

# Supplement COA Checklist

How to read a certificate of analysis before you release a lot.

Brand

Date

## THE COA READ-THROUGH: 6 CHECKS BEFORE YOU RELEASE A LOT

1. **Match.** Product name and lot number match your label and batch record.
2. **Spec.** Every test in your specification appears, with the same limits.
3. **Numbers.** Each result is an actual value with units, not just "Pass".
4. **Method.** Each test names its method.
5. **Dose math.** Convert metals to µg per daily serving and compare with your limits.
6. **Sign-off.** Dated and approved by quality control; filed with the batch record and kept for the Part 111 retention period.

## SUPPLEMENT COA CHECKLIST

- ☐ Written specification on file for identity, purity, strength, composition and contaminant limits
- ☐ Lot number on the COA matches the label and batch record
- ☐ Manufacture and expiration (or retest) dates present
- ☐ Identity result for each dietary ingredient
- ☐ Potency result for each label claim, with units
- ☐ Lead, cadmium, arsenic and mercury results, converted to µg per daily serving
- ☐ Microbial results against your limits
- ☐ Method named for every test
- ☐ Quality control approval and date
- ☐ Asked how finished batches are sampled (every batch or a statistical plan)
- ☐ Independent lab check scheduled (ISO/IEC 17025-accredited lab)
- ☐ COA filed with the batch record for the retention period

## Notes

## SOURCES

21 CFR 111.70, 111.75, 111.260, 111.605 (eCFR); FDA Warning Letter to ProSupps USA (2017); FDA, Lead in Food and Foodwares; OEHHA Proposition 65; ISO/IEC 17025; SupplySide Supplement Journal (Elsner, 2016)

General planning aid, not legal or regulatory advice. Confirm requirements with your manufacturer and regulatory reviewer.