U.S. FOOD & DRUG ADMINISTRATION

The State of Pharmaceutical Quality

As Shared Publicly through OPQ's Annual *Report on the State of Pharmaceutical Quality*

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CDER / OPQ / OQS

OPQ Pharmaceutical Quality Symposium
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Agenda

- Background
- Highlights from past reports
- FY2022 Report on the State of Pharmaceutical Quality
- Planning for the FY2023 Report on the State of Pharmaceutical Quality


Reliable supply chains provide quality drugs when and where patients need them.

- Advance the missions of OPQ and its suboffice Office of Quality Surveillance (OQS):
  - OPQ: Assuring that quality medicines are available for the American public.
  - OQS: Turning intelligence into insights and actions to promote the availability of quality medicines for the American public.
- The Report on the State of Pharmaceutical Quality provides information about the quality of manufacturing sites and their products for drugs legally marketed in the U.S.
- Website: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/report-state-pharmaceutical-quality

Provides insights and trends about site quality and product quality.

Analyzes data for site compliance, postmarket reporting, and testing.

Includes accomplishments of OPQ work (“Commitment to Quality”).

Background

FY2018 Report on the State of Pharmaceutical Quality

Inaugural report focused on demographics and key topics

- Types of sites, by location, industry, and sector
- Product Quality Defect reports
- Types of inspections and outcomes
- Enforcement actions

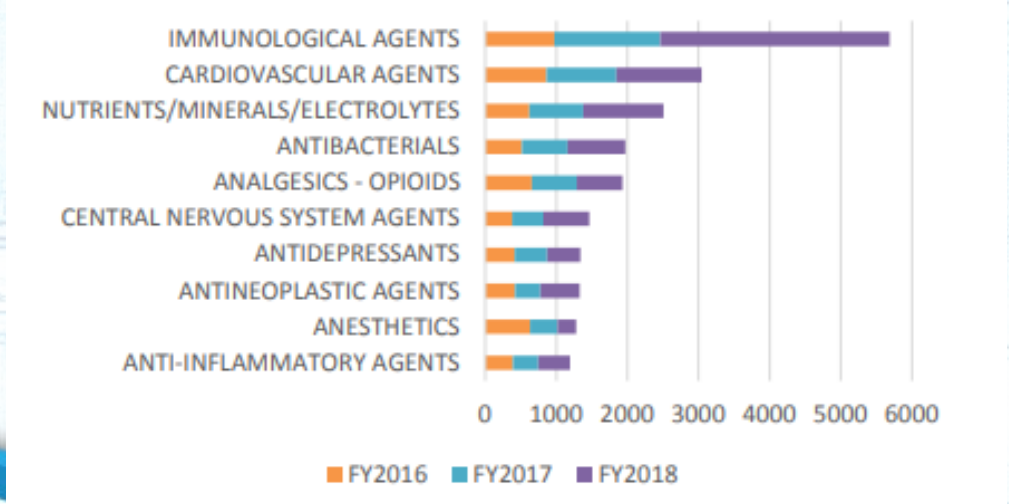


Figure 7. Product Quality Defect counts by USPTC for the past three years

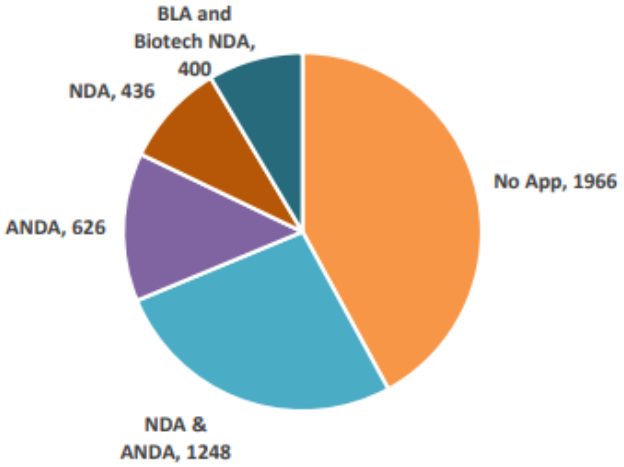


Figure 1. Drug manufacturing sites that manufacture products for the U.S. market by application type for FY2018

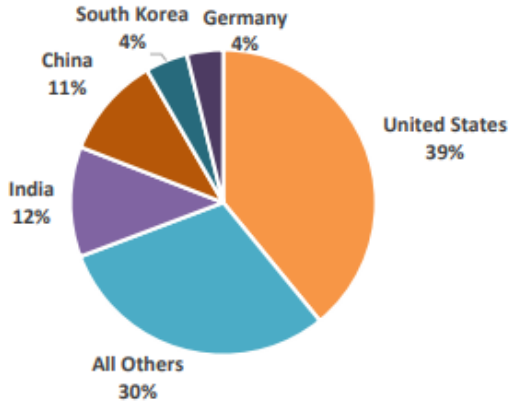


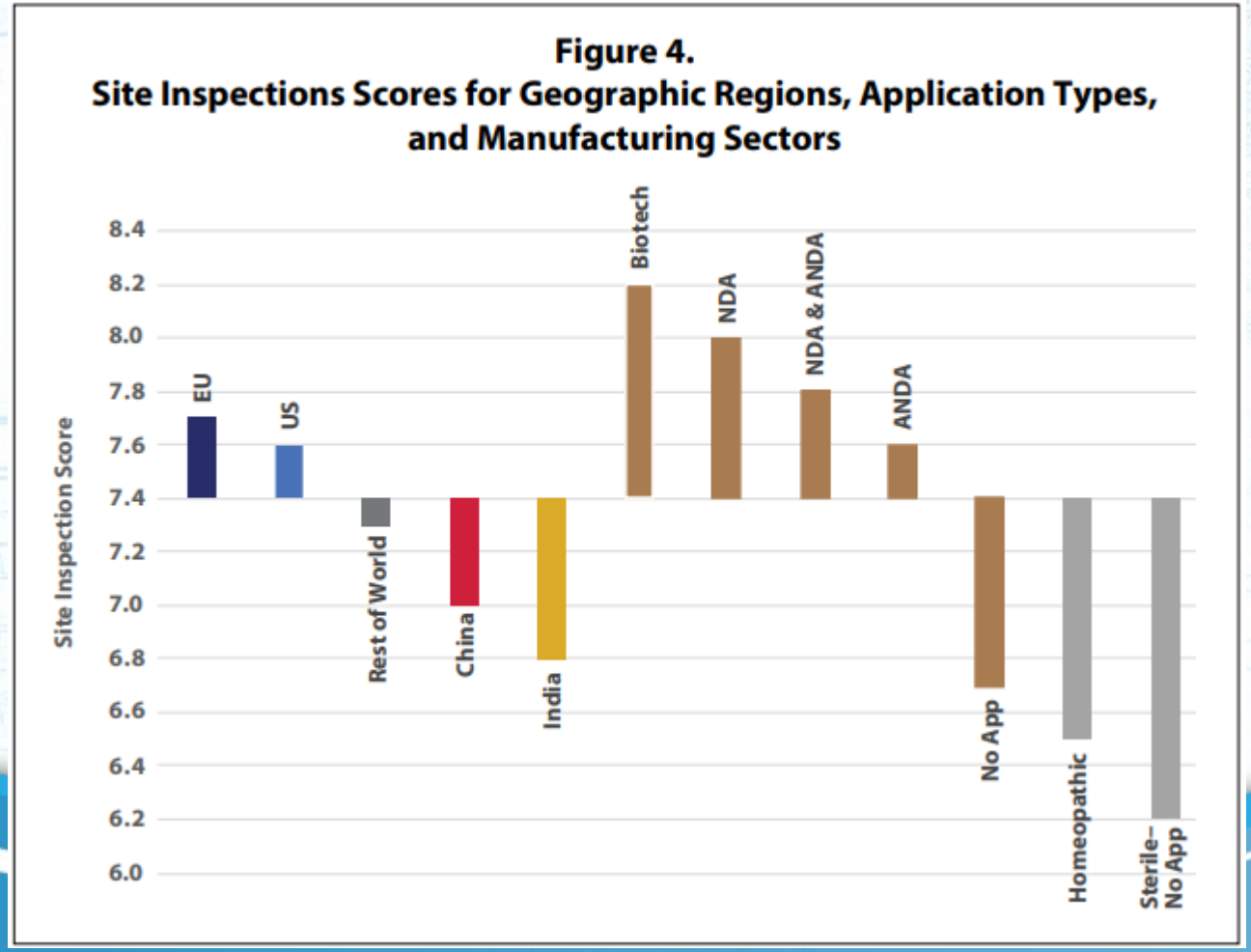
Figure 2. All drug manufacturing sites for the U.S. market by country for FY2018

Highlights from the past

FY2019 Report on the State of Pharmaceutical Quality

Expanded on those same topics

- Changes in demographics
- CFR 211 citations on inspections
- Sampling and testing results



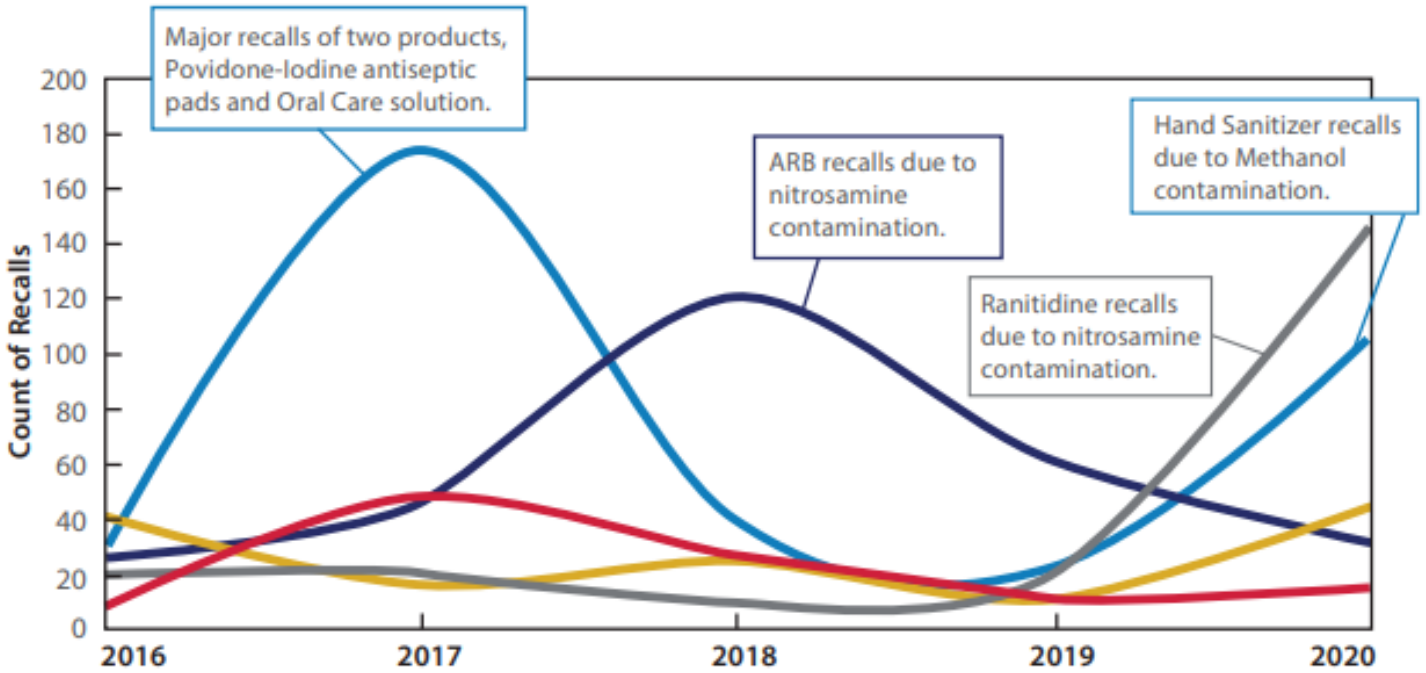
Highlights from the past

FY2020 Report on the State of Pharmaceutical Quality

Analysis of five years of recalls

- Noted microbial or chemical contamination and impurities as driving factors for several wide-scale recalls.

Figure 9. Five Most Recalled Products by USPTC FY2016–2020

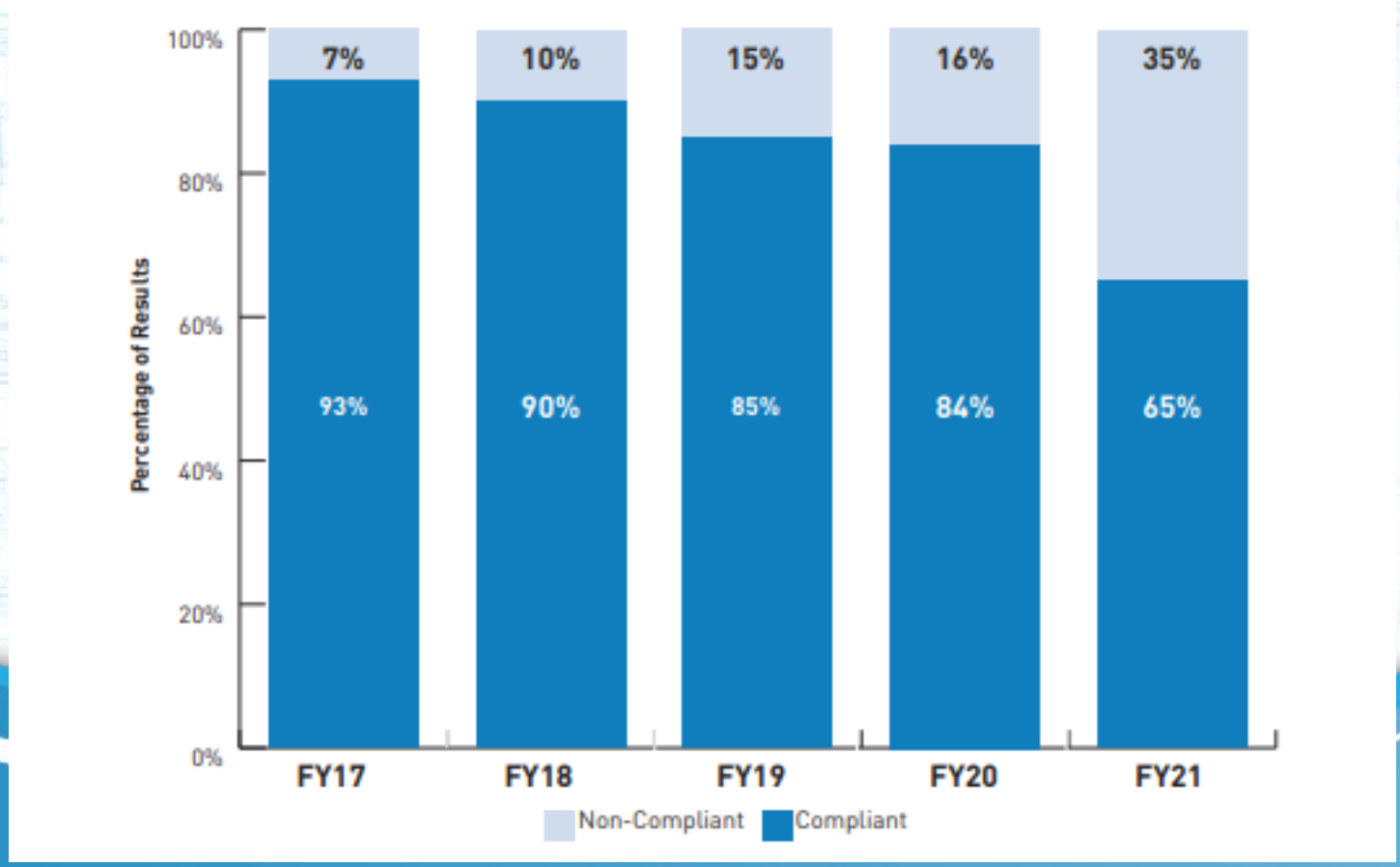


Highlights from the past

FY2021 Report on the State of Pharmaceutical Quality

Drug quality sampling and testing

- During FY2019-FY2020 there was a large increase in non-compliant results (impurity testing) for products containing nitrosamines.
- During FY2021 many non-compliant results (assay and impurity testing) for alcohol-based hand sanitizers.



Highlights from the past

FY2022 Report on the State of Pharmaceutical Quality

The CDER Site Catalog included 4,814 drug manufacturing sites.

Country	Sites	Country	Sites
1. United States	2,019	9. United Kingdom	105
2. India	603	10. South Korea	100
3. China	430	11. Spain	88
4. Germany	187	12. Switzerland	82
5. Canada	158	13. Mexico	64
6. Italy	149	14. Ireland	59
7. France	141	All Others	495
8. Japan	134	**Total**	**4,814**

FY2022 Highlights

Essential Medicines

- Heavy reliance on foreign manufacturing for FDF and especially API.
- 48% of products have at least one domestic API manufacturer and nearly 90% have at least one domestic FDF manufacturer.

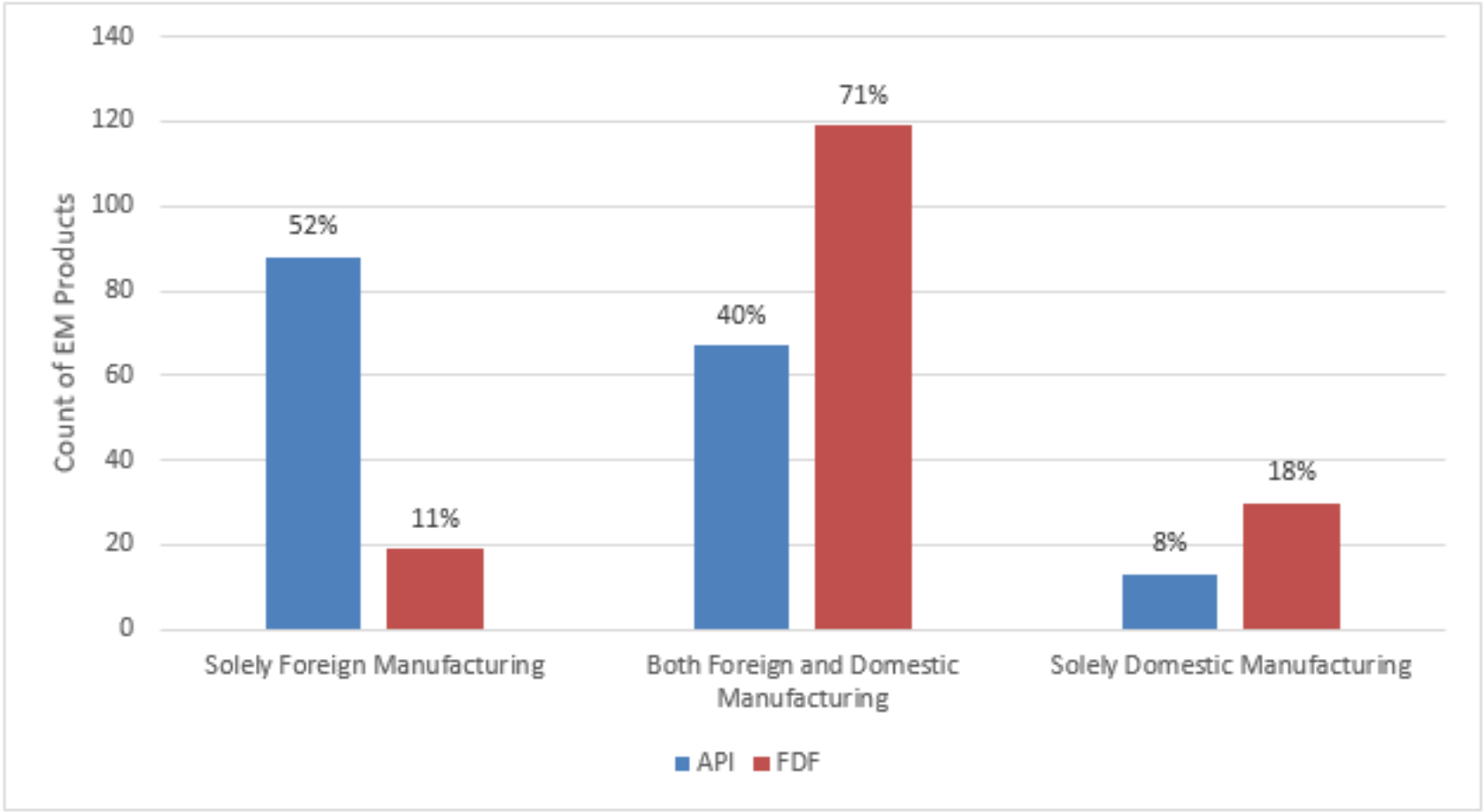
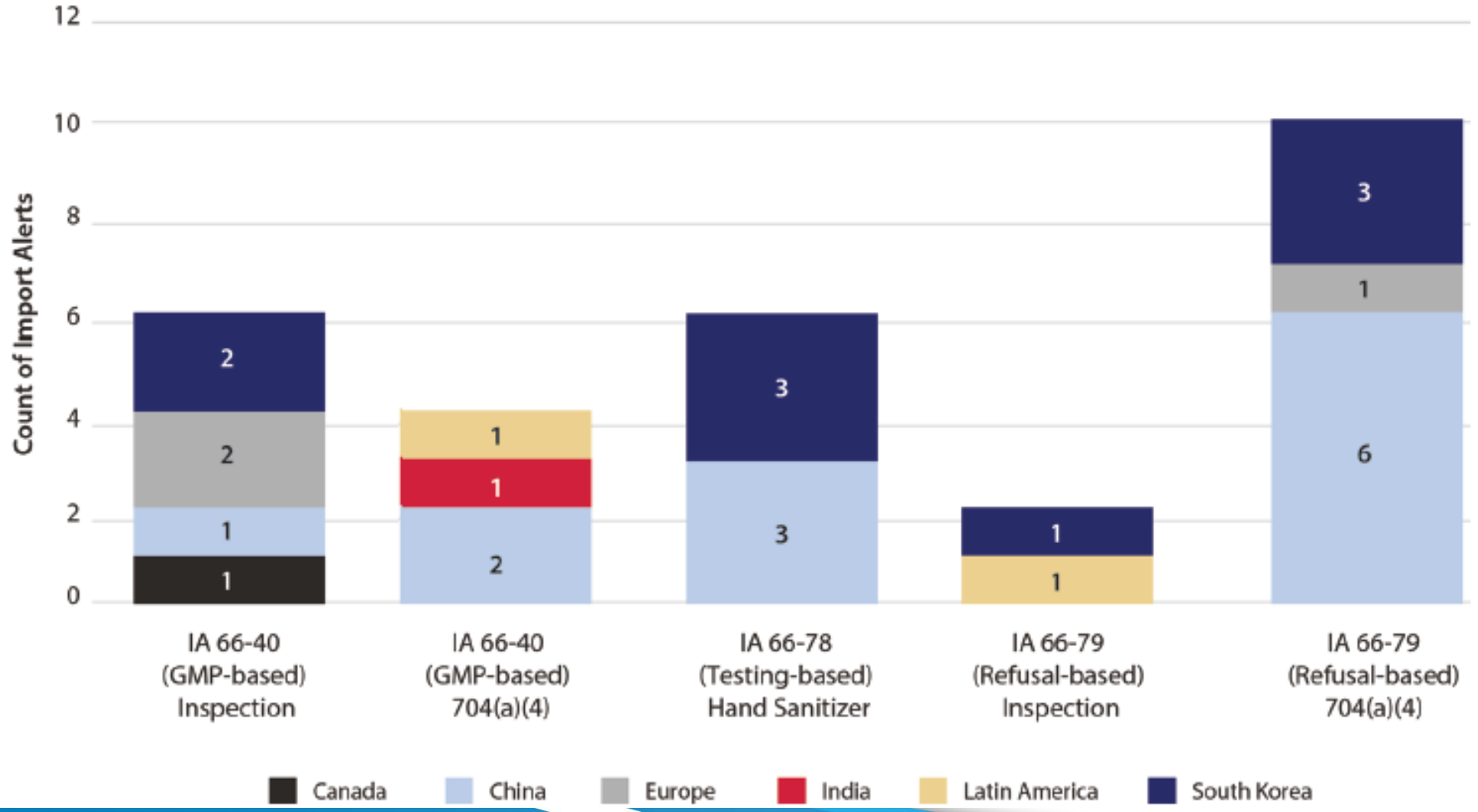


Figure 1. Domestic vs. Foreign Manufacturing for the 168 CDER-Regulated EM Products

Figure 2. FY2022 Drug-Quality-Related Import Alerts by Type and Region



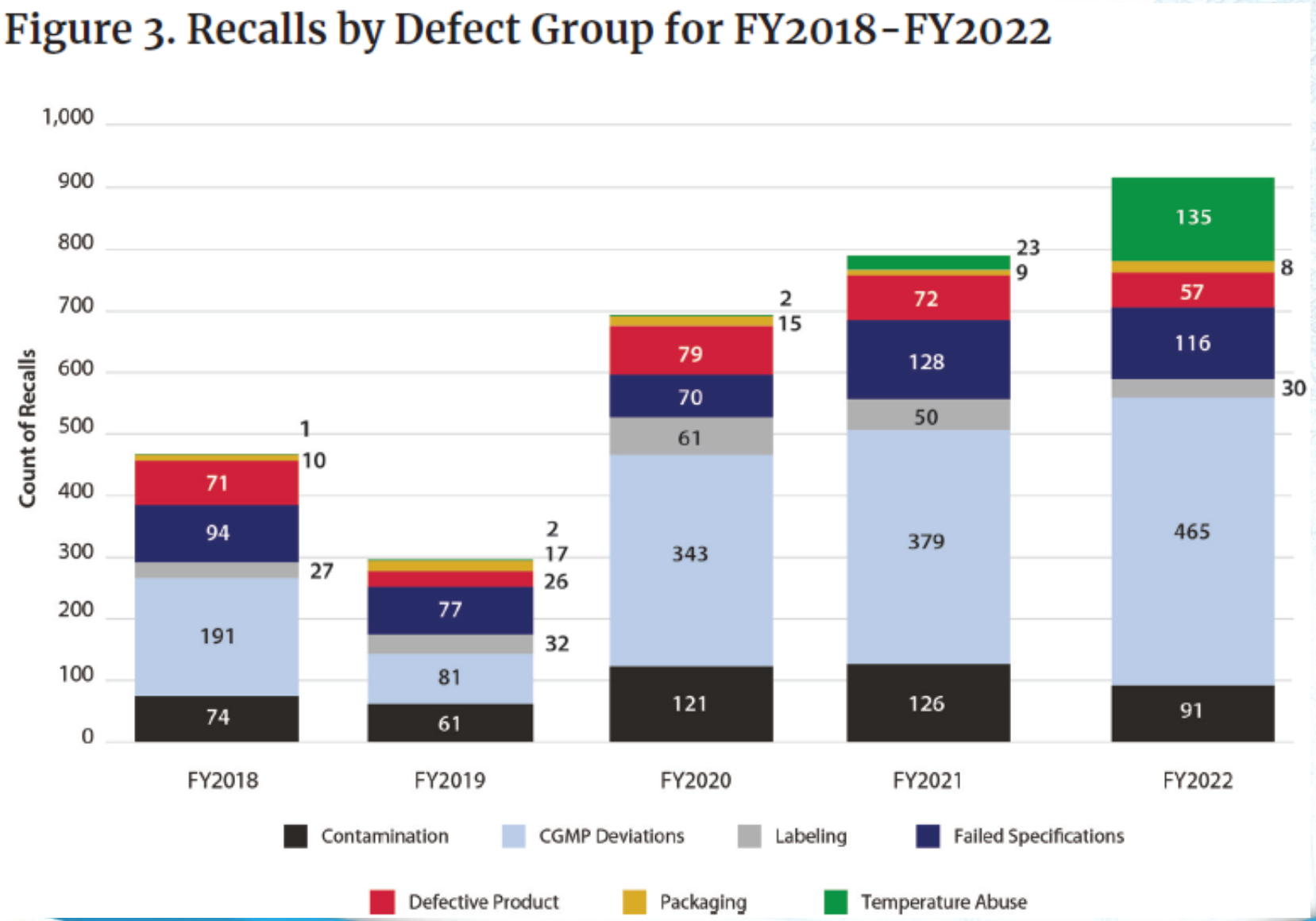
Import Alerts

- In FY2022, FDA issued 28 import alerts to sites for reasons related to drug quality.

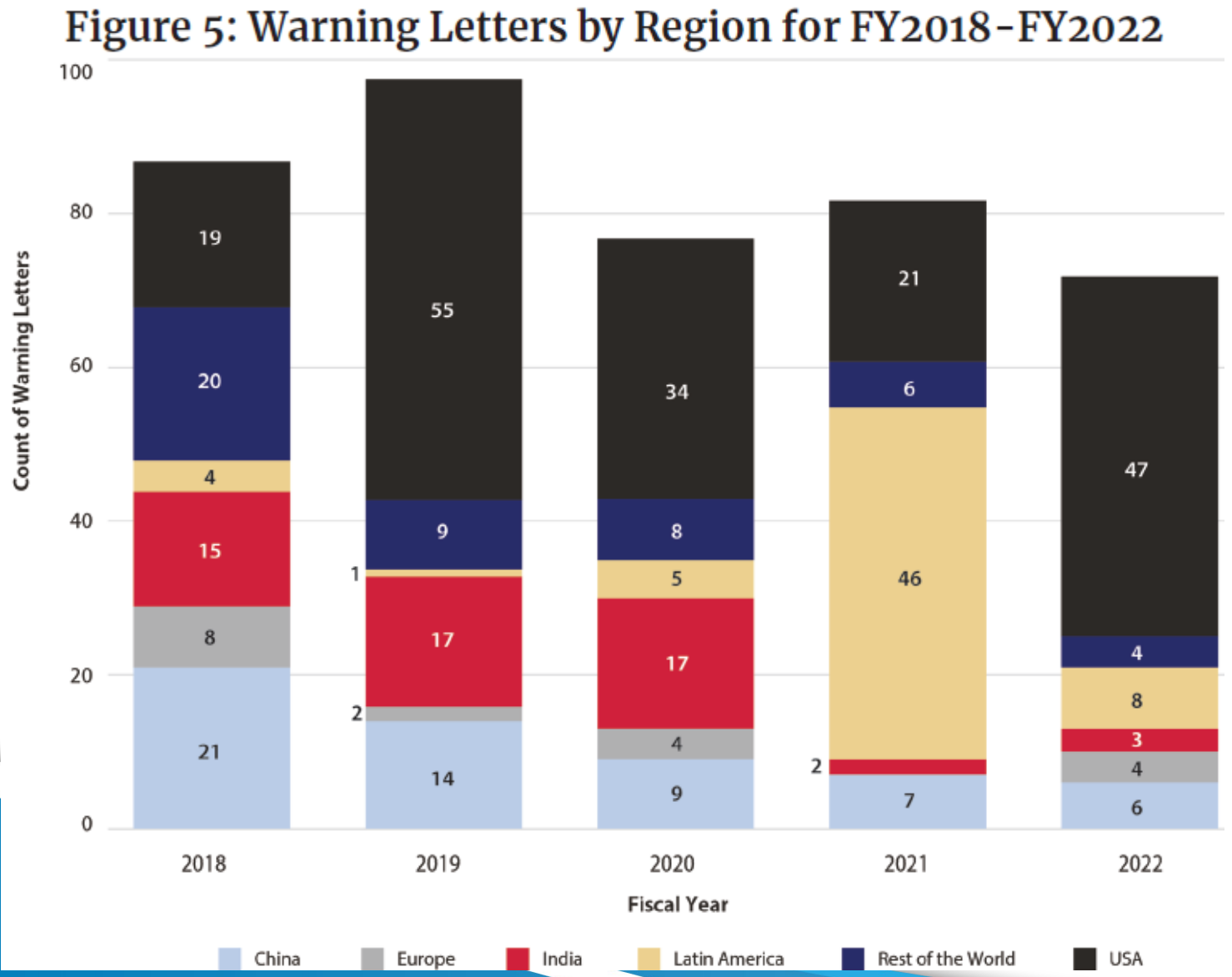
FY2022 Highlights

Recalls

- In FY2022, 166 sites generated 912 recalls. This was the highest number of recalls in five years.



FY2022 Highlights



Warning Letters

- In FY2022, FDA issued 72 CGMP-related warning letters to pharmaceutical manufacturing sites.

FY2022 Highlights

Commitment to Quality

- FDA's New Inspection Protocol Project (NIPP) is improving inspections by developing IT systems to collect and manage inspection data.
- CDER is working with stakeholders to build a program for assessing Quality Management Maturity (QMM) at drug manufacturing sites to strengthen quality management practices and promote supply chain reliability.
- The Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES) requires reporting of amounts manufactured. These data will strengthen drug quality surveillance.
- All together, NIPP, QMM, and CARES amount reporting are creating a more agile and robust pharmaceutical quality landscape.

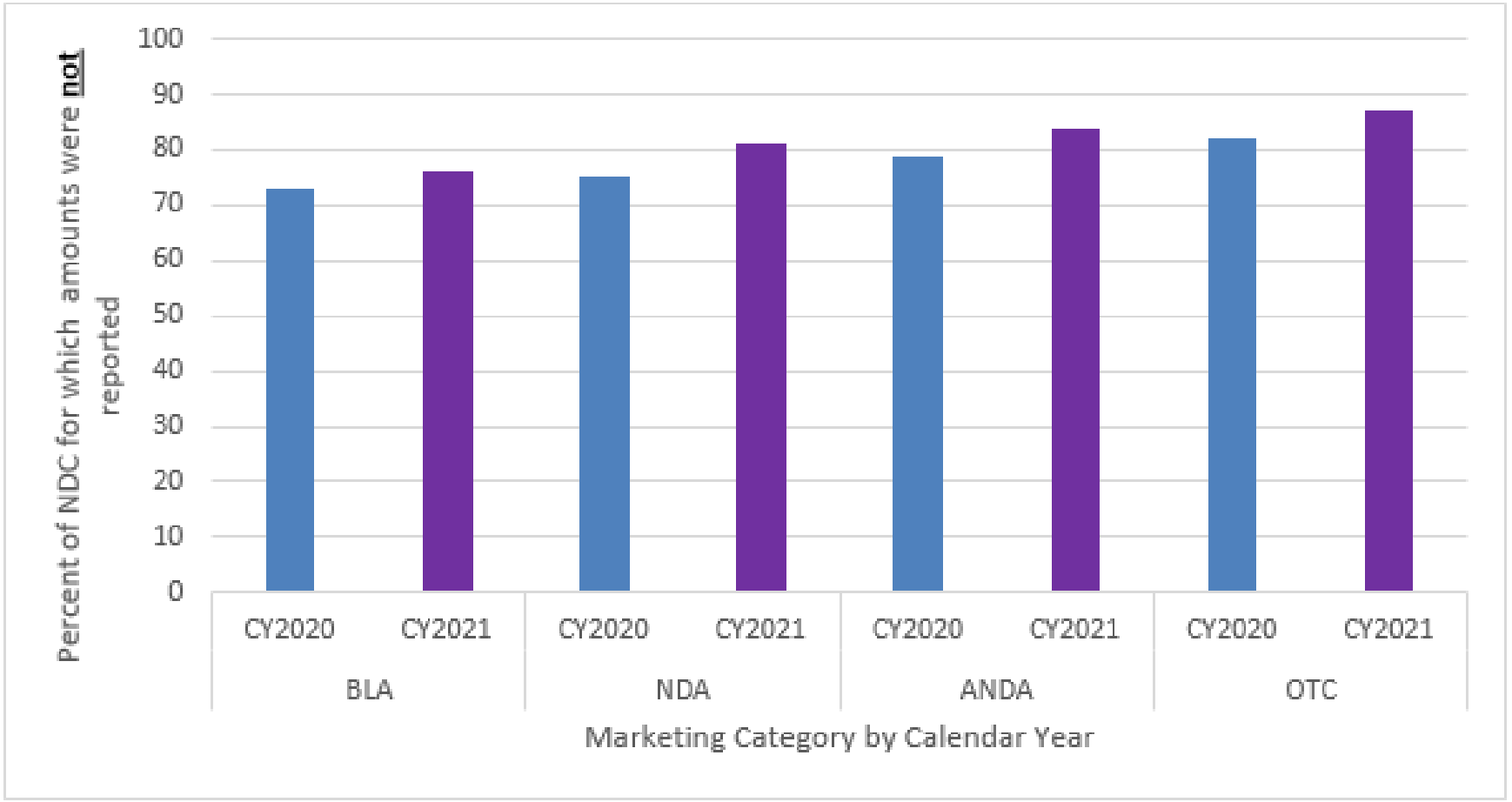


Figure 8. Percent of NDC in EDRLS for which amount reports were not submitted by marketing category

CARES Reporting

Low percentage of Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES) amount reporting across all product types.

Planning for the FY2023 Report on the State of Pharmaceutical Quality

- Continue to assess quality-related data, including product recalls and product quality defect reports, to identify trends in site quality and product quality.
- Using cutting edge and innovative analytics, to analyze data on regulatory actions and product quality testing for insights.
- Share progress about the development and implementation of programs that can better characterize pharmaceutical quality and help assure the availability of drugs.

Looking ahead

Thank you!