BatchBuddy

Private Label Brand

Compliance Checklist

21 CFR Part 111 Brand-Owner Obligations

Key Fact	Private label brands are fully responsible for 21 CFR Part 111 compliance — regardless of who manufactured the product
Audience	Private label supplement and CPG brand owners who use contract manufacturers
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PRIVATE LABEL BRAND FDA LIABILITY — WHAT YOU NEED TO KNOW

Your Compliance Obligations Under 21 CFR Part 111

If your name is on the label and you distribute the product, the FDA holds you responsible for 21 CFR Part 111 compliance — regardless of who manufactured it. This 7-section checklist maps every documentation obligation a private label brand carries. Use it to identify gaps before an FDA inspection, retailer qualification, or recall forces the issue. Rate each item: ✓ **Have it**, ■ **Partial**, or ✗ **Gap**.

1. FINISHED PRODUCT SPECIFICATIONS (§111.70)

Ref	Requirement	Priority	Status
SP-1	Written finished product specifications exist for every product you private label — identity, purity, strength, and composition	**High**	■ Have it ■ Partial ■ Gap
SP-2	Specifications are versioned and controlled — you know which spec governed each production lot	**High**	■ Have it ■ Partial ■ Gap
SP-3	Every lot produced under your label is verified against your specifications before it's released to your customers	**High**	■ Have it ■ Partial ■ Gap
SP-4	Out-of-specification results are investigated and documented — not just accepted	**High**	■ Have it ■ Partial ■ Gap

2. COA REVIEW & MANUFACTURER OVERSIGHT (§111.75)

Ref	Requirement	Priority	Status
COA-1	You receive a COA from your manufacturer for every lot produced under your label	**High**	■ Have it ■ Partial ■ Gap
COA-2	Each COA is reviewed against your finished product specifications — with that review documented	**High**	■ Have it ■ Partial ■ Gap
COA-3	COAs are stored in a retrievable system — not in email inboxes or unorganized folders	**High**	■ Have it ■ Partial ■ Gap
COA-4	Out-of-spec COAs trigger a formal response (rejection or CAPA) — not silent acceptance	**High**	■ Have it ■ Partial ■ Gap
COA-5	A quality agreement with your contract manufacturer is signed and current	**Medium**	■ Have it ■ Partial ■ Gap

3. LOT TRACEABILITY (§111.455 / FSMA 204)

Ref	Requirement	Priority	Status
LOT-1	Every finished product lot can be traced back to the ingredient lots used to produce it	**High**	■ Have it ■ Partial ■ Gap
LOT-2	Every finished product lot can be traced forward to every customer who received it	**High**	■ Have it ■ Partial ■ Gap
LOT-3	A full lot trace can be completed within 24 hours — without waiting for your CM to respond	**High**	■ Have it ■ Partial ■ Gap
LOT-4	Customer distribution records are current and accessible — including direct-to-consumer orders	**High**	■ Have it ■ Partial ■ Gap

4. CAPA & OOS INVESTIGATION (§111.303)

Ref	Requirement	Priority	Status
CAPA-1	A written OOS investigation procedure exists and is followed when a test result falls outside spec	**High**	■ Have it ■ Partial ■ Gap
CAPA-2	Corrective actions are documented with root cause, action taken, and effectiveness check	**High**	■ Have it ■ Partial ■ Gap
CAPA-3	CAPA records are searchable and retained — not buried in email threads	**High**	■ Have it ■ Partial ■ Gap

5. RECALL READINESS (§111 / Dietary Supplement Safety Act)

Ref	Requirement	Priority	Status
REC-1	A written recall procedure exists with documented roles, escalation steps, and notification procedures	**High**	■ Have it ■ Partial ■ Gap
REC-2	You can produce a complete list of all customers who received a given lot within hours	**High**	■ Have it ■ Partial ■ Gap

Ref	Requirement	Priority	Status
REC-3	A recall drill or simulation has been conducted in the past 12 months — results documented	**High**	■ Have it ■ Partial ■ Gap

6. CRYPTOGRAPHIC AUDIT TRAIL & ELECTRONIC RECORDS (§111.475 / 21 CFR Part 11)

Ref	Requirement	Priority	Status
AT-1	All quality records are maintained in a tamper-evident system — changes are logged, not silently overwritten	**High**	■ Have it ■ Partial ■ Gap
AT-2	Electronic records meet 21 CFR Part 11 controls: audit trail, access controls, identity-verified signatures	**High**	■ Have it ■ Partial ■ Gap
AT-3	Records are retained for 1 year past expiration date or 2 years past manufacture date	**High**	■ Have it ■ Partial ■ Gap

7. RETAILER & DISTRIBUTOR QUALIFICATION READINESS

Ref	Requirement	Priority	Status
RQ-1	GMP compliance documentation package can be produced within 24 hours of a retailer request	**High**	■ Have it ■ Partial ■ Gap
RQ-2	Finished product specifications, COA examples, and traceability documentation are ready to share	**High**	■ Have it ■ Partial ■ Gap
RQ-3	Recall procedure is documented in a format that can be shared with a retail buyer or distributor	**Medium**	■ Have it ■ Partial ■ Gap
RQ-4	Third-party GMP audit or equivalent quality documentation is current (within 12–24 months)	**Medium**	■ Have it ■ Partial ■ Gap

90-DAY COMPLIANCE ACTION PLAN FOR PRIVATE LABEL BRANDS

Close your gaps before an inspection, retailer audit, or recall surfaces them

Days 1–30: Specifications & COA Foundation · HIGH PRIORITY

• Write or obtain finished product specifications for every SKU you private label — file them in a controlled system

• Collect COAs from your CM for all lots produced in the past 12 months — review each against your specs

• Identify any lots without documented COA review — flag for retroactive review or CAPA

• Enroll BatchBuddy and begin importing COAs — link each to its corresponding lot record

Days 31–60: Traceability & CAPA · MEDIUM PRIORITY

• Build out lot traceability for all active lots — forward to every customer, backward to ingredient inputs

• Document any known OOS results or deviations as formal CAPA records with root cause and corrective action

• Draft or update your quality agreement with your CM — ensure it covers documentation access rights

• Run first lot trace exercise — verify you can complete a forward and backward trace in under 24 hours

Days 61–90: Recall Readiness & Retailer Package · COMPLETE & VERIFY

- Run a full recall simulation on your live lot data — document results, close gaps
- Assemble your retailer qualification package — specs, COA examples, CAPA log summary, recall procedure
- Verify customer distribution records are complete and current for all open lots
- Generate locked BatchBuddy compliance summary — your quality story in one signed, searchable document