U.S. FOOD & DRUG ADMINISTRATION

FY2024

Report on the State of Pharmaceutical Quality

Center for Drug Evaluation and Research
Office of Pharmaceutical Quality

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Introduction

The Office of Pharmaceutical Quality (OPQ) in the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) assures that drugs legally marketed in the U.S. are safe and effective, and meet quality standards. This 7th Report on the State of Pharmaceutical Quality (FY2024[1]) was produced by OPQ's Office of Quality Surveillance as part of its mission to promote the availability of quality medicines for the American public. This report provides data, trends, and insights about FDA-registered drug manufacturers[2] and the quality of the U.S. drug supply, including biological products regulated by CDER.[3]

Acknowledgement: The CDER Office of Compliance is acknowledged for providing data and review that supported the production of this report.

1 Fiscal Year 2024 (FY2024) was from October 1, 2023, to September 30, 2024.

2 A "manufacturer" is anyone engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug.

3 This report covers CDER-regulated products and excludes products regulated by FDA's Center for Biologics Evaluation and Research (CBER), e.g., blood, vaccines, tissues, and certain other biological products.

Manufacturing Site Demographics

Key Takeaways

At the end of FY2024, CDER's Site Catalog[4] included 4,619 manufacturing sites[5] globally, with 41% of sites located in the U.S.

In FY2024 there were 972 FDA-conducted drug quality assurance inspections, an increase of 27% from the 766 accomplished in FY2023.[6]

There were 198 Mutual Recognition Agreement (MRA) partner inspections classified under the MRAs, the highest number achieved to date.

The number of sites in the CDER Site Catalog[7] increased 11% over the past five years (Table 1). Approximately 30% of this increase was due to sites in the "No Application" sector, which is a similar proportion to the current Site Catalog. Of all FY2024 drug manufacturing sites, 36% are in the "No Application" sector, indicating that all products manufactured at those sites are marketed in the U.S. without approved FDA applications. The majority of this sector includes OTC monograph products, but also includes marketed unapproved prescription drug products and homeopathic products. The remaining 64% of sites manufacture at least one application product, including:

4 The CDER Site Catalog is the curated inventory of registered manufacturing sites, vetted by FDA as legally manufacturing human drugs for the U.S. market. Hence, not all registered human drug sites qualify as "manufacturers" for the CDER Site Catalog.

5 Although they meet the definition of "manufacturer," medical gas manufacturers (based on existing CDER Site Catalog policy) and registered outsourcing facilities (under section 503B of the FD&C Act) are excluded from the count and analyses presented in this report.

6 Counts were revised in August 2025 to remove the inadvertent inclusion of medical gas inspections.

7 FDA removes sites from the CDER Site Catalog if they are not currently engaged in the manufacture of human drugs for the U.S. market and, therefore, are not subject to routine surveillance inspection. This commonly occurs when sites deregister or are no longer active in an approved application.

- Biological products licensed under Biologics License Applications (BLAs)[8]
- Innovator products approved under New Drug Applications (NDAs)
- Generic products approved under Abbreviated New Drug Applications (ANDAs)

Over the past five years, the six countries with the most sites in the FY2024 Site Catalog (U.S., India, China, Germany, Italy, and France) had significant net increases in total listed sites. For five countries (China, Spain, Germany, India, and South Korea), the number of sites increased more than 15%. This curated Site Catalog serves as the foundation for our comprehensive quality surveillance program.

Table 1

Inventory Shift over FY2020-FY2024 for Countries with Greater Than 50 Sites[9]

Country	Sites in the FY2024 Catalog	5-Year Review of Sites in the Catalog			
		Sites Maintained	Sites Removed	Sites Added	% Net Change
United States	1,892	1425	487	611	7%
India	597	450	57	163	18%
China	477	271	93	221	27%
Germany	194	151	11	47	19%
Italy	151	129	12	25	9%
France	135	111	20	28	6%
Canada	132	114	32	21	-8%
Japan	123	108	24	18	-5%
United Kingdom	99	87	23	17	-6%
Spain	94	66	12	31	20%
Switzerland	78	64	6	15	12%
South Korea	77	39	34	46	16%
Ireland	59	53	3	7	7%
All Others	511	361	115	185	14%
Total	**4,619**	**3,429**	**929**	**1,435**	**11%**

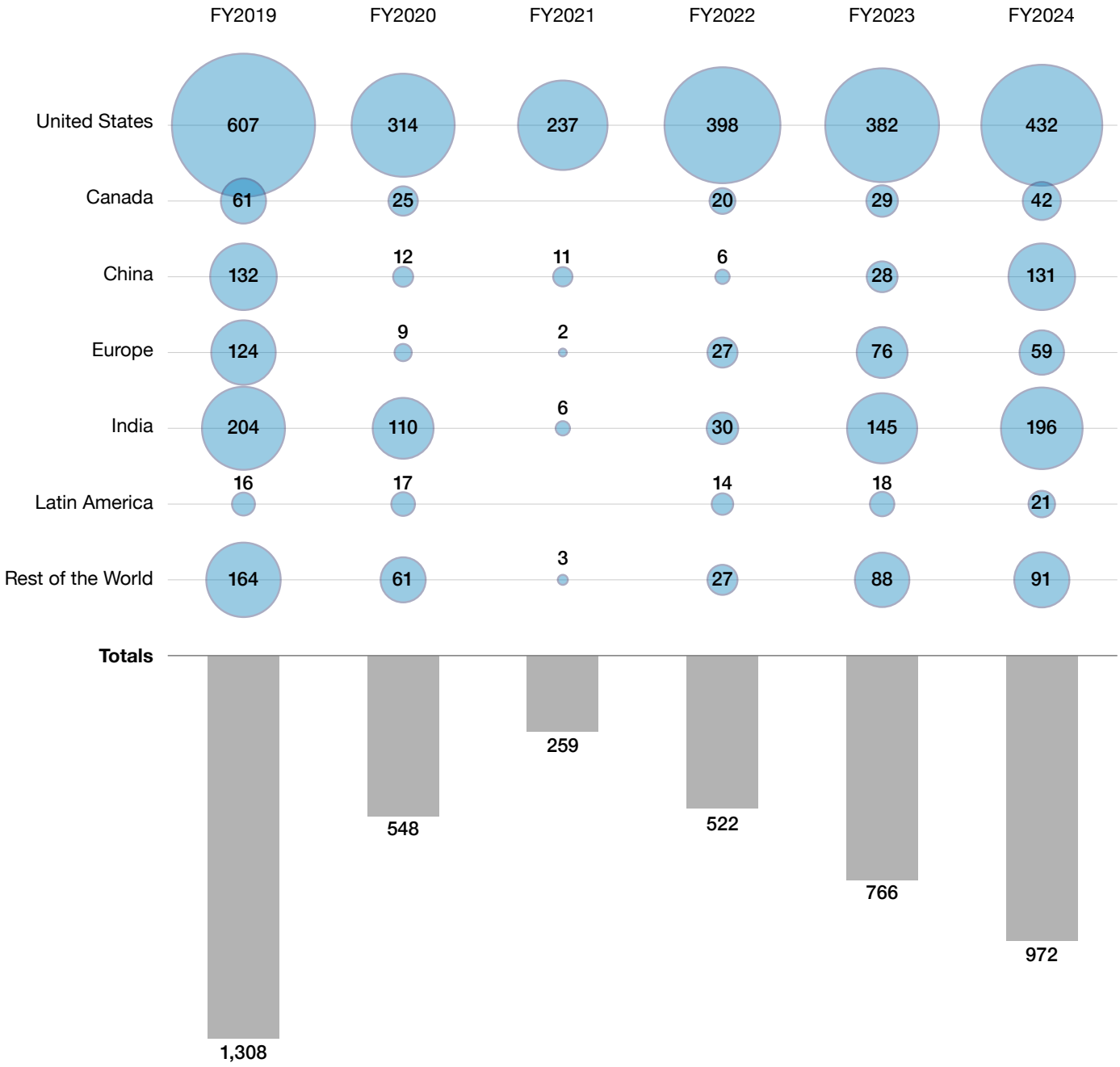
8 See FDA's webpage for further explanation of which therapeutic biological products are regulated by CDER per the original transfer and those subsequently deemed to be BLA products.

9 "Sites Maintained" are sites from the FY2020 Site Catalog that remain in the FY2024 Site Catalog. "Sites Removed" and "Sites Added" are sites that were removed from, or added to, the Site Catalog during FY2020-FY2024. Some sites were added and removed during those five years (in total, there were 245 such sites). Hence the total for FY2024 is equal to "Sites Maintained" + "Sites Added" – "Sites that were Added and Removed."

The number of FDA-conducted drug quality assurance inspections for foreign and domestic manufacturers, which includes surveillance and for-cause inspections, has increased significantly since the COVID-19 Public Health Emergency (PHE).[10] The number of inspections was 522 in FY2022, 766 in FY2023, and 972 in FY2024 (Figure 1).

Figure 1

FDA Drug Quality Assurance Inspections by Country and Region for FY2019-FY2024



10 The duration of this PHE, as determined by the Secretary of Health and Human Services, was January 27, 2020 –May 11, 2023.

Foreign drug quality assurance inspections are accomplished by FDA-conducted inspections or by assessing and classifying inspections from MRA partners. The increase in foreign FDA-conducted drug quality assurance inspections (146 in FY2022, 397 in FY2023, and 555 in FY2024) has been complemented by increased inspections classified under the MRAs: 144 in FY2022, 190 in FY2023, and 198 in FY2024, the highest number achieved to date.

In FY2024, more than 62% of drug quality assurance inspections were at foreign sites —an all-time high. This progress in foreign inspections was particularly evident in India and China, where 34% and 28% of sites in the Site Catalog, respectively, were inspected. By comparison, 24% of the U.S. sites in the Site Catalog were inspected in FY2024.

Inspection outcomes are a measure of site compliance with current good manufacturing practice (CGMP). These CGMP inspections provide information about each site's ability to manufacture drugs according to established quality requirements and in compliance with applicable laws and regulations. Globally, 93% of all sites in the CDER Site Catalog have received no action indicated (NAI) or voluntary action indicated (VAI) as their most recent inspection classification (including both FDA drug quality assurance inspections and inspections from MRA partners). The percentage of sites whose most recent inspection outcome was NAI or VAI varied by country/region, ranging from 87% for India to 98% for Europe (Table 2).

Table 2

Percentage of Sites with Most Recent Inspection Outcomes of NAI or VAI by Country/Region as of FY2024

Country or Region	Count of Inspections	Count of NAI and VAI Outcomes	Percentage of Sites
Europe	1,041	1,023	98%
Latin America	71	67	94%
Rest of the World[11]	316	296	94%
China	323	299	93%
Canada	129	119	92%
U.S.	1,679	1,545	92%
India	544	474	87%
Worldwide	**4,103**	**3,823**	**93%**

11 "Rest of the World" includes all other countries not specifically mentioned or covered by a region in this table.

Drug Product Demographics

Key Takeaways

At the end of FY2024, CDER's Product Catalog contained 383 BLAs, including 63 biosimilar products, a 47% increase from 43 biosimilar products in FY2023.

Following issuance of final guidance, Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amount reporting improved for calendar years (CY) 2023 and 2024.

The CDER Product Catalog is regularly updated for all application and non-application products. Its comprehensive product information comprises proprietary names, active ingredients, manufacturing sites, National Drug Codes (NDC),[12] and other data. At the end of FY2024, the Product Catalog included 14,168 ANDAs (4.4% increase from FY2023), 3,625 NDAs (0.9% increase from FY2023), 383 BLAs (8.2% increase from FY2023), and 140,119 non-application product NDCs (6.7% increase from FY2023). During FY2024, the total count of products increased 6.3% after a similar increase of 6.1% during FY2023.

Postmarket Quality Defects (PQDs)

Every year, CDER receives thousands of PQD reports, including those required by application holders and voluntary reports from consumers, patients, and healthcare professionals. Pursuant to FDA's postmarket regulations in 21 CFR 314.81(b)

12 The NDC is a 10- or 11-digit identifier for drugs listed with FDA that consists of three segments: "labeler code" (manufacturer or distributor), "product code" (drug product: formulation, dosage form, and specific strength), and "package code" (commercial package size and type).

and 21 CFR 600.14, respectively, application holders are required to submit Field Alert Reports (FARs) within 3 working days of receiving information concerning any incident that causes a quality defect and Biological Product Deviation Reports (BPDRs) within 45 days of discovering any event that may affect product quality in distributed products. Voluntary MedWatch (MW) reporting and consumer complaints enable consumers, patients, and healthcare professionals to submit reports when product quality fails to meet expectations. Compared to FY2023, the total number of FY2024 postmarket quality reports decreased 1.5% to 16,837. MedWatch reports, which typically constitute the majority of postmarket reports, increased slightly (0.3%) to 12,588 quality-related reports.[13] Of the 10 products that received the most MW reports, 7 were BLA products and 3 were ANDA products. In addition to potential product malfunction, a contributing factor to the number of MW reports for BLA products is that many BLA products are self-administered drug-device combination products that are subject to user error.

The submission of FARs decreased 7.5% to 3,515 reports compared to FY2023. Several groups of products received fewer FARs in FY2024, including FARs related to manufacturing establishments in the U.S. (9.0% decrease), FARs related to manufacturing establishments in India (3.7% decrease), FARs for generic drugs (8.7% decrease), and FARs from sterile sector (10.3 % decrease). In contrast, the submission of BPDRs increased 17% to 409 reports compared to FY2023.

In FY2024, FDA received 325 quality-related consumer complaints, an 18.3% decrease from FY2023, when there were a higher number of consumer complaint reports, many associated with recalls of OTC eye drops and gel products. During FY2024, consumer complaints came from a wide range of products without a clear pattern. The number of consumer complaints can be strongly influenced by product recalls, introduction of new generics, and FDA press releases about product quality.

Drug Amount Reporting

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act)[14] authorized FDA to enhance prevention and mitigation of possible drug shortages by augmenting its drug supply chain visibility. On February 26, 2024, FDA implemented the final guidance on Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act. It describes:

- The recommended time frame for submitting CY reports is no later than March 31 of the following CY.[15]
- Reporting recommendations for drug products in finished package form, drug products not in finished package form, and APIs.

13 Quality-related MW reports are voluntary postmarket reports from health professionals, patients, and consumers concerning product quality issues (not adverse events) such as defective components, contamination, poor packaging, and suspected counterfeit products.

14 The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020 to aid response and ease economic impacts of COVID-19.

15 CY2023 amount reports were due July 31, 2024. On November 21, 2024, FDA sent an email notification to manufacturers who had not yet submitted their CY2023 reports.

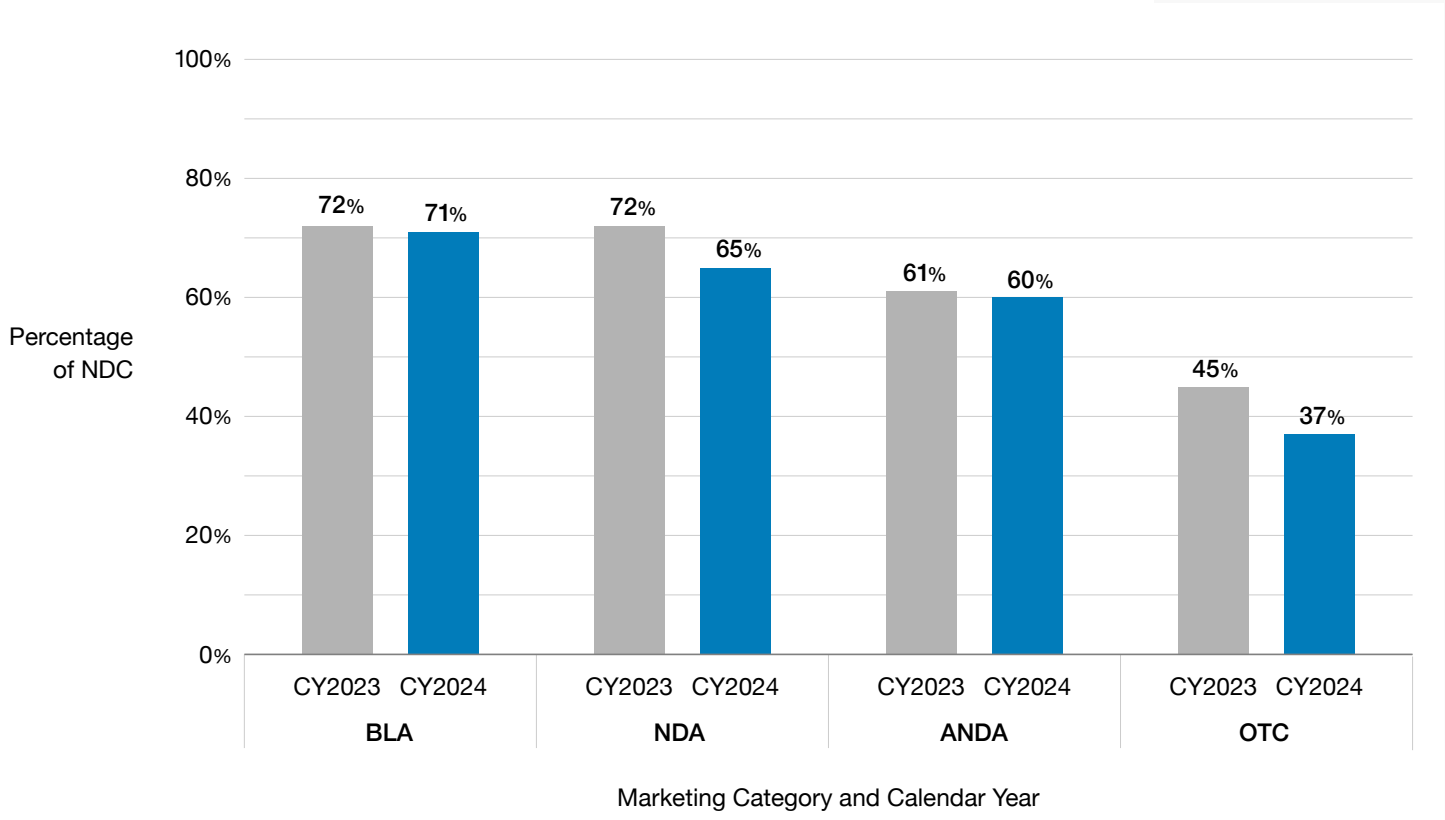
- Reporting requirements for registrants across the drug supply chain, including contract manufacturers.
- How FDA plans to use data from the reporting program.

Figure 2 shows the reporting rate for active CDER-regulated products listed in FDA's Electronic Drug Registration and Listing System (eDRLS).[16] This figure excludes medical gases and registrants who are repackers and relabelers. Drug amount reports for CY2024 can be submitted through December 31, 2025. The CY2023 and CY2024 reporting periods show improvements in the reporting rate, especially for application products (BLA, NDA, and ANDA). The reporting rate for OTC monograph products continues to trail application products.

Despite incomplete drug amount reporting, FDA leveraged the available submitted data to inform the FY2025 Site Selection Model for surveillance inspections. Additionally, these data have provided valuable supply chain insights for certain products, like insulin, where drug amount reporting is more robust. FDA has sent reminder emails describing future compliance actions to registrants who have failed to report amounts.

Figure 2

Percentage of NDC for Active Listed CDER-regulated Drugs (excluding medical gas) for which Registrants (excluding repackers and relabelers) Submitted Drug Amount Reports, by Marketing Category



16 CARES amount data are current as of April 2, 2025.

Import Alerts, Recalls, and Warning Letters

Key Takeaways

Of all sites placed on quality-related import alert, 65% were manufacturers of OTC monograph drug products and 25% were API manufacturers.

During the past five years, 72% of actions (e.g., warning letters, import alerts, and regulatory meetings) taken against API manufacturers were for sites that only supply compounding pharmacies, even though these sites represent just 18% of API manufacturers in the Site Catalog.

The number of recalled products (421) was the lowest in five years. The most common defect group was contamination.

Compared with FY2023, domestic warning letters related to drug quality decreased from 59 to 41, while foreign warning letters increased from 35 to 64.

Import Alerts

Import Alerts help stop violative products from entering the U.S. During FY2024, FDA added 75 sites to import alerts[17] for reasons related to poor drug quality (Figure 3).[18] The largest percentage of these import alert additions were associated with sites in China (39%), India (13%), and Europe (13%). For China, the number of import alert additions is disproportionate because sites in China represent only 17% of foreign sites in the catalog.

More than 60% of quality-related import alerts additions in FY2024 were based on record requests under the Federal Food, Drug, and Cosmetic Act (FD&C Act) §704(a)(4). The use of these mandatory record requests can result in import alert additions when responses are deficient or when establishments are not responsive. In particular, for manufacturers of OTC monograph drug products, the most common reason to be placed on import alert was quality-related deficiencies identified in their responses to §704(a)(4) records requests. For non-sterile API manufacturers, the most likely reason was failure to respond to these records requests.

In terms of manufacturing sectors, the majority of sites placed on quality-related import alerts (65% in FY2024 and 90% in FY2023) were manufacturers of OTC

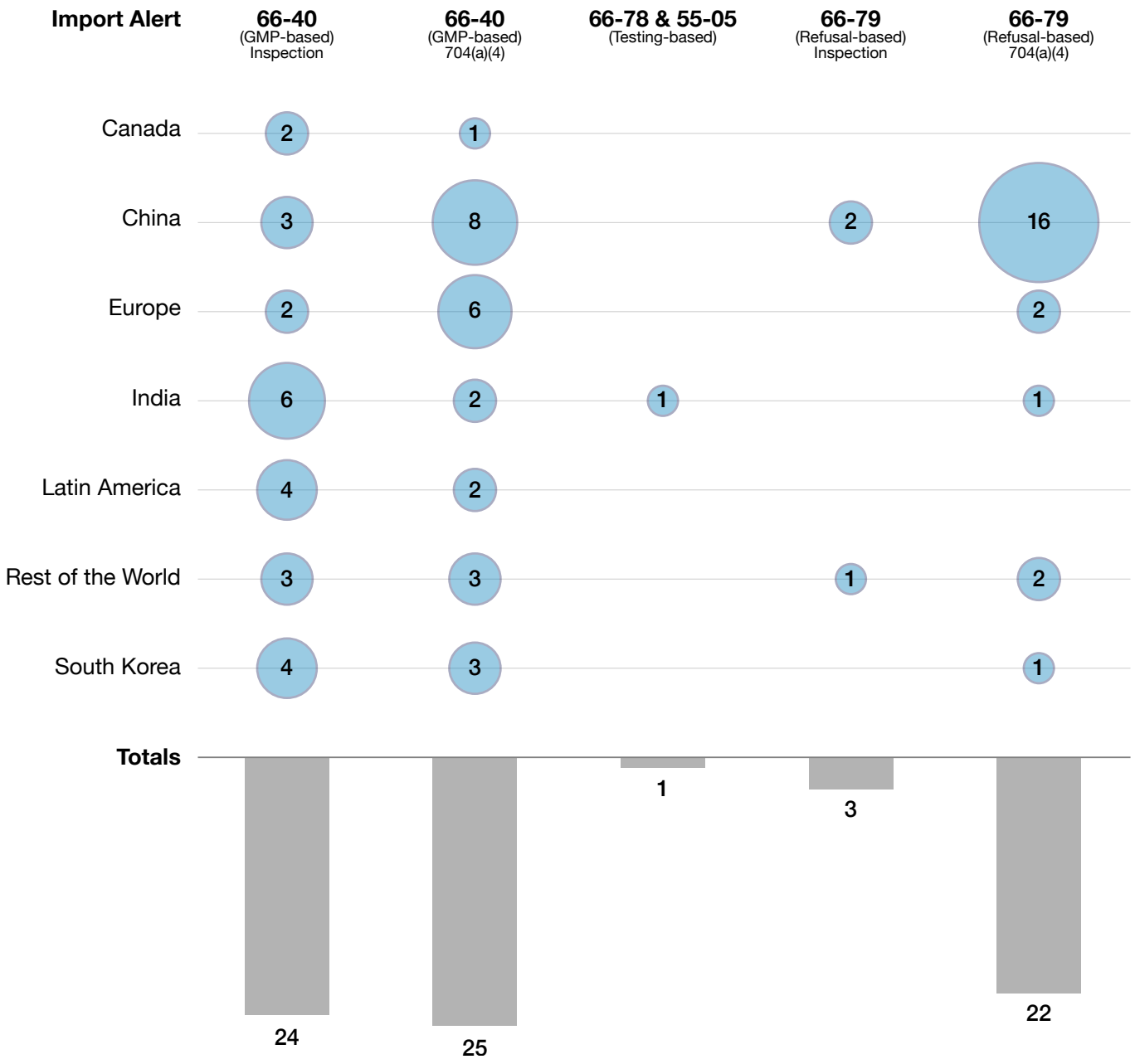
17 This count includes import alert additions that were initiated by CDER and the Office of Regulatory Affairs (since October 1, 2024, it is called the Office of Inspections and Investigations).

18 The subset of import alert reported here are for 66-40 (GMP-based) §704(a)(4), 66-40 (GMP-based) Inspection, 66-78 (Testing-based), 66-79 (Refusal-based) Inspection, and 66-79 (Refusal-based) §704(a)(4), 55-03 (GMP-based) Heparin, and 55-05 (Testing-based).

monograph drug products. In addition, for FY2024, API manufacturers represented 25% of quality-related import alert additions (this was only 2% in FY2023). This FY2024 increase in quality-related import alerts for API manufacturers was primarily due to API manufacturers supplying bulk product to domestic compounding pharmacies, for which most of the import alerts resulted from §704(a)(4) record requests.

Figure 3

FY2024 Drug-Quality-Related Import Alerts Additions by Type and Region



FDA continues to leverage and adapt §704(a)(4) record requests as an important surveillance tool. In previous years, quality-related import alerts based on §704(a)(4) record requests were primarily for sites manufacturing products with specific potential consumer hazards (e.g., methanol in hand sanitizers or diethylene glycol (DEG)/ethylene glycol (EG) in drug products). In FY2024, the use of §704(a)(4) record requests continued for newly registered sites and for sites without inspection history. As a result, 40% of all quality-related import alerts were based on §704(a)(4) record requests to sites that have not been inspected by FDA. In this way, §704(a)(4) record requests protect U.S. consumers and patients from imported drug products that were manufactured at sites not meeting FDA quality standards.

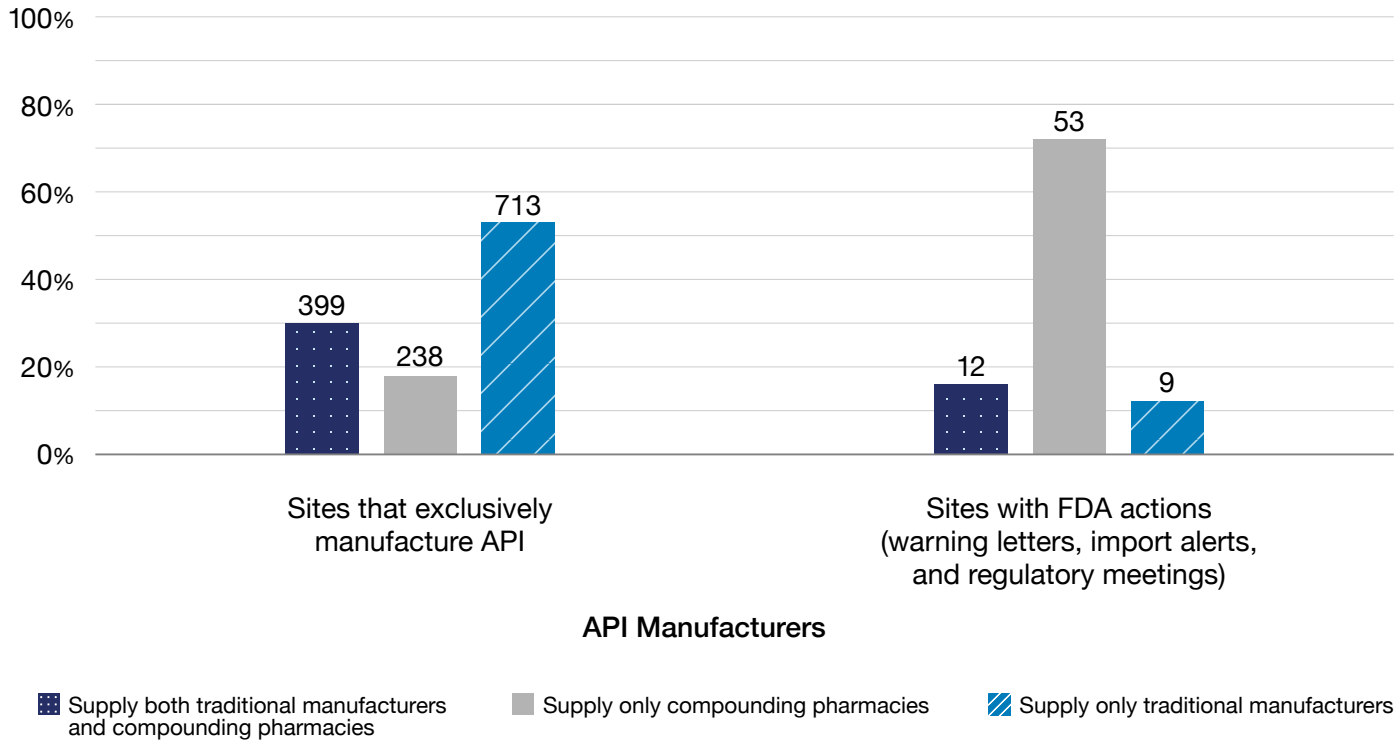
A Deeper Insight: API Manufacturers for Domestic Compounding Pharmacies

In recent years the compounding pharmacy industry has grown to meet excess demand for specialized clinical need and commercially manufactured products in shortage. FDA maintains oversight of compounding pharmacies, under section 503A of the FD&C Act, and outsourcing facilities, under section 503B of the FD&C Act, who may directly or indirectly procure APIs from global suppliers. Sites that manufacture API, whether for commercial drug products or compounding pharmacies, are required to register with FDA; however, inspections do not always occur prior to API being supplied to non-application drug product sites and compounding facilities. Of note, section 503A pharmacies are not subject to CGMP requirements and might not test their API prior to use. This is why FDA urges compounders to know their suppliers of bulk drug substance or API, and excipients, and know whether the supplier is testing the component to ensure it is of appropriate quality to use in drugs.

FDA's surveillance of API suppliers for compounding sites reveals a concerning trend about non-compliance with CGMP. Over the past five years, 72% of API manufacturing sites subject to FDA regulatory actions (e.g., warning letters, import alerts, and regulatory meetings) were sites that exclusively supply compounding pharmacies. This is notable because these sites represent only 18% of API manufacturers in the Site Catalog. (Figure 4). Due to this trend, FDA has prioritized these higher risk sites for future surveillance. Violative API manufacturing sites that only supply compounding pharmacies tend to be located in China (51%) and India (30%). FDA will continue to prioritize the use of its surveillance and compliance tools for higher risk sites, including these types of API manufacturers.

Figure 4

Sites that Exclusively Manufacture API and FDA Actions Taken for FY2020-2024



Recalls

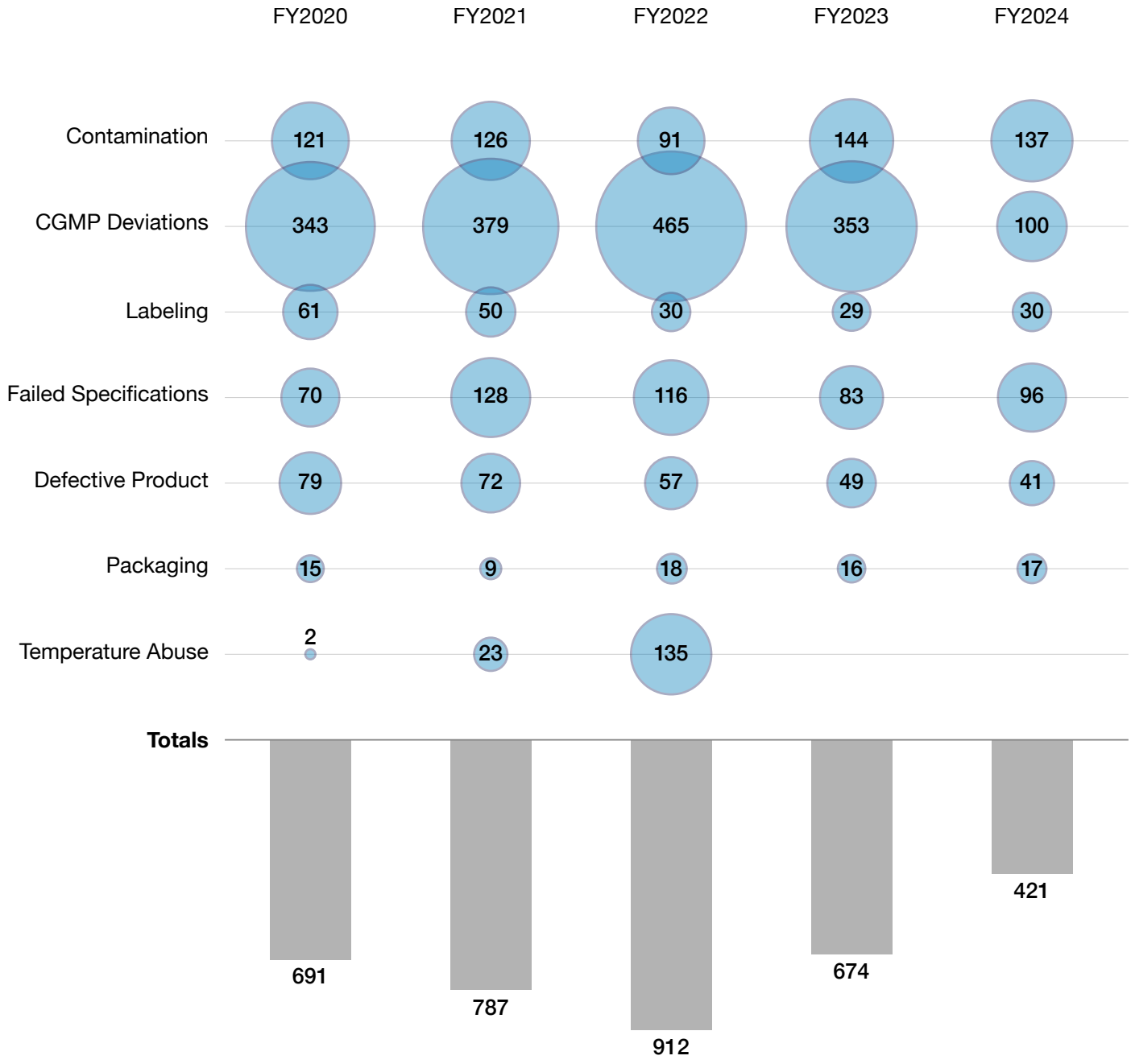
A drug recall is a voluntary action taken by a manufacturer to remove a defective or potentially harmful product from the market. In FY2024, 165 sites generated 260 recall events,[19] 15% more recall events than in FY2023. Although the number of recall events increased, the number of recalled products per event in FY2024 was the lowest in five years, resulting in only 421 recalled products (Figure 5). Based on the reasons for recalls provided by the recalling firms, recalls related to CGMP deficiencies were approximately 50% for FY2020-FY2023; however, in FY2024 this defect group represented only 24% of the recalls.

Contamination recalls include those for microbial contamination (31%), sterility assurance issues (28%), foreign material/particulates contamination (20%), product mix-up/cross contamination (17%), and chemical contamination (4%). Notably the number of products recalled due to failed specifications increased from FY2023. Most of these failed specification recalls were discovered during stability testing and are related to impurities above specification limits (46%) and dissolution failures (36%). Countries with the highest number of sites identified as responsible for FY2024 recalls were the U.S. (48%) and India (41%), followed by Canada (4%), Spain (2%), and Japan (1%).

19 Recalls can be analyzed by product NDC numbers recalled (recall number) or by recalling event. Multiple product NDC numbers and lot numbers may be listed within a single recall event. Classified (I, II, III) recalls are included in this analysis. Recalls of drug products not in the CDER Product Catalog (e.g., compounded drugs and those marketed without an approved application, or not marketed under an over-the-counter monograph) and those voluntarily removed by a market withdrawal are not included in this analysis.

Figure 5

Recalled Products by Defect Groups for FY2020-FY2024



Contamination issues were prominent in the four FY2024 recall events that impacted the most products:

- 22 product recalls attributed to a single manufacturing site for non-sterility of OTC ophthalmic drug products.
- 11 product recalls attributed to a single manufacturing site for CGMP deficiencies: microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.
- 11 product recalls attributed to a single manufacturing site due to

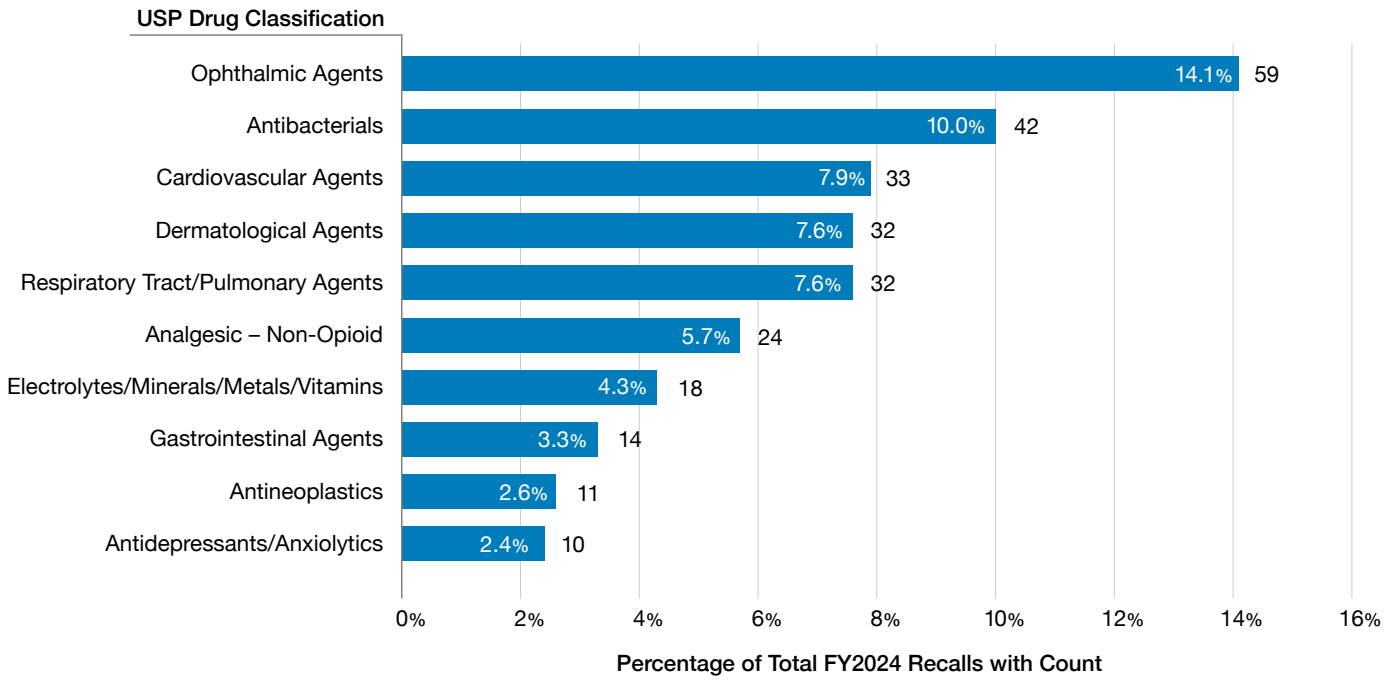
out-of-specification API and violative grade of propylene glycol used during the manufacturing process.

- 10 product recalls attributed to a single manufacturing site for lack of assurance of sterility for homeopathic sterile eye drops.

In FY2024, ophthalmic agents, classified as such in the 2024 United States Pharmacopeia Drug Classification[20] (USP DC), had the highest percentage of recalls (Figure 6). These top ten USP DC categories made up 66% of the 421 FY2024 recalls.

Figure 6

Top Ten Recalls in FY2024 by USP Drug Classification



A Deeper Insight: Study of Quality for Store-Branded OTC Drug Products

During FY2020-FY2024, there were more than 450 drug recall events covering more than 1,900 OTC drug products. For this five-year period, we compared the recall rates of store-branded OTC products from the top U.S. retailers[21] against those of other OTC products (Figure 7). This analysis revealed that, on average, 0.31% of top store-branded OTC products were recalled annually, compared to 0.35% of other OTC products. These recall rates for store-branded OTC products and for other OTC products are statistically similar. This aligns with our finding that 93% of manufacturers producing top store-branded OTC products also manufacture other OTC drug products, including name brands and smaller store brands. Given this overlap in manufacturing, it is

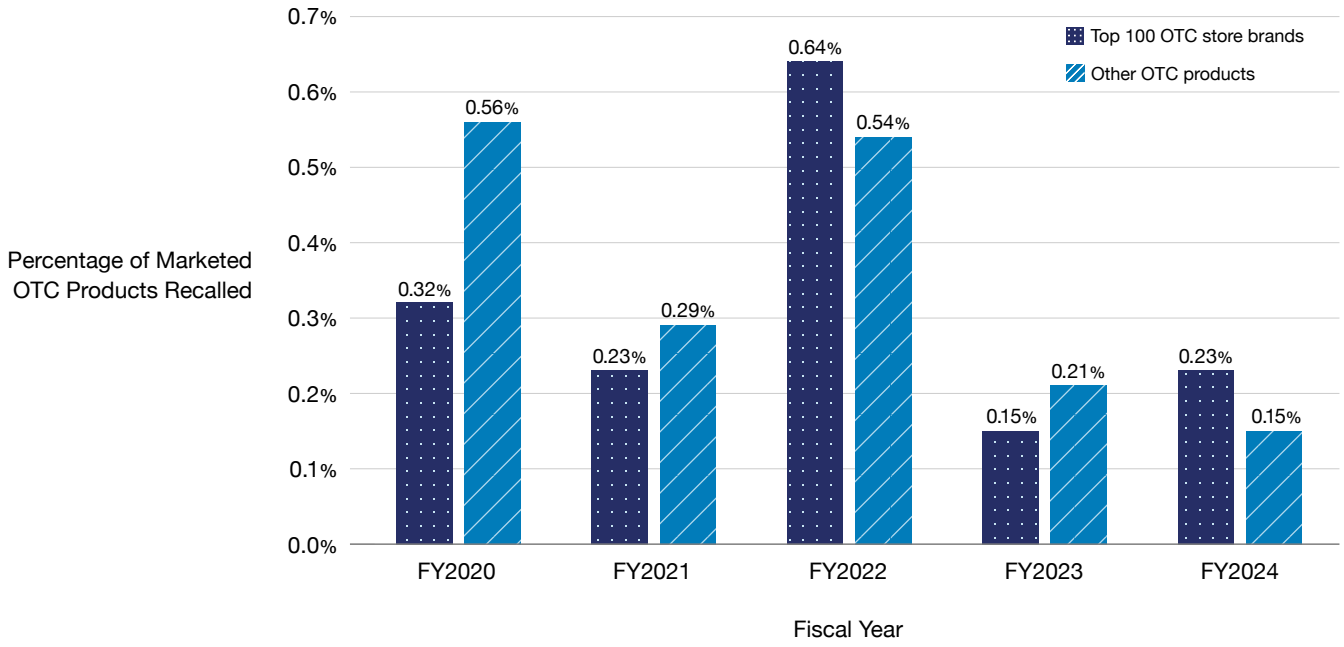
20 The USP DC is updated annually and published mid-December for the upcoming year. The version (year) used for classification is indicated. This report primarily uses the Tier 1 USP DC Category.

21 Using the Top 100 Retailers 2024 List provided by the National Retail Federation.

logical that manufacturing quality issues leading to recalls would affect all these products similarly. Moreover, a small group of shared manufacturers is responsible for the majority of store-branded OTC recalls. During the five-year period studied, just 15 manufacturers accounted for 94% of the 407 recalled store-branded OTC products.

Figure 7

Percentage of Marketed OTC Products That Were Recalled for FY2020-2024



Warning Letters

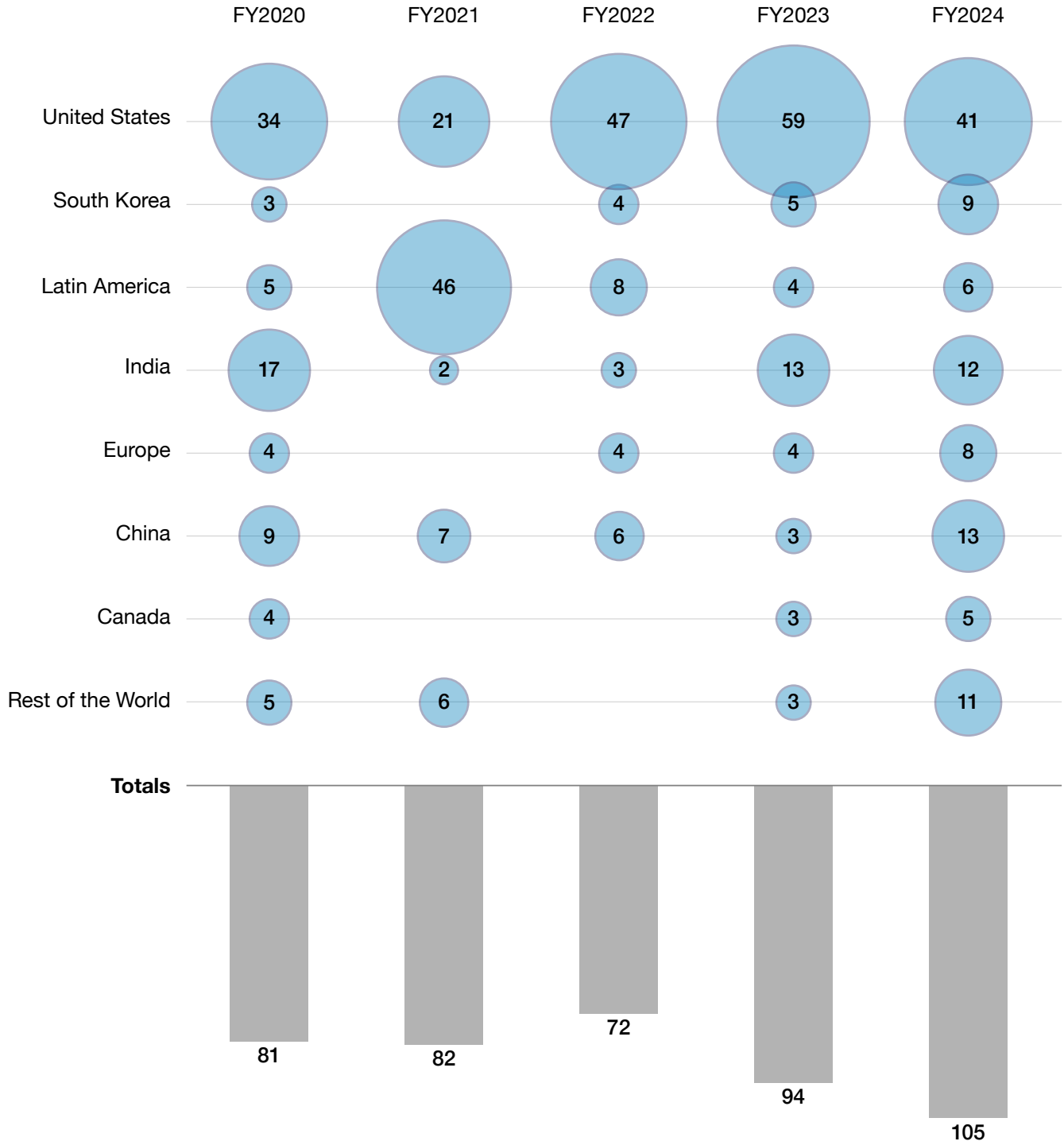
In FY2024, FDA issued 105 warning letters to human drug manufacturing sites for reasons related to drug quality (Figure 8), on the basis of inspection, §704(a)(4) records requests, and product testing. This was the highest number of human drug, quality-related warning letters issued in the past five years. The FY2024 increase was driven largely by inspection-based warning letters, which increased by 21% from FY2023, and resulted from the increased number of FY2024 inspections. During the past three years, the proportion of warning letters issued to foreign sites increased, in part because FDA performed more drug quality assurance inspections at foreign sites (see Figure 1). A searchable FDA database provides details about FDA warning letters back to 2020.

Unlike the overall increase in warning letters that was inspection-based, the increased number of FY2024 warning letters issued to sites in China was primarily due to quality deficiencies identified in §704(a)(4) records requests (8 of the 13 warning letters). Nine sites in South Korea, all of which are manufacturers of OTC monograph products, received warning letters. Of note, six of these nine warning letters issued to sites in South Korea included citations for failing to test for dangerous substances (DEG/EG or methanol) in drug product components. In

response to drug contamination outbreaks,[22] FDA has more closely scrutinized related manufacturers using various surveillance and compliance tools, including testing, inspections, and §704(a)(4) record requests.

Figure 8

Warning Letters by Country and Region for FY2020 – FY2024



22 There have been recent fatal poisonings of consumers who ingested drug products manufactured with contaminated components (e.g., methanol contamination of hand sanitizers in the U.S. (2020) and DEG/EG contamination of children's cough syrup in other countries that caused more than 300 deaths (2022)).

VISUALIZING DEEPER INSIGHTS

Using Product Snapshots to Assess Quality and Illustrate Supply Chains for ADHD Drugs

Key Takeaway

FDA can marshal diverse data sources for a comprehensive product snapshot to assess potential quality signals, and after review, determine if surveillance or enforcement tools should be deployed.

Recent ADHD stimulant medication shortages in the U.S. are attributed to increased demand, supply chain constraints, and manufacturing limits, as outlined in a joint FDA-Drug Enforcement Administration (DEA) letter. The FDA proactively monitors product quality through supply chain information, complaints, and other signals, integrating these data with distribution volumes and factors such as recalls.

Figures 9 through 12 present integrated product snapshots for two ADHD medications, a stimulant (Figures 9 and 11) and a non-stimulant (Figures 10 and 12), featuring timelines of shortages, MedWatch reports, recalls, distribution volume (using IQVIA National Sales Perspective[23] Extended Units[24]), newly approved NDAs and ANDAs, and supply chain network schematics for FY2019 and FY2024.

23 The IQVIA National Sales Perspectives measures "sales for pharmaceutical products across multiple distribution channels, including retail, mail, and non-retail. Data are collected from wholesalers, distributors and pharmaceutical manufacturers representing 90% of the pharmaceutical market and projected to a national total."

24 Extended units are defined, for example, as tablets or capsules for oral solids and milliliters for injections.

The stimulant product, with an API subject to DEA production quotas, shows four times higher distribution volume, product shortages, high numbers of MedWatch reports, multiple recalls, ongoing application approvals, and an increasingly complex supply chain that is primarily domestic. In contrast, the non-stimulant product exhibits no shortages or recalls, stable MedWatch reports, no new application approvals since FY2021, and linear supply chains that are primarily foreign.

FDA uses these diverse data to assess potential quality signals and determine the need for additional appropriate surveillance or regulatory activities. For example, FDA is reviewing the recent increase in MedWatch reports for extended-release ADHD stimulant products to determine necessary responses, which may include additional information requests, sampling and testing, or inspections. During supply disruptions or shortages, FDA can use supply chain data to identify sources of quality problems and opportunities for additional capacity, ensuring a comprehensive approach to maintaining drug quality and availability.

Figure 9

Product Snapshot for Stimulant ADHD Medication

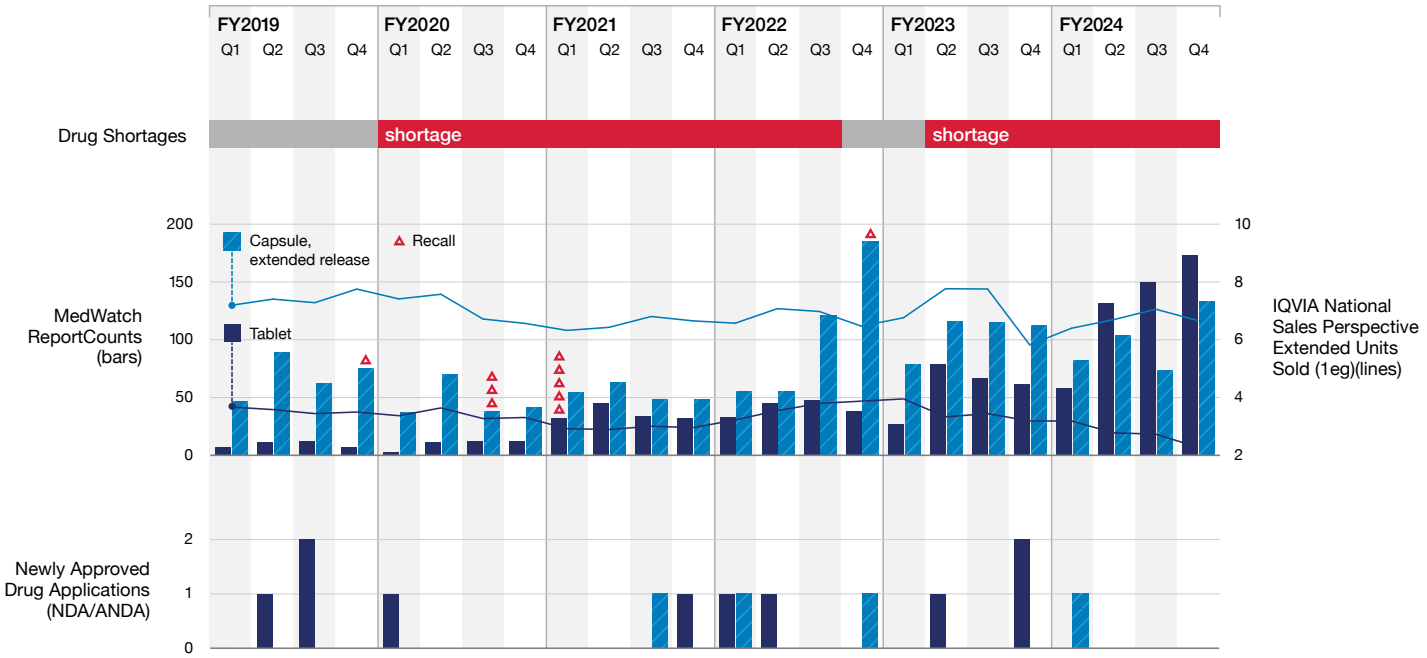


Figure 10

Product Snapshot for Non-Stimulant ADHD Medication

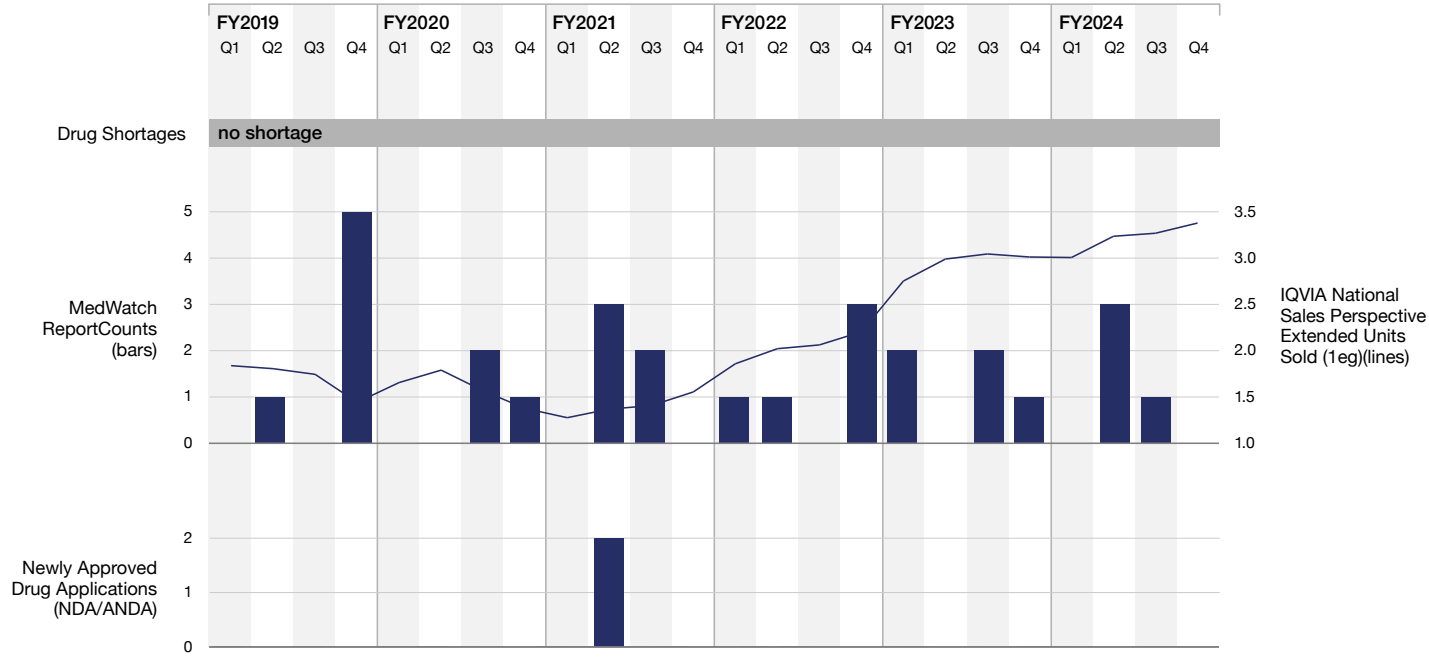


Figure 11

Stimulant Supply Chain Networks (FY2019-FY2024)

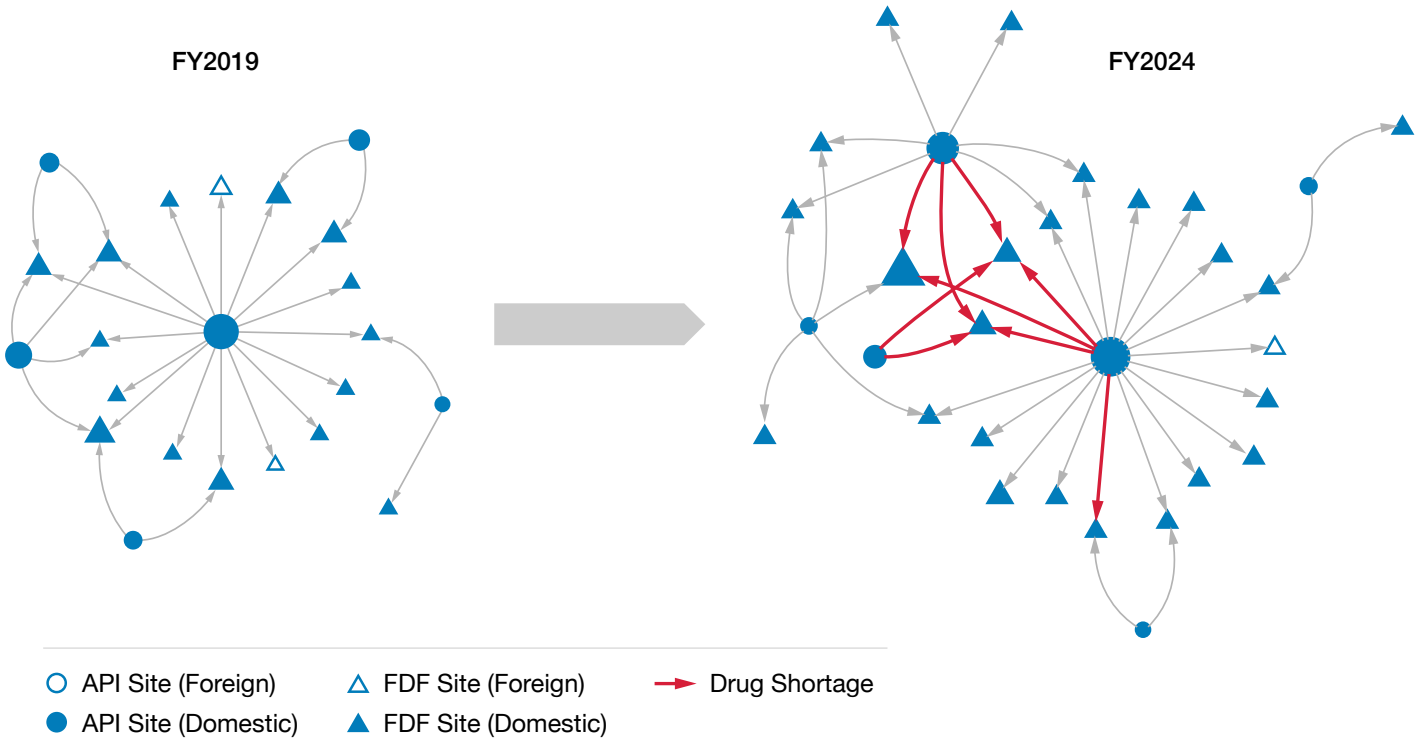
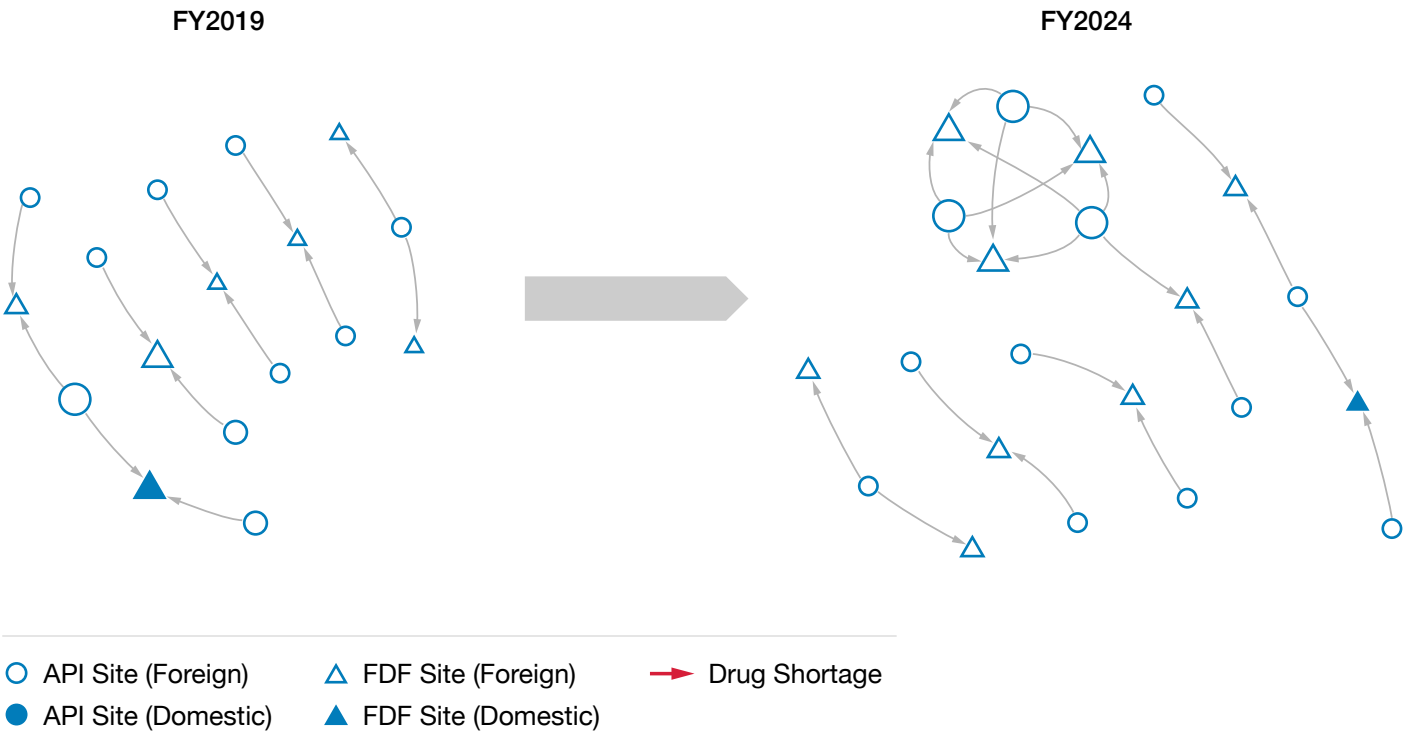


Figure 12

Non-Stimulant Supply Chain Networks (FY2019-FY2024)



Active Pharmaceutical Ingredient (API) and Final Dose Form (FDF) sites.
Nodes are sized according to IQVIA National Sales Perspectives.

Commitment to Quality

Key Takeaway

In response to an emerging trend from postmarket quality reports, FDA tested fifteen solid oral dosage form drug products that were repackaged in unit-dose blister packages and found no “out of specification” results.

Sampling and Testing

To minimize the exposure of U.S. patients and consumers to noncompliant drug products, FDA’s Drug Quality Sampling and Testing (DQST) Program tests prescription drugs, OTC products, and API. Sample results from more than a decade are available online.

Drug product repackagers typically obtain bulk drug products from manufacturers and repackage them into smaller, more convenient unit-dose blister packages for distribution to nursing homes and hospitals. In FY2024, the DQST Program completed a focused assignment on the quality of solid oral dosage form drug products that were repackaged in unit-dose blister packages. FDA initiated this assignment after identifying a trend of recalls and postmarket reports related to impurity, dissolution, and assay stability failures for products that were repackaged as unit-dose blister packages. These failures could pose quality risks and safety hazards to patients and consumers. The root cause analysis in many of the postmarket reports found that the drug products in unit-dose blister packages were not stable at room temperature storage conditions.

As a proactive effort, FDA surveyed 15 drug products from similar repackaging sites. Samples of both immediate and extended-release formulations were collected from six U.S. repackaging sites. The product classes included sulfonylureas, antipsychotics, statins, antidepressants, anticonvulsants, and immunosuppressants. FDA tested samples based on the issues seen in recalls and postmarket reports: (a) identification and assay testing to ensure that the products contained active ingredients at the amount specified by their product labels, (b) dissolution testing to ensure drug products dissolved as designed while releasing the drug active ingredient, and (c) organic impurities testing to ensure that products did not exceed specifications for known and unknown impurities as approved in the application. For the fifteen products tested, FDA obtained no "out of specification" results, suggesting that for the drugs sampled, the repackaging operations do not appear to be significantly impacting product quality.

Continuing to Assure Quality

This report furthers OPQ's mission to assure that quality medicines are available to the American public by providing transparent, data-driven insights into pharmaceutical quality. OPQ has maintained a strong commitment to public transparency by consistently communicating the state of pharmaceutical quality through comprehensive data, findings, and analyses. This valuable information contextualizes FDA's actions and strengthens our partnership with the public.

Recognizing the dynamic nature of pharmaceutical quality, OPQ remains poised to address emerging challenges. Looking ahead, OPQ anticipates that a proactive approach to quality management will significantly bolster supply chain resilience and assure the consistent availability of quality medicines. FDA is actively expanding its data sources and developing sophisticated visualization tools to enhance decision making, optimize resource allocation, and provide deeper context for data interpretation.

FDA's ongoing commitment to monitor sites and products through rigorous inspections, product testing, and postmarket data assessment remains unwavering. Continually improving these practices is part of the forward-thinking strategy to safeguard public health by efficiently regulating the pharmaceutical industry.

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