

## SECTION 4.3

# EAC Authorization Decision Tree

## PURPOSE

Codify the authorization standard an FDA investigator will apply when reconstructing a compounding decision under the "Essentially a Copy" provision of FDCA Section 503B. This tree must be embedded in order intake. Release shall be blocked until the authorization outcome is determined and documented.

## ORDER RECEIVED FOR COMPOUNDING

*Is the requested drug on the current FDA Drug Shortage List?*

### A. ON SHORTAGE LIST

Verify listing status and effective dates against FDA Shortage Database at time of order. Document allocation attempts from approved manufacturers. Capture authorization rationale with timestamp.

CONDITIONAL AUTHORIZE

### B. NOT ON SHORTAGE LIST — SIGNIFICANT DIFFERENCE DOCUMENTED

Verify prescriber-signed Significant Difference attestation (Section 4.4). Confirm difference is clinical, not cost or preference. Link attestation to order and lot.

AUTHORIZE

### C. NOT ON SHORTAGE LIST — NO SIGNIFICANT DIFFERENCE

Order does not meet 503B "clinical need" standard. Cost, preference, and shortage rumor are non-authorizing rationales. Notify ordering account in writing.

BLOCK RELEASE

### AUTHORIZATION STANDARD

*"Clinical need" is not satisfied by commercial shortage, backorder, price, or formulary preference. Authorization requires demonstration that the FDA-approved product cannot meet a defined clinical requirement for the patient population.*

FDA Guidance for Industry – Bulks List, §III.B (Apr 30, 2026 revision)

### DECISION ANCHOR

Every order that exits this tree carries a reconstructable authorization record: branch taken, evidence reviewed, decision owner, timestamp. If the order cannot produce all four under inspection, the authorization did not occur.

### THIS IS 1 OF 43 PAGES

The full playbook includes 12 ready-to-use templates and a 90-day implementation plan for surviving the June 29 enforcement window. Stop-loss policy, Significant Difference attestation, ISO 5 reconstruction drill, role scorecards, and the 30-second reconstruction test.

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