BATCHBUDDY

CBD Brand

# FDA Enforcement Readiness Checklist

Prepare Before the Policy Finalizes

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|---|---|
| **Context** | In March 2026, the FDA submitted its first formal CBD enforcement policy to OIRA — the first concrete federal framework since the 2018 Farm Bill. Eight years of enforcement discretion is ending. |
| **Audience** | CBD finished product brands — tinctures, gummies, topicals, capsules, wellness products |
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WHAT THE FDA'S MARCH 2026 OIRA SUBMISSION SIGNALS

## Five Areas the Incoming CBD Enforcement Framework Will Focus On

While the full policy text remains confidential during OIRA review, the FDA's enforcement history and public statements indicate the coming framework will concentrate on these five areas. Rate your current readiness against each:

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|---|---|
| **cGMP Compliance** | Brands must prove their products were manufactured under documented quality controls — batch records, in-process testing, release signatures. The absence of cGMP documentation is the fastest path to a warning letter. |
| **COA Accuracy** | The actual CBD and THC content must match label claims, verified by DEA-registered labs. The FDA has already cited COA manipulation in enforcement letters — this will be a primary audit focus. |
| **Health Claim Enforcement** | "Treats anxiety," "supports immune function," "anti-inflammatory" — all at high enforcement risk if unqualified. Disease or drug-like claims without FDA approval will be the top enforcement target. |
| **Label Completeness** | Batch numbers, QR-code COA links, THC content statements, serving size, and required warnings. Labels that can't be traced back to a specific, documented batch will be flagged. |
| **Recall Readiness** | The FDA's mandatory recall authority under the framework means brands need traceable lot records — forward to every customer, backward to every supplier lot. This is a new expectation for most CBD brands. |

## SECTION 1: cGMP DOCUMENTATION

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **GMP-1** | Written batch records exist for every production lot — formula, ingredient lot inputs, in-process checks, yield, and release disposition | **Critical** | ■ Ready ■ Partial ■ Gap |
| **GMP-2** | Batch records are completed at production close — not reconstructed retroactively before an inspection | **Critical** | ■ Ready ■ Partial ■ Gap |
| **GMP-3** | Qualified personnel review and sign off on each batch record before product release | **Critical** | ■ Ready ■ Partial ■ Gap |
| **GMP-4** | In-process testing is documented within the batch record — not tracked in separate spreadsheets | **High** | ■ Ready ■ Partial ■ Gap |
| **GMP-5** | Production deviations are documented immediately at the time of occurrence, linked to the batch | **High** | ■ Ready ■ Partial ■ Gap |
| **GMP-6** | Personnel training records exist for all staff involved in production — roles and completion dates documented | **High** | ■ Ready ■ Partial ■ Gap |

## SECTION 2: COA ACCURACY & SUPPLIER OVERSIGHT

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **COA-1** | Every finished product lot has a COA from a DEA-registered testing laboratory | **Critical** | ■ Ready ■ Partial ■ Gap |
| **COA-2** | COA results are reviewed against your product specifications — not just filed | **Critical** | ■ Ready ■ Partial ■ Gap |
| **COA-3** | COA CBD content matches the label claim within acceptable variance | **Critical** | ■ Ready ■ Partial ■ Gap |
| **COA-4** | Total delta-9 THC is at or below 0.3% (dry weight) — documented and verified for every lot | **Critical** | ■ Ready ■ Partial ■ Gap |
| **COA-5** | COAs cover full contaminant panels — pesticides, heavy metals, mycotoxins, residual solvents | **High** | ■ Ready ■ Partial ■ Gap |
| **COA-6** | Out-of-spec COA results trigger a documented investigation — not silent acceptance | **Critical** | ■ Ready ■ Partial ■ Gap |
| **COA-7** | COA chain of custody is complete — every COA linked to the specific lot it covers | **High** | ■ Ready ■ Partial ■ Gap |

## SECTION 3: LABEL COMPLIANCE

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **LBL-1** | Every label includes the batch or lot number traceable to a production record | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LBL-2** | CBD content per serving and per container matches the COA for that lot | **Critical** | ■ Ready ■ Partial ■ Gap |

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **LBL-3** | Total THC content is accurately stated — delta-9 basis, verified by lot COA | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LBL-4** | No disease claims, drug claims, or implied FDA approval on any label or marketing material | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LBL-5** | QR-code COA linkage implemented where required by state (NY, TX, FL) | **High** | ■ Ready ■ Partial ■ Gap |
| **LBL-6** | Required warnings are present and legible — THC content statement, keep away from children | **High** | ■ Ready ■ Partial ■ Gap |

## SECTION 4: LOT TRACEABILITY

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **LOT-1** | Every finished product lot can be traced backward to every ingredient lot used in production | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LOT-2** | Every finished product lot can be traced forward to every customer who received it | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LOT-3** | A full lot trace can be completed within 24 hours — without manual reconstruction | **Critical** | ■ Ready ■ Partial ■ Gap |
| **LOT-4** | Customer distribution records are complete and current — including DTC orders | **High** | ■ Ready ■ Partial ■ Gap |

## SECTION 5: RECALL READINESS

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **REC-1** | A written recall procedure exists with documented roles, escalation, and FDA notification steps | **Critical** | ■ Ready ■ Partial ■ Gap |
| **REC-2** | You can produce a complete list of all affected customers within 4 hours of a recall declaration | **Critical** | ■ Ready ■ Partial ■ Gap |
| **REC-3** | A recall simulation or drill has been run in the past 12 months — results documented | **High** | ■ Ready ■ Partial ■ Gap |
| **REC-4** | Your recall procedure accounts for mandatory recall authority — the FDA can compel it, not just request it | **Critical** | ■ Ready ■ Partial ■ Gap |

## SECTION 6: CAPA & DEVIATION MANAGEMENT

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **CAPA-1** | A written CAPA procedure exists and is followed for every OOS result and production deviation | **High** | ■ Ready ■ Partial ■ Gap |
| **CAPA-2** | Root cause, corrective action, and effectiveness verification are documented for every CAPA | **High** | ■ Ready ■ Partial ■ Gap |

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **CAPA-3** | Open CAPAs are tracked to closure — not abandoned after the corrective action is taken | **High** | ■ Ready ■ Partial ■ Gap |

SECTION 7: CRYPTOGRAPHIC AUDIT TRAIL

| Ref | Requirement | Priority | Status |
|---|---|---|---|
| **AT-1** | All quality records are maintained in a tamper-evident system — changes are logged, not silently overwritten | **Critical** | ■ Ready ■ Partial ■ Gap |
| **AT-2** | Every record shows who created it, when, and that it hasn't been altered since | **Critical** | ■ Ready ■ Partial ■ Gap |
| **AT-3** | Electronic records meet 21 CFR Part 11 controls: audit trail, access controls, identity-verified signatures | **High** | ■ Ready ■ Partial ■ Gap |
| **AT-4** | Records are retained for a minimum of 2 years past manufacture date or 1 year past expiration | **High** | ■ Ready ■ Partial ■ Gap |

90-DAY PRE-ENFORCEMENT ACTION PLAN

## Get BatchBuddy infrastructure in place before the FDA policy finalizes

### Days 1–30: Batch Records & COA Audit

CRITICAL — START NOW

- Audit your last 12 months of production — identify every lot with incomplete batch records
- Collect COAs for all active lots — verify CBD content against labels, flag any mismatches immediately
- Enroll BatchBuddy and begin importing COAs — link each to its corresponding lot and label claim
- Audit all active labels for batch lot number, COA QR linkage, and prohibited claims

### Days 31–60: Traceability & CAPA

HIGH PRIORITY

- Build lot traceability for all active lots — forward to customers, backward to ingredient inputs
- Document any known OOS results or label deviations as formal CAPA records
- Draft or verify your recall procedure — confirm mandatory recall authority scope is covered
- Run first lot trace exercise — verify 24-hour completion capability

### Days 61–90: Recall Simulation & Audit Readiness

COMPLETE & VERIFY

- Run full bidirectional recall simulation on live lot data — document and close any gaps
- Generate BatchBuddy compliance summary — cGMP records, COA chain, CAPA log, recall simulation result
- Review all marketing and label copy for health claims — remove or qualify any at-risk statements
- Brief your team on the FDA submission and what documentation they should be prepared to produce