AAM GRx+Biosims

FDA ANDA Prioritization Pilot

A new incentive for U.S. generic drug manufacturing & testing

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Pilot eligibility: All three conditions must be demonstrated

Applicants should substantiate the domestic pathway when requesting prioritization.



1

U.S. bioequivalence pathway

Pivotal BE testing conducted in the United States, or the ANDA qualifies for a waiver of BE testing.

2

U.S. finished dosage form

Finished dosage form manufacturing site is located in the United States.

3

U.S. API source

The API supplier is located in the United States.

Priority Review: An Onshoring Catalyst

FDA links priority review eligibility to an entirely domestic testing and manufacturing pathway.

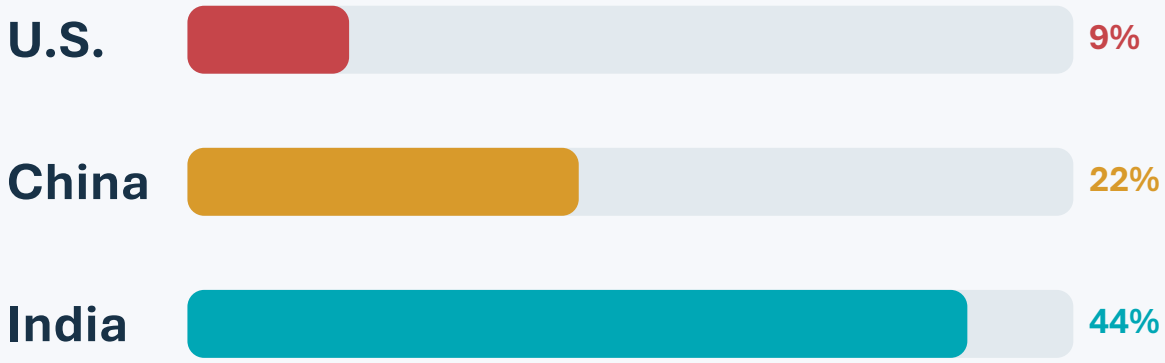
Priority review is now an explicit onshoring incentive for qualifying original ANDAs

53%
Brand products manufactured outside the U.S.

69%
Gx products manufactured outside the U.S.

9%
API manufacturers located in the U.S.

API manufacturing footprint



- The incentive applies only when all three domestic criteria are met
- FDA expects faster review, not reduced approval standards
- Value depends on early alignment of portfolio, BE strategy, API sourcing, finished-dose site, and inspection readiness

Request mechanics: Use MAPP 5240.3 and make the basis explicit

FDA evaluates prioritization at submission and expects a clear, supported request.

Cover letter

State “Priority Review Requested” and identify the ANDA number.

Pilot basis

Reference the U.S. manufacturing and testing pilot as the prioritization basis.

Qualification evidence

Provide sufficient support for BE or waiver, U.S. FDF site, and U.S. API supplier.

Submission-specific request

Request priority review for each applicable submission

What “priority review” can mean

Shorter goal date when applicable, or **expedited review** with FDA striving to act as soon as possible.

Important limitation

If FDA has already assigned a goal date, granting priority review does not shorten that existing goal date.

The pilot sits within a broader FDA onshoring agenda

1 PreCheck

Aims to improve readiness of new U.S. facilities

Facility Readiness Phase: Early technical advice, pre-operational reviews, and potential use of a facility-specific DMF

Application Submission Phase: Pre-submission engagement intended to resolve issues and expedite quality assessment and inspections

2 GDUFA "America First" Proposals

Seeks to incentivize both new and existing U.S. facilities

Includes U.S. manufacturer ANDA fee waiver, foreign fee differential increase, early inspections for U.S. manufacturers expanding capacity

3 ANDA prioritization pilot

Rewards domestic execution

Priority review request tied to domestic BE or waiver, U.S. FDF manufacturing, and U.S. API supply.



Facility strategy, evidence strategy, and regulatory timing must be designed as one integrated pathway

Strategic implications for the portfolio

The economics of prioritization must be assessed against sourcing, site, study, and execution trade-offs

OPPORTUNITY

- Potentially faster review for qualifying U.S.-made generics
- Enhanced case for domestic network investment
- Earlier patient access when execution is launch-ready

CONSTRAINTS

- All three pilot criteria appear cumulative
- Domestic API availability may be the limiting factor
- Priority review does not cure CMC, facility, or inspection gaps

DECISIONS

- Which pipeline assets can realistically qualify?
- Does expected review value justify domestic cost and complexity?
- Can supply continuity be maintained at commercial scale?

Recommendation: Screen selectively and advance only where the complete domestic pathway is credible before submission.

Risk Areas and Potential Impact

Supply continuity

Domestic API Availability

Supply Chain Concentration

Drug Shortage / Supply Continuity Risk

Manufacturing economics

Capacity Constraints

Technology Transfer & Validation Risk

Increased Cost of Goods

Regulatory & market risk

Uncertain Regulatory Benefit

Implementation Uncertainty

Pilot Program Changes

Competitive Disadvantage

Absence of Additional Market Incentives

Summary

The pilot offers a potentially useful benefit, but only for the right targets and when the complete U.S. testing and manufacturing pathway is credible and otherwise economically feasible.

Execution priorities

The greatest opportunity will come from identifying appropriate assets early and ensuring that regulatory acceleration is matched by manufacturing, inspection, supply, and launch readiness.

Additional considerations

Downstream commercialization and reimbursement implications should be assessed and identified early.