

# Market Compliance Checklist

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Markets: US FDA · EU EFSA · UK · AU TGA · Canada NHP · SEA · Halal & Kosher

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**HOW TO USE:** Check each box as you verify compliance. [CRITICAL] = non-negotiable requirement.

Add notes in the text fields. Save (File > Save As) and email to: Mc5896538@outlook.com

NuCoreBio provides full regulatory support for all markets listed.

— PRODUCT REFERENCE

## Product & Company Information

Product Name / Formula Reference:

Company / Brand:

Target Market(s):

Prepared by:

Date:

# United States

FDA DSHEA · 21 CFR Part 111 · FTC Guidelines

## Manufacturing & GMP

- [CRITICAL]** Production facility complies with 21 CFR Part 111 cGMP
  - *Dietary supplement GMP — separate from food GMP (21 CFR 110)*
- Batch records maintained for all production runs
  - *Raw material lot numbers, weights, in-process checks*
- Written SOPs for every manufacturing step
- Personnel training records documented

## Labeling — Supplement Facts Panel

- [CRITICAL]** Supplement Facts panel formatted per 21 CFR 101.36
  - *Serving size, amount per serving, % Daily Value*
- [CRITICAL]** All ingredients in descending order by weight
  - *Proprietary blends: list all + total blend weight*
- [CRITICAL]** Allergen statement — Top 9 US allergens (FALCPA)
  - *Milk, Eggs, Fish, Shellfish, Tree Nuts, Peanuts, Wheat, Soybeans, Sesame*
- Net quantity of contents on principal display panel
- Manufacturer name & address on label
- Lot number and expiration/best-by date

## Claims — Structure/Function vs. Disease

- [CRITICAL]** ONLY structure/function claims — NO disease claims
  - *"Supports healthy testosterone" ✓ "Treats low testosterone" ✗*
- [CRITICAL]** FDA disclaimer on label for all S/F claims
  - *"This statement has not been evaluated by the FDA..."*
- Claims substantiated — documentation on file
- NDI notification filed if using post-Oct 1994 New Dietary Ingredient
  - *75-day advance notice to FDA required*

## Required Testing

- [CRITICAL]** Identity verification per incoming ingredient lot
  - *HPLC, TLC, or validated analytical method*
- [CRITICAL]** Finished product potency testing — verify label claims
- [CRITICAL]** Heavy metals: Pb, Cd, As, Hg — USP <232>
- [CRITICAL]** Microbial per USP <2021>: TPC, Yeast/Mold, E.coli, Salmonella

### US Compliance Notes:

# European Union

EFSA · Novel Food Reg. 2015/2283 · Reg. 1169/2011

**CRITICAL — EU Novel Food Regulation:**  
Ingredients not significantly consumed in the EU before May 15, 1997 require pre-market authorization. This is the #1 reason US formulas cannot be sold in the EU without reformulation or prior authorization. Verify every active ingredient.

## Novel Food — High-Risk Ingredients

- [CRITICAL]** Epimedium / Icariin — Novel Food, NOT authorized in EU
- [CRITICAL]** NMN (Nicotinamide Mononucleotide) — Novel Food, authorization pending
- [CRITICAL]** Melatonin — classified as MEDICINE in most EU member states
- [CRITICAL]** CBD / Cannabidiol — Novel Food, ongoing authorization process
- NR (Nicotinamide Riboside) — Novel Food authorized with conditions
- Sea cucumber / marine peptides — verify EU Novel Food status

## EU Labeling — Regulation 1169/2011

- [CRITICAL]** NO FDA-style disclaimer language — PROHIBITED in EU
  - "Not evaluated by FDA..." is forbidden on EU labels
- [CRITICAL]** EU Nutrition Declaration per 100g AND per serving
  - Energy, fat, saturates, carbs, sugars, protein, salt
- [CRITICAL]** Health claims ONLY from EU authorized list (Reg. 1924/2006)
  - Non-listed claims are prohibited even if scientifically true
- [CRITICAL]** Maximum dosage limits for vitamins and minerals respected
  - Apply most restrictive member state limits
- [CRITICAL]** Allergen labeling per Annex II — 14 EU allergens highlighted
  - Bold, italic, underline or different color in ingredient list
- Label in official language of each target EU country

### EU Compliance Notes:

## ■ ■ United Kingdom (Post-Brexit)

MHRA · FSA · UK Food Supplements Regulations

- [CRITICAL]** UK Novel Food list is SEPARATE from EU — check food.gov.uk
  - *EU Novel Food authorization does not apply in the UK*
- [CRITICAL]** MHRA borderline product classification check required
  - *Some supplements are medicines under Human Medicines Regulations 2012*
- UK FSNR (Food Supplements England Regulations 2003) compliance
- GB address required on label

## ■ ■ Australia & New Zealand

TGA ARTG · Complementary Medicines · FSANZ

- [CRITICAL]** Product listed/registered on TGA ARTG before sale
  - *AUST L or AUST R number required on label*
- [CRITICAL]** All ingredients from TGA Permitted Ingredients list
  - *Ingredients not on list require TGA approval*
- [CRITICAL]** Permitted indications only — TGA-approved wording
  - *Non-standard claims require evidence + TGA approval*
- [CRITICAL]** GMP under TGA-licensed manufacturing conditions

## ■ ■ Canada

Health Canada · NHP Regulations · SOR/2003-196

- [CRITICAL]** Product License (NPN) required before sale in Canada
  - *Apply through Health Canada NNHPD — allow 6–24 months*
- [CRITICAL]** All ingredients match NHP monograph or new evidence filed
- [CRITICAL]** Label MUST be bilingual — English AND French
  - *All mandatory elements in both official languages*
- [CRITICAL]** GMP compliance — Div 1A of NHP Regulations

Notes (UK / AU / CA):

## ■ Southeast Asia

BPOM (Indonesia) · HSA (Singapore) · FDA Thailand · NPRA (Malaysia)

- [CRITICAL]** Indonesia BPOM: product registration required
  - *Halal certification often mandatory for Muslim-majority market*
- Singapore HSA: notification required, permitted ingredient list applies
- Thailand FDA: import permit required, label in Thai for retail sale
- Malaysia NPRA: product registration, Halal certification beneficial
- Philippines FDA: Certificate of Product Registration required
- Vietnam DAV: product announcement / registration required

## ■ Halal & Kosher Certification

Multi-Jurisdiction Religious Compliance

### ■ Halal Requirements

- [CRITICAL]** All ingredients Halal-verified — no pork-derived sources
  - *Gelatin, stearates, glycerin must be plant-based or Halal animal*
- [CRITICAL]** No alcohol or intoxicants in formula or processing aids
- [CRITICAL]** Production on dedicated Halal line or verified clean changeover
  - *Cross-contamination invalidates the certificate*
- Halal certificate issued per production batch
  - *Recognized bodies: JAKIM (MY), MUI (ID), SFDA (SA)*

### ■ Kosher Requirements

- [CRITICAL]** All ingredients Kosher — no treif sources
  - *Gelatin, glycerin, animal enzymes must be Kosher-certified*
- [CRITICAL]** Production under certified Kosher supervision (OU, Star-K, cRc)
- Kosher certificate per product and production run

#### SEA / Halal / Kosher Notes:

**NuCoreBio provides full regulatory compliance support for ALL markets in this checklist.**  
Submit your formula + target markets for a free regulatory feasibility assessment.  
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