Executive Summary

Generic and biosimilar manufacturers are fundamentally committed to product quality. A continuous and significant investment in quality excellence manifests the industry's deeper purpose of safeguarding patients and its responsibility to protect public health through rigorous science, robust quality systems, and resilient supply chains. As a result, AAM and its member companies' have an outstanding track record for safety and ensuring U.S. patients have access to high-quality, safe and effective generic and biosimilar medicines.

Every process that generic and biosimilar manufacturers engage in - from raw material sourcing, to manufacturing, distribution and post-approval monitoring - is purposefully and carefully designed and implemented to ensure Americans can rely on the treatments they use every day. Industry best practices include the adoption of Quality by Design ("QbD") principles to proactively build quality into the entire pharmaceutical product lifecycle.

The U.S. has high standards, long considered the gold standard globally, to ensure the safety, efficacy, and quality of all pharmaceuticals manufactured for U.S. patients, regardless of where they are manufactured and whether they are originator, generic, or biosimilar medicines. FDA applies these high standards not only during the approval process but also throughout the product life cycle. These quality standards and regulatory requirements, by design, include multiple safeguards and redundancies to help ensure quality. Generic drug and biosimilar manufacturers' commitment to product quality and the industry's implementation of these multiple, layered safeguards pursuant to FDA oversight ensures generic and biosimilar medicines are of consistently high quality.

Some misunderstandings about and mischaracterizations of FDA actions involving generic and biosimilar medicines have the potential to unnecessarily undermine confidence in those medicines. These misunderstandings include the concern that FDA has inappropriately allowed drugs from noncompliant facilities that are under import alert into the country to mitigate drug shortages, and the use of the FDA's Adverse Event Reporting System ("FAERS") system to make quality comparisons between products.

Preventing drug shortages is essential to protecting public health as drug shortages can result in patient injury or death and the risks of patient injury from specific CGMP violations may be small. FDA balances the risks and benefits in each specific situation and relies on additional safeguards when necessary to ensure patient safety. Because of limitations in FAERS, FDA has said that the information in the reports cannot be used to estimate the incidence (occurrence rates) of the events reported, and, therefore, the reports are not useful measures of quality nor should they form the basis for product quality comparisons across products.

Based on misunderstandings and mischaracterizations of the quality of generic and biosimilar medicines, some have suggested the need for FDA to conduct increased broad, untargeted post-approval testing of drugs and biologics and unannounced inspections of foreign facilities. AAM believes broad untargeted testing that is neither risk-based nor aligned with accepted and approved test methods is unlikely to provide helpful information and could, instead, generate misleading results and distract from meaningful quality signals. With regard to unannounced inspections of foreign facilities, although pre-announced inspections remain effective, AAM supports expanding the use of unannounced foreign inspections, where appropriate, to better align FDA's oversight of domestic and foreign facilities.

AAM and its members remain committed to continuous quality improvement and to working collaboratively with FDA and other stakeholders to promote a regulatory environment that supports patient access to high-quality, safe, and effective generic and biosimilar medicines.

Association for Accessible Medicines Quality Position Statement

I. Introduction

The Association for Accessible Medicines ("AAM" or "we") represents the manufacturers of finished generic and biosimilar products, manufacturers of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar industry. AAM works to expand patient access to high-quality, safe and effective generic and biosimilar medicines by promoting a forward-looking and sustainable regulatory and policy environment and by advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

Generic medicines are the backbone of the U.S. prescription drug market, supplying more than 9 out of every 10 prescriptions, but only accounting for 12% of total U.S. prescription drug spending.[1] Biosimilars, new to the market only ten years ago, have already generated $56.2 billion in savings.[2] AAM and its members are committed to the manufacture and supply of high-quality, safe and effective generic and biosimilar medicines, in accordance with U.S statutory requirements, Food and Drug Administration ("FDA" or the "Agency") regulations and guidance, and industry best practices.

Recent misunderstandings and mischaracterizations of generic and biosimilar quality have the potential to unnecessarily undermine confidence in the industry that supplies 90% of the prescription medicines dispensed to patients in the U.S. today. It seems timely, therefore, to reiterate our industry's longstanding commitment to quality and outline how manufacturers' quality systems and FDA's regulatory framework work together to protect patients and ensure the production of consistently high-quality generic and biosimilar medicines.

[1] See AAM, 2025 U.S. Generic and Biosimilar Medicines Savings Report (September 2025) ("2025 Savings Report") at 10.
[2] *Id.*

II. Generic and Biosimilar Manufacturers' Quality Systems and FDA's Regulatory Framework Work in Tandem to Ensure the Production of High Quality Generic and Biosimilar Medicines

A. Generic and Biosimilar Medicine Manufacturers Are Committed to Quality

Generic and biosimilar manufacturers are fundamentally committed to product quality. A continuous and significant investment in quality excellence manifests the industry's deeper purpose of safeguarding patients and its responsibility to protect public health through rigorous science, robust quality systems, and resilient supply chains. Every process that generic and biosimilar manufacturers engage in - from raw material sourcing, to manufacturing, distribution and post-approval monitoring - is purposefully and carefully designed and implemented to ensure Americans can rely on the treatments they use every day.

Many generic and biosimilar manufacturers have adopted Quality by Design ("QbD") principles to proactively build quality into the entire pharmaceutical product lifecycle, rather than relying on end-product testing. The principles include establishing a quality target product profile ("QTP") that identifies critical quality attributes ("CQAs") of the drug product, critical material attributes ("CMAs") that cover materials used in the manufacturing process, critical process parameters ("CPPs"), and a control strategy based on these attributes that includes specifications for the drug substance, excipients, and drug products as well as controls for each step in the manufacturing process that ensures product quality.[3] QbD also includes a continuous improvement capability.[4] In implementing QbD, Industry best practices include robust process validation, rigorous raw material testing, advanced data integrity systems and proactive quality management to prevent recalls and supply chain disruptions.

B. Quality Standards and Regulatory Requirements, By Design, Include Multiple Safeguards and Redundancies to Help Ensure Quality

Generic and biosimilar prescription medicines, like their respective reference listed drugs and reference products (referred to throughout as

[3] Yu LX, Amidon G, Khan MA, Hoag SW, Polli J, Raju GK, Woodcock J. Understanding pharmaceutical quality by design. AAPS J. 2014 Jul;16(4):771-83. doi: 10.1208/s12248-014-9598-3.
[4] *Id.*

their originator counterparts), undergo a demanding development process and quality testing that supports an application submitted to FDA for market approval. The U.S. FDA has high standards, long considered the gold standard globally, to ensure the safety, efficacy, and quality of all pharmaceuticals manufactured for U.S. patients, regardless of where they are manufactured and whether they are originator, generic, or biosimilar medicines. FDA applies these high standards not only during the approval process but also throughout the product life cycle.

The most important regulatory requirements are FDA's Current Good Manufacturing Practice regulations (CGMPs).[5] CGMPs cover the entire manufacturing process and are intended to ensure that the facilities, methods, and controls used in the manufacture of all approved drugs and biologics, including generics and biosimilars, establish and maintain their identity, strength, potency, quality, and purity.[6] CGMPs require all drug and biologic manufacturers to implement systems that ensure proper design, monitoring, and control of manufacturing processes, facilities, and personnel, providing an essential tool in ensuring pharmaceutical quality.[7]

CGMPs include multiple safeguards and built-in redundancies at each step of the manufacturing process to prevent defective or contaminated drugs from reaching America's patients.

These CGMPs are supplemented by FDA guidance, including International Council for Harmonisation ("ICH") guidelines adopted by the FDA, applicable United States Pharmacopeia ("USP") standards, and pharmaceutical Quality Management System ("QMS") best practices in the manufacture of generics and biosimilars, all applied with patient safety as the number one priority.

As an additional safeguard, after approval, FDA also requires manufacturers to report adverse events of which they become aware, and the Agency engages in risk-based testing and surveillance of marketed products and conducts periodic inspections to evaluate whether facilities remain in compliance with regulatory requirements.

[5] 21 CFR Parts 210 and 211.
[6] FDA. Facts About the Current Good Manufacturing Practice (CGMP). Accessed February 9, 2026.
[7] *Id.*

C. Generics and Biosimilars in the U.S. Are of High Quality

AAM and its member companies' have an outstanding track record for safety and ensuring U.S. patients receive safe and effective, high-quality generic and biosimilar medicines. Generic and biosimilar medicines comprised 90% of all prescriptions filled in the U.S. in 2024.[8] That equates to about 3.9 billion generic prescriptions and 435 million brand prescriptions filled in 2024. These drugs and biosimilar medicines are produced at approximately 3,000 manufacturing facilities worldwide.[9] As explained above, the regulatory requirements and stringent quality standards for generics and biosimilars are designed to ensure that these products are as safe and effective as their originator counterparts, and FDA conducts inspections of manufacturing facilities to verify that the facilities are complying with regulatory requirements.

Generic drug and biosimilar manufacturers' commitment to product quality and the industry's implementation of these multiple, layered safeguards pursuant to FDA oversight ensures release of any defective product into the market is a relatively rare occurrence.

III. Addressing Misunderstandings About and Mischaracterizations of Generic and Biosimilar Medicines Is Essential to Maintaining Confidence in the Drug Supply

A. FDA's Approach to Addressing Shortages of Drugs on Import Alert Appropriately Safeguards Quality While Preserving Patient Access to Lifesaving and Life-Sustaining Medicines

Generic drugs play an important role in preventing, mitigating and resolving drug shortages, especially for essential, older, and hospital administered medicines. When the originator or a generic manufacturer experiences a disruption, other generic manufacturers may be able to increase production or enter the market quickly if they already hold FDA approval. FDA actively uses regulatory flexibility to support drug availability during shortages including expedited reviews, temporary enforcement discretion, and prioritization of inspections and approvals.

---

[8] 2025 Savings Report, *supra* note 1.

[9] FDA, Center for Drug Evaluation and Research ("CDER"), 2025. FY2024 Report on the State of Pharmaceutical Quality ("FY2024 Report on Quality") at 4-5. The CDER maintains a "CDER Site Catalog" described as "a curated inventory of registered manufacturing sites vetted by FDA as legally manufacturing human drugs for the U.S. market." FY2024 Report on Quality at 4. According to the report, 64% of the sites listed in the Catalog manufacture at least one NDA, ANDA, or biological product license application ("BLA"), which include biosimilars.

It has been reported that FDA is allowing drugs from noncompliant facilities that are under import alert into the country. In fact, FDA has typically only allowed drugs or biologics to be imported from a facility that is under import alert due to noncompliance with CGMPs if restricting importation may cause or exacerbate a shortage of that medicine in the U.S., and no alternative treatment would be available. Preventing drug shortages in these circumstances is essential to protecting public health, as drug shortages can result in patient injury or death and the risks of patient injury from specific CGMP violations may be small. As explained by FDA, CGMP violations do not necessarily mean the finished drug product is of poor quality, contaminated, or otherwise defective.[10] Furthermore, FDA will typically only permit importation of these critical medicines if certain safeguards are followed, such as the manufacturer's use of a third-party consultant to provide an additional level of review, examination, or testing of product before the product is released to the market, and assurance is provided by the manufacturer that the third-party's findings will be sent to FDA before the product is released.

It is in the best interest of patients who need these critical medicines that FDA continue to exercise smart, risk-based regulatory discretion, applied on a case-by-case basis, to prevent or mitigate drug shortages while maintaining appropriate quality safeguards. Because of this, AAM supports these targeted and effective policies to mitigate and prevent drug shortages and protect patients, as we have discussed at length in various forums.[11]

B. Adverse Event Reporting Is Essential for Detecting Potential Safety Signals, But It Is Not Designed to Be Used as a Quality Metric

AAM supports FDA's robust adverse event reporting requirements, which play an important role in helping FDA and manufacturers identify and evaluate potential safety signals for further investigation. These signals can help manufacturers identify emerging quality or safety issues, take corrective action when needed, and ultimately better protect patients.

[10] Facts About the Current Good Manufacturing Practice (CGMP), supra note 6. FDA may pursue regulatory action for CGMP noncompliance, regardless of whether the drug or biologic is contaminated or otherwise defective.
[11] See, e.g., AAM, Drug Shortages: Causes and Solutions (June 22, 2023), and IQVIA, Drug Shortages in the U.S. 2023 (November 15, 2023)

However, a numerically higher number of adverse event reports is not necessarily indicative of poor quality. FDA's Adverse Event Reporting System ("FAERS") includes duplicate and incomplete reports.[12] In addition, manufacturers are required to report adverse events irrespective of causation,[13] and there are many reasons why a patient may experience an adverse event that are unrelated to a particular drug or biologic. For example, adverse event reports may be related to the underlying disease being treated or caused by some other drug taken concurrently. In addition, many factors can influence whether any given adverse event is voluntarily reported by patients or healthcare practitioners such as the length of time a product has been marketed and any publicity about a patient or patients who experienced a similar adverse event.[14]

Accordingly, as explained by FDA, the information in the reports cannot be used to estimate the incidence (occurrence rates) of the events reported,[15] and, therefore, the reports are not useful measures of quality nor should they form the basis for product quality comparisons across products.

C. Increased Broad, Untargeted Post-Approval Testing of Drugs and Biologics Is Unlikely to Provide Helpful Information

Generic drug and biosimilar manufacturers are required to conduct comprehensive, scientifically rigorous testing before their medicines can be released into the market. In addition, FDA conducts post-approval oversight, including testing of finished products and components collected during inspections, surveillance sampling, and targeted, risk-based testing of marketed products. This risk-based framework is grounded in validated and FDA-recognized analytical methods, scientific expertise, and regulatory context. By contrast, broad, untargeted post-approval testing conducted by third parties using methodologies that may not be validated, standardized, or aligned with FDA-recognized approaches is unlikely to provide meaningful or reliable information regarding product quality. Such testing can generate misleading or incomplete conclusions, create unnecessary public confusion, produce false positives and false negatives, and divert attention and resources away from legitimate quality

[12] FDA. FDA Adverse Event Reporting System (FAERS) Public Dashboard ("FAERS Public Dashboard"). Accessed February 7, 2026.
[13] *Id.* See also 21 C.F.R. 314.80(a) and 21 C.F.R. 600.80(a) (defining adverse experience as any adverse event associated with use of the product "whether or not considered" product related).
[14] FAERS Public Dashboard, Frequently Asked Questions (FAQs), "Does FAERS data have limitations?" Accessed February 7, 2026.
[15] FDA Adverse Event Reporting System (FAERS) Public Dashboard, *supra* note 13.

signals and established regulatory processes. FDA's science- and risk-based oversight framework remains the most appropriate and reliable mechanism for ensuring the continued quality, safety, and effectiveness of generic drugs and biosimilars.

Requiring FDA to conduct testing would impose a significant resource burden on FDA with limited, if any, benefit, as broad-based testing is not an effective means of identifying noncompliant products yet will increase costs and divert limited Agency resources from proven quality surveillance activities. Untethering testing from FDA's current risk-based approach and evaluating products for which there is no evidence of a suspected problem further complicates interpretation of the testing results.

Ultimately, flooding the market with incorrect or suspect test results, or even valid results from which no conclusions can be drawn, could unnecessarily undermine confidence in a particular drug and possibly even the entire drug supply. Relatedly, these results could also distract manufacturers, the public, and FDA from monitoring and addressing legitimate product quality issues that are based on reliable testing.

D. Pre-Announced Inspections Are Effective and AAM Supports Efforts to Increase the Number of Unannounced Foreign Inspections

FDA conducts both pre-approval inspections ("PAIs") and surveillance inspections. PAIs are typically pre-announced, regardless of whether they are domestic or foreign so that investigators can observe the product being manufactured during the inspections.

The law requires FDA to conduct surveillance inspections using a risk-based approach that FDA has employed successfully for years.[16] Domestically and abroad, FDA conducts both pre-announced and unannounced surveillance inspections, with domestic surveillance inspections more often unannounced because they do not require coordination with foreign governments. FDA typically has pre-announced routine surveillance inspections of facilities abroad to ensure that appropriate records and personnel would be available when investigators

[16] 21 U.S.C. 360(h)(3).

arrive at the facility.[17] However, on May 6, 2025, the FDA announced its intent to expand the use of unannounced inspections at foreign manufacturing facilities, building on its pilot program in India and China to bring foreign oversight more in line with domestic inspection practices.[18]

Although pre-announced inspections are effective oversight tools domestically and abroad,[19] AAM supports expanding the use of unannounced foreign inspections, where appropriate, to better align FDA's oversight of domestic and foreign facilities.

IV. Conclusion

AAM and its members are committed to the manufacture of safe, effective, and high-quality generic drugs and biosimilars. Overall, the quality of generic and biosimilar medicines in the U.S. is high and well-supported by current policies and practices. AAM continues to support efforts to promote a positive regulatory and policy environment to expand patient access to high-quality, safe and effective generic and biosimilar medicines.

[17] See, e.g., FDA Guidance for Industry, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection" (June 2024) at p. 7

[18] FDA. FDA Announces Expanded Use of Unannounced Inspections of Foreign Manufacturing Facilities. Accessed February 7, 2026.

[19] Notably, Congress has acknowledged the utility of pre-announced inspections for medical devices in particular. The FDA Reauthorization of Act of 2017 ("FDARA") went as far as requiring FDA to pre-announce all inspections (other than for-cause inspections) of medical device establishments. See FDARA section 702(a) (amending 21 U.S.C. 374). Congress found that, *inter alia*, a "Greater transparency concerning the timing and nature of routine inspections of device establishments would improve the quality and efficiency of the inspection process." H.R. 1736, Section 1. Findings, paragraph 5.