US MARKET COMPLIANCE CHECKLIST

Dietary supplements - brand owner edition

This checklist summarises the practical requirements most often reviewed before a dietary supplement is sold in the United States and on Amazon. Work through it section by section with your manufacturer, your importer and your regulatory adviser. Requirements are set by the authorities, change over time, and depend on the finished product and its claims.

A. Facility and Manufacturing

- [ ] Manufacturer operates under current Good Manufacturing Practice (21 CFR Part 111).
- [ ] Facility is registered with the U.S. Food and Drug Administration (FDA).
- [ ] Third-party certification held and current (ISO 22000, HACCP, cGMP audit report).
- [ ] Written quality agreement in place, including roles for deviations and recalls.
- [ ] Facility address, licence number and certificate validity dates verified.

B. Product Label (FDA 21 CFR 101)

- [ ] Statement of identity - the words "Dietary Supplement" appear on the principal display panel.
- [ ] Net quantity of contents in both metric and U.S. customary units.
- [ ] Supplement Facts panel with serving size, amount per serving and % Daily Value.
- [ ] Other Ingredients listed in descending order of predominance by weight.
- [ ] Name and place of business of the manufacturer, packer or distributor.
- [ ] Allergen statement ("Contains:") for any of the eight major allergens.
- [ ] Country of origin declared, with a lot code and best-before / expiry date.
- [ ] Any structure/function claim carries the DSHEA disclaimer.

C. Claims and Advertising

- [ ] Structure/function claims are truthful, not misleading and substantiated.
- [ ] No claim to diagnose, treat, cure or prevent any disease (drug claim).
- [ ] No "FDA approved" or "FDA registered product" wording anywhere.
- [ ] No prohibited ingredients or unapproved novel ingredients (e.g. certain botanicals).
- [ ] Advertising substantiation file maintained for every claim used.
- [ ] Website and advertising copy reviewed against the same standard as the label.

D. Testing and Documentation

- [ ] Certificate of Analysis issued for every finished batch.
- [ ] Identity, assay, heavy metals and microbiological testing on each batch.
- [ ] Stability / shelf-life data supporting the claimed best-before date.
- [ ] Specification sheet, MSDS and nutritional panel available on request.
- [ ] Lab testing performed by an accredited third-party laboratory where required.
- [ ] Sample retained from each batch for the shelf life of the product.

E. Amazon-Specific Requirements

- [ ] Product complies with the Amazon Dietary Supplements policy.
- [ ] GMP certificate or COA ready to upload if requested by Amazon.
- [ ] Expiration date on the product meets the minimum remaining shelf life set by Amazon.
- [ ] Listing images follow image standards; no promotional text or claims on the main image.
- [ ] Product title and bullet points free of prohibited claims and restricted terms.
- [ ] Restricted ingredients screened against Amazon's prohibited and restricted lists.
- [ ] Correct category and required attributes completed before publishing.

F. Importer and Distribution

- [ ] U.S. importer identified and Foreign Supplier Verification Program (FSVP) applied.
- [ ] Prior Notice submitted to FDA before each shipment.
- [ ] U.S. agent or responsible party address available for the label.
- [ ] Commercial invoice, packing list, COA and MSDS prepared for customs.
- [ ] Product liability insurance confirmed for the destination market.

G. Recordkeeping and Post-Market

- [ ] Batch production and control records retained for the required period.
- [ ] Complaint handling and adverse event reporting procedure in place.
- [ ] Recall procedure documented and tested; traceability from batch to customer.
- [ ] Label revisions and artwork approvals version-controlled.
- [ ] Records available to the importer and to regulators on request.

What Hubogen provides: Certificate of Analysis for every batch, MSDS, specification sheet, nutritional panel, allergen statement and stability data. We supply the manufacturing and quality documentation; market registration, import and label approval remain with you or your regulatory adviser. We do not act as your legal registrant in any market.

General information only. This document does not constitute legal or regulatory advice. Verify current requirements with the FDA, your importer and your own regulatory adviser.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.