Advancing Inspection and Remote Assessment Efficiencies to Accelerate Approvals

Bhupesh Singh Bisht
Director Regulatory Strategies and Labeling

Nov 03, 2026

Disclaimer

The views and opinions expressed herein are solely those of the author(s) and should not be construed as representing the official position, views, or strategies of Apotex.

What FDA is doing, and how the generic industry must be ready

1. **FDA's expanding inspection toolkit**
   Onsite inspections, RRAs, 704(a)(4) records requests/Remote Interactive Evaluation (RIE)

2. **Why this matters**
   Facility signals now drive first-cycle approval, launch reliability

3. **The regulatory shift**
   From episodic inspection to continuous, data-driven facility intelligence.

4. **FDA Enhancements and GDUFA IV**
   Where the generic industry can shape policy, and the actions to take now.

5. **Policy asks and takeaways**
   Where the generic industry can shape policy, and the actions to take now.

APOTEX

Multiple complementary mechanisms, not a single replacement for onsite inspection.

Onsite inspections

PAI, surveillance, for-cause and follow-up

Remote Regulatory Assessments

Records review and remote interactive evaluation (RIE)

Section 704(a)(4)

Records requested in advance of or in lieu of inspection

Mutual Recognition Agreements

Reliance on trusted foreign GMP inspection information

One-day assessments

Short, focused screening for selected lower-risk facilities

APOTEX

Match oversight intensity to facility risk while retaining authority to escalate

Timely approval are increasingly enabled by strong alignment between application review and facility compliance

Inspection readiness is now approval readiness

Portfolio leverage

One facility signal can affect multiple applications, products and supply relationships

Approval efficiency

Facility issues can undermine review efficiency and delay approval

Launch reliability

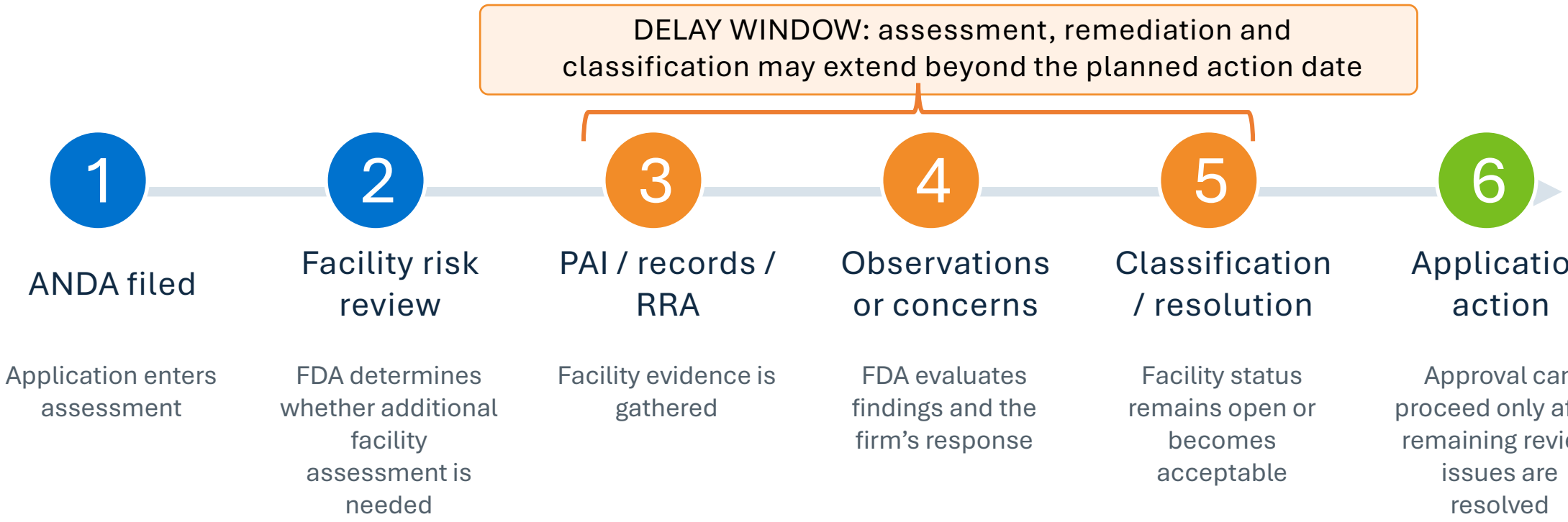
Facility status can affect first-cycle approval, supply planning and launch confidence

Address facility risk before it becomes a late-cycle approval barrier.



Efficiency comes from resolving facility questions early with evidence-ready responses.

How a facility issue can move onto the approval critical path



The delay is created when unresolved facility questions remain on the approval pathway near the application goal date.

From episodic inspection to continuous regulatory oversight

1 PAST STATE

Scheduled, even-driven oversight

Inspections were typically centered around an onsite visit.

Readiness was event-based

Sites prepared around anticipated inspections

2 REGULATORY SHIFT

Oversight extends beyond inspection

Records requests, remote assessments and risk signals enable earlier regulatory scrutiny

Scrutiny starts earlier

Issues can surface before an inspection or classification

3 CURRENT STATE

Continuous facility intelligence

Facility readiness, data integrity and remediation credibility influence regulatory decisions

Evidence quality sets the pace

Timely, credible evidence can accelerate issue resolution

FDA oversight is becoming more continuous, data-driven and risk-based

Industry to shift the operating model from reactive inspection response to proactive approval-readiness governance.

FDA assessment and facility pathways: GDUFA III and proposed IV

Assessment communications

IR/DRL requests
Resolve issues during assessment

Imminent actions
Notice of approaching FDA action

Major deficiencies & delays
Visibility into issues and timing

Classification changes
Procedures during assessment

Meetings & teleconferences
Clarification and resolution

Facility transparency and Remediations

Classification database
Public facility status

Foreign regulators
Eligible U.S. compliance status

Risk-based site selection
Inspection prioritization

Post-warning letter meetings
Feedback on corrective plans

Reinspection
Certain OAI facilities eligible

Proposed GDUFA IV – readiness and Resolution

Pre-submission correspondence
Earlier planning and shorter priority review goals

Domestic surveillance requests and Facility reinspection
Before ANDA/PAS/API DMF,.
Separate request path after remediation

Inspection communication
Classification: 90 days
Database updates: 30 days

Post-PAI meetings
Clarify / resolve deficiencies before goal date

Post-warning letter meetings
Remediation progress and unresolved issues

Readiness at submission
Not ready: 15-month goal
Potential extension: 30 months

Align assessment responses, facility readiness and remediation plans with the relevant FDA pathway.

Policy Initiatives and key takeaways

More efficient oversight requires earlier communication, targeted regulatory tools and continuous facility readiness

Policy priorities

Earlier facility-risk communication

Signal facility-related approval risks before late-cycle action

Expand use of remote assessments

Use RRAs to clarify issues and verify remediation when appropriate

Align inspections with review priorities

Prioritize inspection resources around pending applications and goal dates

Key takeaways

Oversight is becoming more continuous

Inspections, RRAs, records requests, and reliance tools work together

Readiness must be continuous

Facility evidence must be ready throughout the application lifecycle

Speed + credibility drive resolution

Rapid, evidence-based responses help resolve facility issues earlier

The shared goal: identify facility risk earlier, resolve issues faster and prevent avoidable approval delays

Thank you

APOTEX