STRATEGIC RESEARCH AND PERSPECTIVES SERIES

FDA Oversight of Imported Medicines

Approval requirements, border screening, and strategic safeguards for United States healthcare organizations

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POSITION

Imported medicines should be judged by verifiable authorization, manufacturing integrity, and documented custody, not by country of origin. Affordability and importation policy should expand only in step with the inspection capacity and public safety reporting needed to prove that patients are protected.

Strategic imperatives

- **Verify the pathway before the price.** Every imported product should be tied to a lawful regulatory basis before a purchasing commitment is made.
- **Treat the border as one checkpoint, not the safety system.** Entry screening does not replace manufacturing oversight, supplier qualification, or post-market surveillance.
- **Fund inspection capacity as patient-safety infrastructure.** Persistent foreign-inspection workforce gaps are a strategic vulnerability for every health system that depends on global supply.
- **Measure savings and safety together.** Importation programs should publish both, using denominators that allow fair comparison.

Executive perspective

Healthcare organizations should evaluate an imported medicine through its lawful marketing pathway, manufacturing controls, and documented supply chain. Country of origin alone is an inadequate safety measure. A medicine manufactured abroad can meet United States standards; a familiar brand purchased through an unauthorized foreign seller may lack those assurances. The strategic priority is reliable access with verifiable quality, rather than a blanket preference for domestic or foreign production. [1]

The term FDA clearance is often associated with medical devices. For medicines, the relevant questions are whether the product has the required approval or other lawful regulatory basis

and whether a particular shipment is admissible. Border screening is one component of oversight. It does not substitute for evaluation of clinical safety and effectiveness, manufacturing compliance, or ongoing quality surveillance. [2,3]

This paper addresses finished human medicines entering the United States, including commercial supply, limited personal importation, and the Section 804 pathway for certain Canadian prescription drugs. It is written for healthcare executives, procurement and pharmacy leaders, and policymakers. The recommended operating model assigns a pharmacist and a regulatory lead shared accountability for product verification before purchasing commitments are made.

What FDA verifies

FDA describes several applicable requirements: an approved application or another authorized pathway, foreign establishment registration, drug listing, compliant labeling, and current good manufacturing practice. New drug applications, abbreviated applications for generics, biologics licenses, and investigational applications serve different purposes. Certain nonprescription medicines may instead meet an applicable OTC monograph. Active pharmaceutical ingredients also have applicable import requirements. The correct pathway depends on the product and intended use. [2]

Registration identifies an establishment; listing records a product. Neither establishes FDA approval. FDA specifically cautions that inclusion in the National Drug Code directory does not demonstrate that a medicine is approved or legally marketable. A supplier displaying an NDC or a registration certificate therefore has not answered the central authorization question. [4]

Oversight component	What it addresses	What it cannot establish alone
Product authorization	Lawful regulatory basis for the exact medicine	Condition of a particular shipment
Registration and listing	Establishment and product identification	FDA approval or product quality
Manufacturing oversight	Production controls and compliance	Freedom from every possible batch defect
Import review	Admissibility using entry information and further review	Clinical appropriateness for each patient
Procurement verification	Supplier identity and documented custody	A replacement for regulatory requirements

How border screening works

Import entry information identifies the manufacturer, importer or consignee, product description, intended use, and relevant affirmations of compliance. FDA compares these declarations with its databases, and its PREDICT system supports electronic risk-based screening. Missing or inconsistent information may trigger additional review or detention; FDA can also examine products and analyze samples. Accurate entry data can facilitate review, but electronic processing does not mean that every unit received laboratory testing. [3]

A shipment that appears to violate the Federal Food, Drug, and Cosmetic Act can be refused. Detention provides an opportunity to supply evidence concerning admissibility or a permissible means of bringing the product into compliance. If a shipment is refused, FDA states that it must generally be exported or destroyed under agency and Customs and Border Protection supervision within 90 days of the refusal notice. Purchasing policies should distinguish a shipment awaiting review from stock released for patient use. [5,6,7]

The practical inference is that quality cannot depend entirely on what happens at the border. A procurement record should link the exact formulation and strength to the lawful pathway, manufacturing site, supplier, lot, expiration date, and storage conditions. This is a recommended organizational safeguard, not a claim that every listed field is universally required for every import category.

Personal importation and Canadian programs

FDA states that personal importation of an unapproved foreign drug is illegal in most circumstances. Its policy describes situations in which personnel may exercise enforcement discretion, including certain serious conditions without effective domestic treatment, absence of promotion to United States residents, no unreasonable risk, and written confirmation of personal use. A quantity generally no greater than a three-month supply and treatment documentation are part of the considerations. These conditions do not create an automatic exemption or authorize clinic resale. Rules for visiting foreign nationals and controlled substances require separate attention. [8]

Section 804 programs allow states and Indian tribes to propose time-limited importation of certain prescription medicines from Canada. FDA authorization, an eligible product, and program-specific requirements remain necessary. The framework includes authentication, testing, relabeling, records, and other controls. It excludes categories such as biological products, controlled substances, certain infused or injected medicines, and medicines subject

to risk evaluation and mitigation strategies. Program authorization should not be described as unrestricted approval of all Canadian medicines. [9,10]

An executive evaluating lower-cost sourcing should therefore ask which pathway applies before assessing the price. Personal-use discretion and a state importation program solve different problems. Neither should be repurposed as an informal route for a wellness practice or hospital to buy otherwise unauthorized stock.

Inspection capacity and residual uncertainty

GAO has documented persistent problems in FDA oversight of foreign drug manufacturing, including workforce constraints and challenges involving inspection notice and interpreters. Its 2025 workforce report discusses retention and the agency's use of alternative inspection tools. These findings support investment in inspection capacity and better oversight metrics. They do not establish that all medicines from a particular country are defective, and historical inspection figures should not be presented as the probability that a specific shipment is unsafe. [11]

Risk assessment should distinguish the severity of a possible failure from its likelihood. A compromised sterile medicine warrants a different response from a paperwork discrepancy. Organizations should examine the exact site and product, relevant import alerts and compliance history, supplier responsiveness, and the availability of alternative authorized supply. Any resulting classification remains an organizational judgment requiring qualified review.

Policy and strategic recommendations

Stakeholder	Recommended action	Measure of success
Congress and federal appropriators	Fund and retain FDA foreign-inspection staff; require public reporting of inspection coverage by product risk	Inspection coverage and staff retention reported annually
FDA	Link site, batch, import, and recall data in a shared surveillance view with protected commercial data	Time from signal to action on implicated lots
States and tribes using Section 804	Publish verified savings alongside quality findings and adverse events per units imported	Savings and safety reported on the same denominator

Stakeholder	Recommended action	Measure of success
Health system executives	Require a product-specific verification file before any new supplier is approved	Share of purchases with complete verification
Pharmacy and procurement leaders	Contract for lot identity, temperature records, recall cooperation, and refusal contingencies	Recall response time; unresolved discrepancies

Before adding a supplier, pharmacy and procurement teams should document authorization, site identity, supplier legitimacy, and shipment custody, resolving discrepancies before distribution rather than relying on a broker's assurance or an NDC. Escalation to regulatory counsel should be routine when the pathway is unclear, and every clinically important medicine should have an alternative sourcing plan. Country rankings without adjustment for product volume, formulation, and inspection intensity would be misleading and should not drive purchasing.

Strategic lens

Healthcare improvement. Medication quality is a patient-safety outcome. Verification files, recall drills, and lot-level incident tracking convert regulatory requirements into measurable reliability.

Resilience and stewardship. Diversified, documented supply reduces shortage risk and the waste created when stock is detained, refused, or destroyed. Resilient sourcing is also responsible resource stewardship.

Scientific advancement. A national surveillance model linking manufacturing, testing, shipment, and clinical data would enable rigorous, denominator-based comparison of importation pathways.

Research priorities and decision standard

A stronger surveillance system would link manufacturing-site information, batch testing, shipment findings, recalls, and clinical reports while protecting commercially sensitive and patient data. Researchers should use denominators such as lots or doses distributed and compare similar products. Voluntary adverse-event reports can identify signals, but cannot alone determine incidence or causation.

The recommended decision standard is documented eligibility and accountable sourcing, supported by continued quality monitoring. The most useful policy evaluation would test whether an importation pathway improves access without increasing verified quality failures, while accounting for the medicines and populations involved.

Research approach

This paper is a targeted narrative evidence synthesis for strategic decision-making, with sources reviewed on 1 October 2026. It prioritizes official regulatory material and government oversight reports. It is not a systematic review or original empirical study. Findings are distinguished from the author's recommendations. Regulatory pathways, product eligibility, and program status change and should be confirmed with FDA and qualified regulatory counsel for any specific transaction.

References

[1] FDA. Human Drug Imports. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports

[2] FDA. General Requirements for Importing Human Drugs. https://www.fda.gov/drugs/human-drug-imports/general-requirements-importing-human-drugs

[3] FDA. Importing Human Drugs. https://www.fda.gov/industry/importing-fda-regulated-products/importing-human-drugs

[4] FDA. National Drug Code Database Background Information. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information

[5] FDA. Shipment Admissibility. https://www.fda.gov/drugs/human-drug-imports/shipment-admissibility

[6] FDA. Detention and Hearing. https://www.fda.gov/industry/fda-import-process/detention-hearing

[7] FDA. Import Refusals. https://www.fda.gov/industry/fda-import-process/import-refusals

[8] FDA. Personal Importation. https://www.fda.gov/industry/import-basics/personal-importation

[9] FDA. Importation Program under Section 804 of the FD&C Act. https://www.fda.gov/drugs/human-drug-imports/importation-program-under-section-804-fdc-act

[10] Electronic Code of Federal Regulations. 21 CFR Part 251, Section 804 Importation Program. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-251

[11] GAO. Drug Safety: FDA Should Implement Strategies to Retain Its Inspection Workforce. GAO-25-106775. 2025. https://www.gao.gov/products/gao-25-106775

About the author

Jayne J. Smith, MSN, MBA, RN, is a nurse executive with more than 15 years of combined clinical, operational, and financial leadership experience. Her nursing leadership spans multi-site home health, assisted living, memory care, long-term care, hospice, and case management in rural communities, alongside prior multi-state business leadership in strategy, human resources, and operations. She is completing a Doctor of Nursing Practice.

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