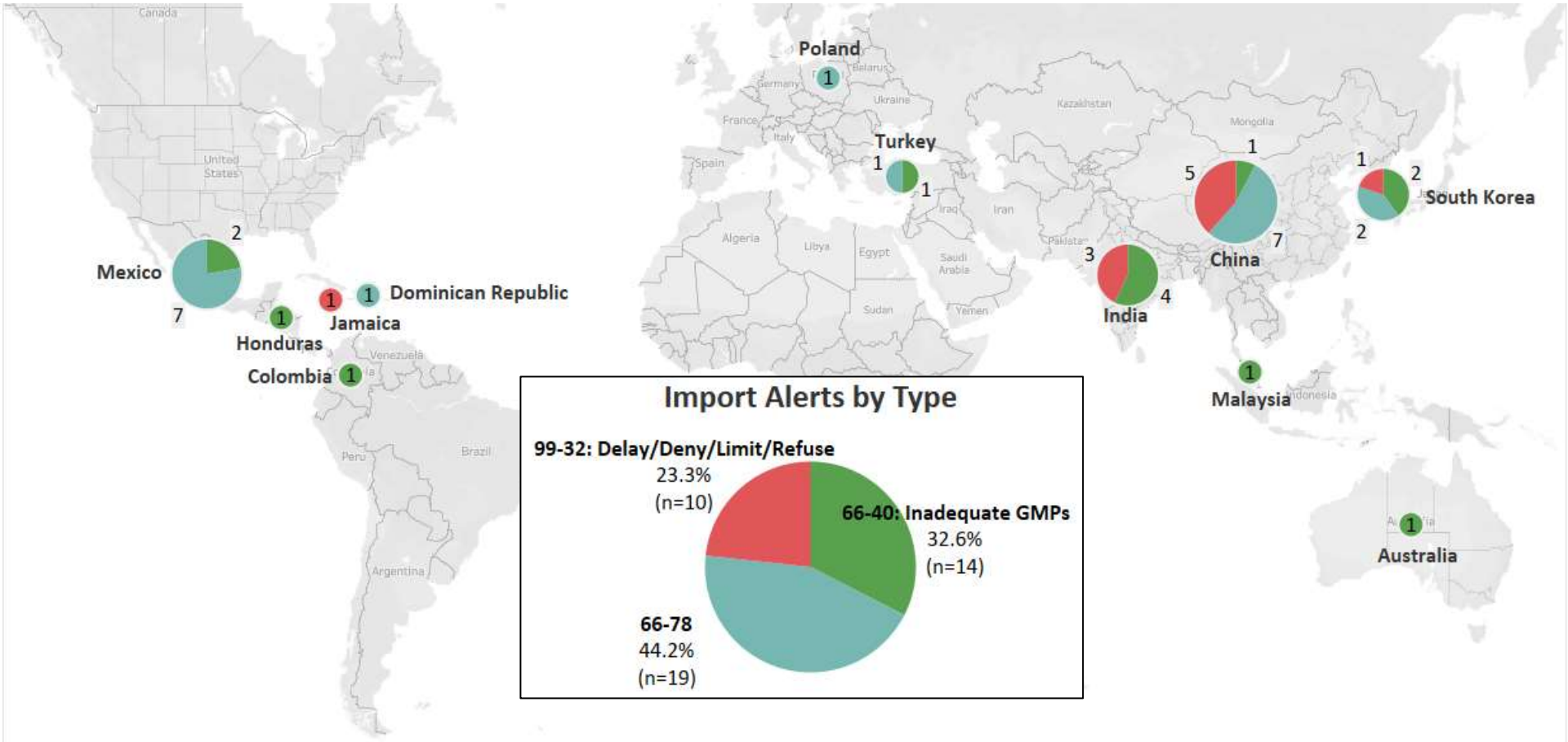
FY2021 Regulatory Actions



Excludes compounding-related actions

Actions Taken October 1, 2020 to September 30, 2021

Import Alert Cases FY2021



66-40: Inadequate GMPs
66-78: Analytic Test Results
99-32: Delay/Deny/Limit/Refuse Inspection

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FY 2021 Actions and Use of Alternate Tools

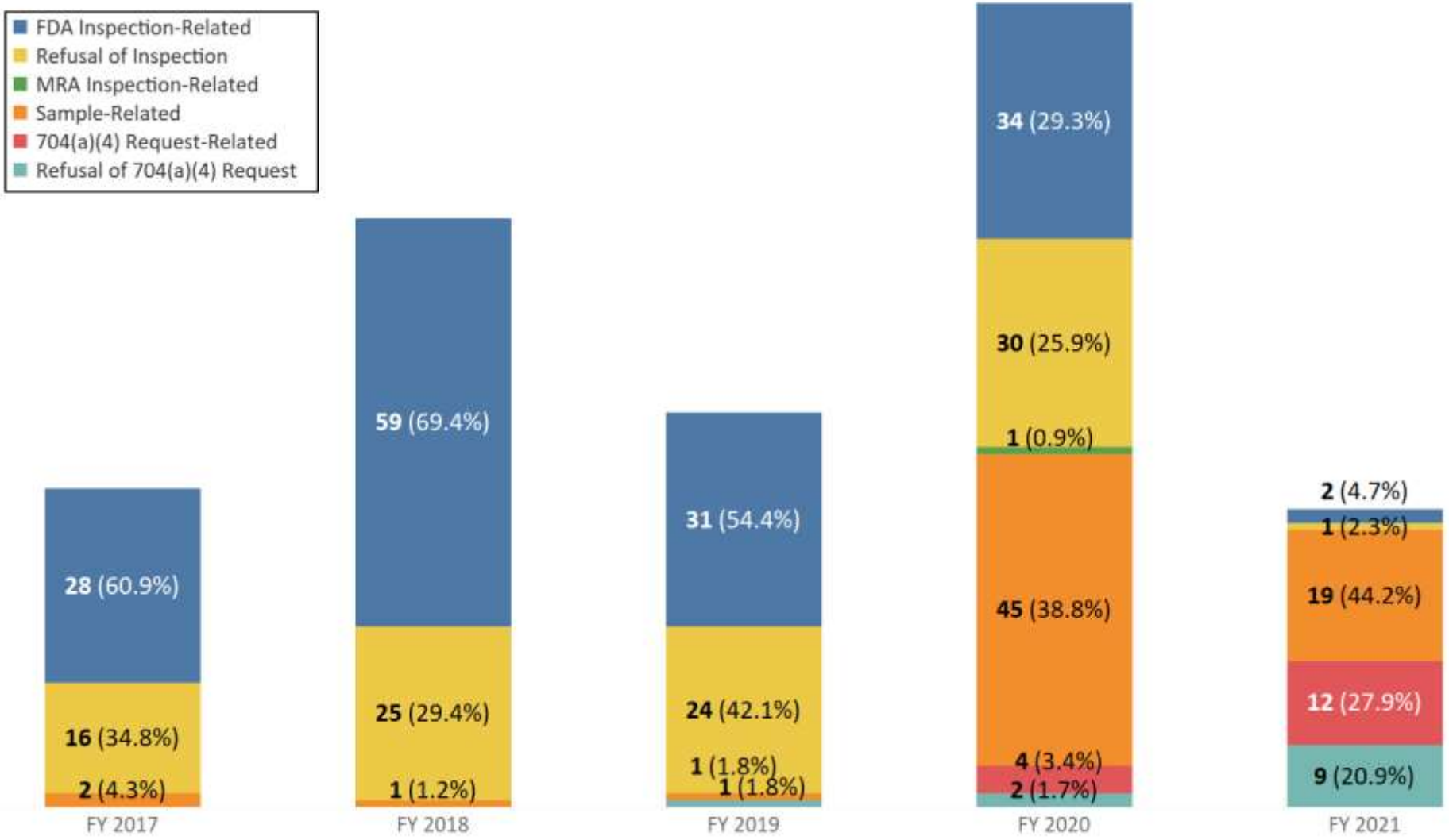
Alternates To Inspections

- Historically, OMQ actions primarily used evidence from FDA inspections
- While FDA inspections continued during the pandemic, on a mission critical basis, the number of inspections were reduced due to Covid related safety and travel restrictions
- FDA utilized alternate tools in order to protect public health

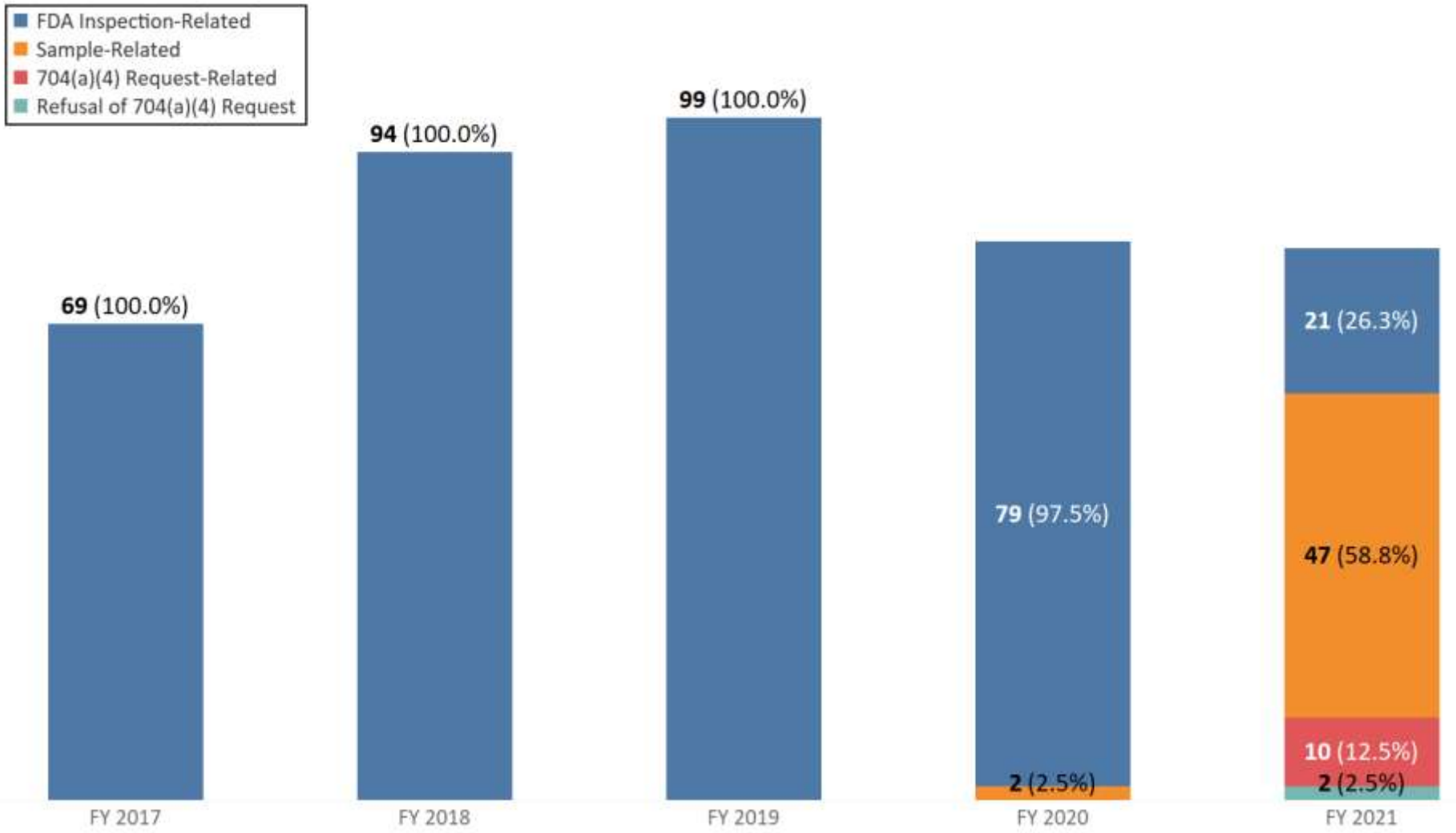
Alternates To Inspections

- OMQ utilized the following alternates to take action against poor quality drugs:
  - Import Sampling (import or domestic)
  - Mutual Recognition Agreement (MRA) Inspections
  - 704(a)(4) Requests (records and other information)
    - Based on CGMP findings,
    - Or refusal to provide information pursuant to the request

Shift in Source of Drug Adulteration Regulatory Actions –Import Alert Cases

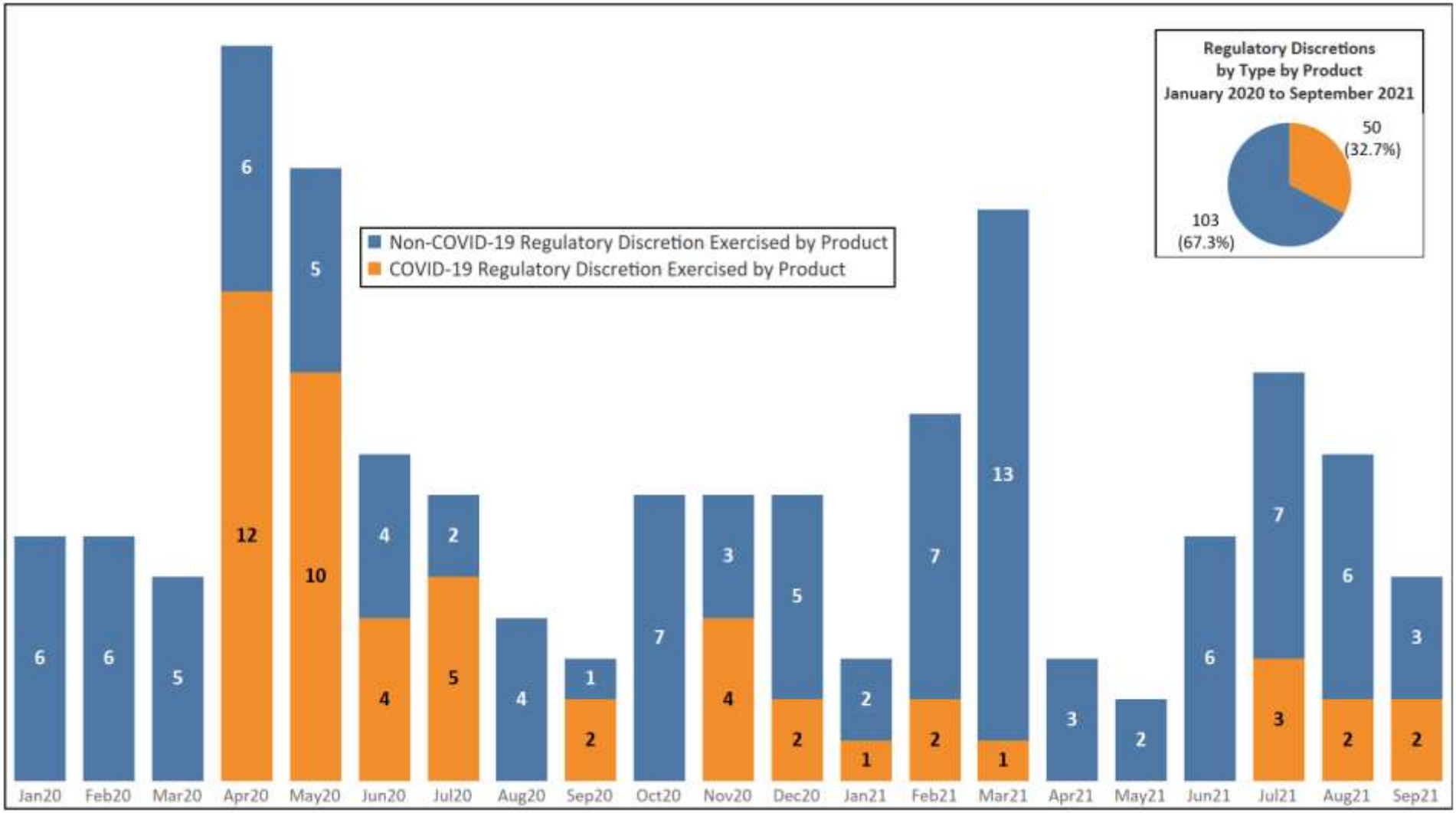


Shift in Source of Drug Adulteration Regulatory Actions –Warning Letters



Regulatory Discretions

Regulatory Discretions



Hand Sanitizers

FDA's Actions to Address Hand Sanitizer Access Problems

- Issued three guidance documents outlining temporary policies to provide flexibility to firms to help meet demand during the public health emergency
- FDA continually assessed needs and circumstances related to the temporary policies and updated/modified the guidances throughout the pandemic

COVID-19 Hand Sanitizer Guidances

- Compounding Guidance

  Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

- Manufacturing Guidance

  Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)

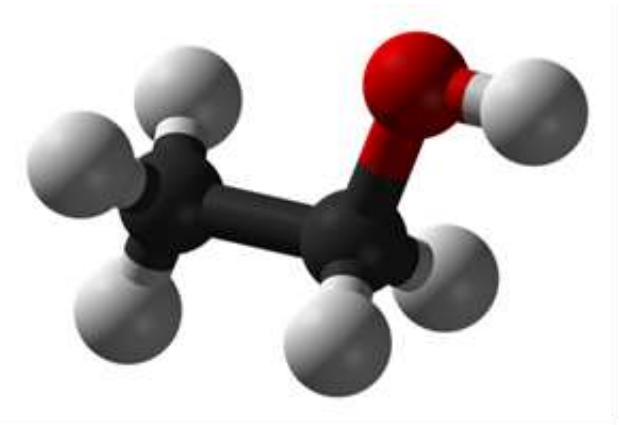
- Active Ingredient Guidance

  Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)

Substitution: Ethanol vs Methanol

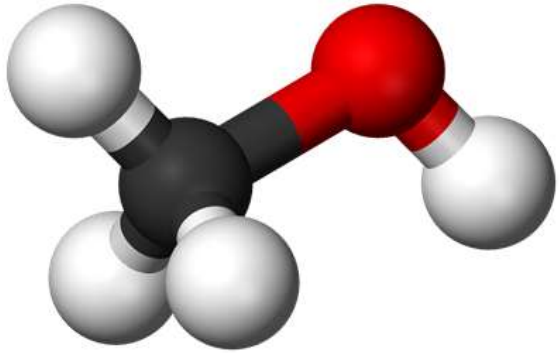
Ethanol

- Acceptable Active Ingredient for hand sanitizer



Methanol

- Poison

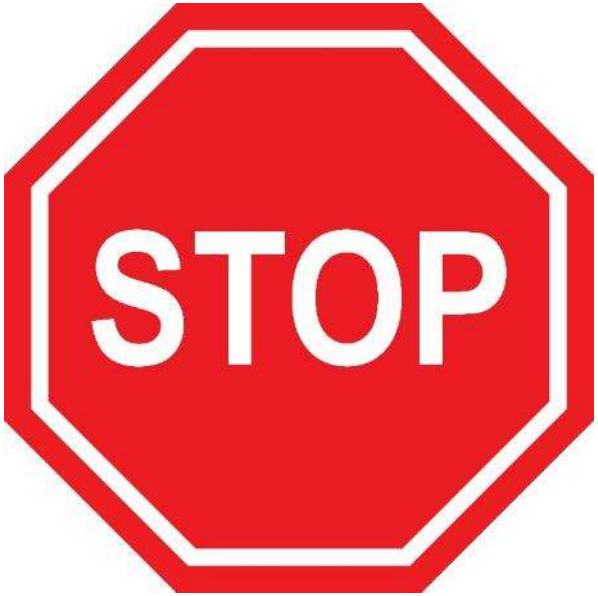


Actions Taken

- FDA has taken multiple actions when encountering substitution
  - Contact with firms about taking market action to limit patient exposure
  - Drugs and drug products manufactured by these firms added to import alert 66-78
  - Warning Letters issued
- Continuing heightened surveillance of hand sanitizers
  - Both imported and domestically produced
- Drugs linked to violative manufacturers are added to a Do Not Use List for consumers
  - *https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use*

Hand Sanitizer From Mexico

- On January 26, 2021, FDA placed all Hand Sanitizer made in Mexico on Import Alert
  - *https://www.accessdata.fda.gov/CMS_IA/importalert_1171.html*
  - Prevents these hand sanitizers from legally entering the United States



- Implemented due to the prevalence of methanol substitution in hand sanitizer manufactured in Mexico
  - 84% of samples were found violative.
- First time FDA has used a Country/Area import alert for drug products
  - More commonly used in foods.

Recent Update on Temporary Policies

- On October 12th, FDA announced the withdrawal of the temporary polices related to Hand Sanitizer
  - Decision based on sufficient availability of supply for consumers and healthcare professionals
  - Hospital supply now typically comes from traditional manufacturers
  - Manufacturing under the temporary policies must cease by 12/31/21
  - Hand sanitizer made under the temporary policies must be distributed from manufacturers by 3/31/22
  - Hand Sanitizer made after 12/31/21 must be fully compliant with the Act, including CGMP requirements.

In Summary

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- OMQ works to minimize consumer exposure to unsafe, ineffective, and poor quality drugs.
- We take actions against firms with poor CGMP or when other information calls into question the quality of drugs for U.S. patients.


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