WINDSHIRE CONSULTING

AMT Designation Program

Pre-Submission Readiness Checklist

Section 506L, FD&C Act · Based on FDA Final Guidance, December 2024

FDA Review Deadline	Program Sunset Date
180 calendar days from receipt	**October 1, 2032 — no requests accepted after this date**

1. Eligibility Confirmation Gate 1

- ☐ **Novel technology confirmed:** FDA has limited prior assessment experience with this technology.
- ☐ **Substantial improvement documented:** Technology demonstrably improves the manufacturing process while maintaining equivalent or superior drug quality.
- ☐ **Statutory pathway identified:** Designation basis confirmed as (a) reducing development time, (b) maintaining supply of a critical drug, or (c) addressing a drug on the 506E shortage list. REQUIRED
- ☐ **Application type clarified:** Confirm whether the eventual submission will be an NDA/ANDA or BLA — cross-referencing rights differ materially. BLA SPONSORS: SEEK GUIDANCE FIRST

2. Process Maturity Requirements Gate 2

- ☐ **Process development data available:** Multiple runs demonstrating the technology consistently and reliably produces product meeting quality specifications. PROOF-OF-CONCEPT ALONE IS INSUFFICIENT
- ☐ **Control strategy defined:** PAT approach and process controls are sufficiently described to support a credible context of use submission.
- ☐ **Scale confirmed:** Technology has been demonstrated at a scale sufficient to make the proposed context of use technically defensible, not aspirational.
- ☐ **Quality specifications established:** CQAs identified and manufacturing data shows specifications are consistently met within the proposed context of use.

3. Context of Use Definition Gate 3

- ☐ **Context of use scoped correctly:** Neither too narrow (limiting downstream referencing utility) nor too broad (unsupported by available data). CRITICAL DECISION
- ☐ **Multi-product referencing strategy considered:** If designation is intended to support multiple products, confirm authorized party structure and data referencing rights are legally documented.

☐ **Designation holder identified:** Confirm whether sponsor, CMO, or technology developer will hold the designation and establish contractual arrangements accordingly.

4. Submission Readiness Gate 4

☐ **Early FDA engagement assessed:** Determined whether interaction through the AMT program's own framework is warranted before submission, or whether technology maturity supports proceeding directly. ETT/CATT NO LONGER A PREREQUISITE

☐ **Specific regulatory questions answered from early interactions (if applicable):** Bounded, specific CMC questions identified for FDA interactions — early meetings should not be used for open-ended feasibility exploration.

032 sunset mapped against development timeline: Confirmed the technology can support a credible submission before October 1, 2032, accounting for remaining development and partner application cycles. TIME-SENSITIVE

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⚠ Note for BLA Sponsors

The cross-application data referencing benefit that makes AMT designation particularly valuable for NDA platform technologies operates differently for biologics. The February 2024 BLA master file final rule codifies that BLAs cannot rely on a master file for drug substance, drug intermediate, or drug product information — regardless of AMT designation. This tension between the AMT program's intent and existing BLA policy remains an open regulatory issue. Biologics sponsors should seek expert guidance before committing resources to a designation request.

Let's Connect. We can help you through this process!

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