

Manufacturer Certification Checklist

Questions to ask a supplement or skincare manufacturer before you sign.

Brand

Date

THE 3-LAYER CERTIFICATION CHECK

- 1. Layer 1, the law:** confirm the facility's FDA registration (and MoCRA registration for cosmetics, or drug establishment registration for OTC) and ask how it meets the GMP rule for your category.
- 2. Layer 2, the audit:** ask for current audit certificates (NSF, ISO 22716 or similar) if your retailers require them, and check the scope covers your product format.
- 3. Layer 3, the claim:** for every word you plan to print (organic, kosher, halal, gluten-free, vegan, cruelty-free), confirm which certifier backs it and that it covers your exact formula and facility.

QUESTIONS TO ASK BEFORE YOU SIGN

- ☐ Which facility will make my product, and is it registered with FDA for this category?
- ☐ How does the facility meet 21 CFR 111 (supplements) or 21 CFR 210/211 (OTC)? Does it follow ISO 22716 for cosmetics?
- ☐ Which third-party audits are current, and when do they expire?
- ☐ Does the audit scope include my format (capsules, gummies, lotions, liquids)?
- ☐ Can you provide organic, kosher or halal certificates that name this facility and my formula?
- ☐ Who certifies the organic content, and does the formula reach 95% or 70%?
- ☐ If I claim gluten-free, how is the under-20-ppm limit verified?
- ☐ What standard backs any vegan or cruelty-free claim?

Notes

SOURCES

FDA, food facility registration fee Q&A; 21 CFR 111.70, 111.75; 21 CFR 330.1; MoCRA (Foley & Lardner, EcoMundo 2026); ISO 22716; NSF/ANSI 455-2; USP Verified Mark; USDA AMS organic fact sheet; OU Kosher; FDA gluten-free and cruelty-free pages

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