NUTRACEUTICAL AND DIETARY SUPPLEMENT INSURANCE

Insurance Readiness Checklist

For supplement brands, private label companies and distributors

Underwriters review a supplement or nutraceutical company by its products, ingredients, manufacturing partners, quality controls and claims history. Gather the items below before you apply. Missing quality documents and unclear manufacturing roles are common reasons a submission takes longer than it should. This checklist does not guarantee a quote, coverage, or a price, and it is not legal or regulatory advice. Whether a product or claim is lawful is a question for your regulatory counsel.

COMPANY NAME	PRODUCT OR BRAND	DATE

1 Your business and how you sell

Tells the underwriter who you are in the supply chain.

- ☐ Company name, address, website, year started, and number of employees.
- ☐ Gross revenue for the last 12 months and your estimate for the next 12 months, split domestic and other territory.
- ☐ Revenue split: you manufacture, a third party makes your branded products, you are a contract manufacturer, you wholesale other brands, or you sell retail.
- ☐ Where you sell: your own website, Amazon or other marketplaces, retail stores, wholesale, practitioners, other countries.
- ☐ Trade organizations you belong to (for example AHPA, ABC, NPA, UNPA, AAHP).

2 Products and formulas

Only the products you list are considered, so list them all.

- ☐ Each product or product line: name, delivery form (capsule, powder, gummy, liquid), date first sold, and annual sales.
- ☐ Whether the formula or design is yours or your customer's.
- ☐ Your three best sellers: customer, who actually makes it, failure rate, daily production and largest batch value.
- ☐ Any product meant for weight loss or gain, muscle building, sexual enhancement, children, or prenatal and postnatal use, with percent of revenue.
- ☐ Any new product planned in the next 12 months, and any product or ingredient you dropped for a reason other than low sales.

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3 Ingredients and suppliers

Ingredient choices are one of the first things reviewed.

- ☐ Full ingredient list for each product, and where each key ingredient comes from.
- ☐ Whether any product contains an ingredient on the carrier's restricted list. Tell your advisor even if it is only one product.
- ☐ Your main ingredient suppliers: name, location, and what they supply.
- ☐ Whether you buy ingredients directly, and who tests them when they arrive.

4 Manufacturing and quality control

Shows how a defect would be caught before it reaches a customer.

- ☐ Your three largest contract manufacturers: name, location, and their quality certifications.
- ☐ Whether you or your manufacturer follow current good manufacturing practice, and proof such as a certificate or audit report.
- ☐ Certificates of analysis and the testing done on incoming materials and finished products, in-house or third party laboratory.
- ☐ Batch or lot records that let you trace a product back to its ingredients.
- ☐ A written quality assurance plan and a written product recall procedure.
- ☐ Date of your last FDA inspection, any FDA 483 and your response.

5 Labels, claims and reviews

Labeling problems are a common source of claims and declinations.

- ☐ Current labels, marketing claims, and required warnings for each product.
- ☐ Who reviews labels and formulas before sale (internal counsel, outside counsel, or a third party).
- ☐ Any time your labeling was questioned by the FDA, FTC or another authority.
- ☐ Any adverse event reported to you or to the FDA in the last 3 years.

6 Insurance and loss history

Shows continuous coverage and claims.

- ☐ Current general liability and product recall coverage: effective date, limits, deductible, premium and insurer.
- ☐ Limits and deductibles you want for the next term, and your effective date.
- ☐ Five years of currently valued loss runs, if available.
- ☐ Any product recall in your history, and any incident that could become a claim.
- ☐ Retailer or marketplace insurance requirements (additional insured wording, minimum limits).
- ☐ Your standard sales contract or terms of use, and principals' resumes if you have operated under 3 years.

What happens next

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1 Submit
Complete the online application and upload your quality plan, recall procedure, certificates of analysis and loss runs.

2 Review
A licensed WHINS advisor reviews your application, prepares the submission and approaches the markets we work with.

3 Options
You receive quote options and terms to review, subject to underwriting.



YOUR WHINS ADVISOR

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