RISK NAVIGATOR

Dietary supplements

Life sciences

About Markel's Risk Solution Services team

Risk Solution Services provides technical insight related to existing and potential insured risk at Markel. The team partners with our customers, claims and underwriters to educate on both current and future risk trends and supports our customers with a broad offering of risk management solutions.

Email our team at
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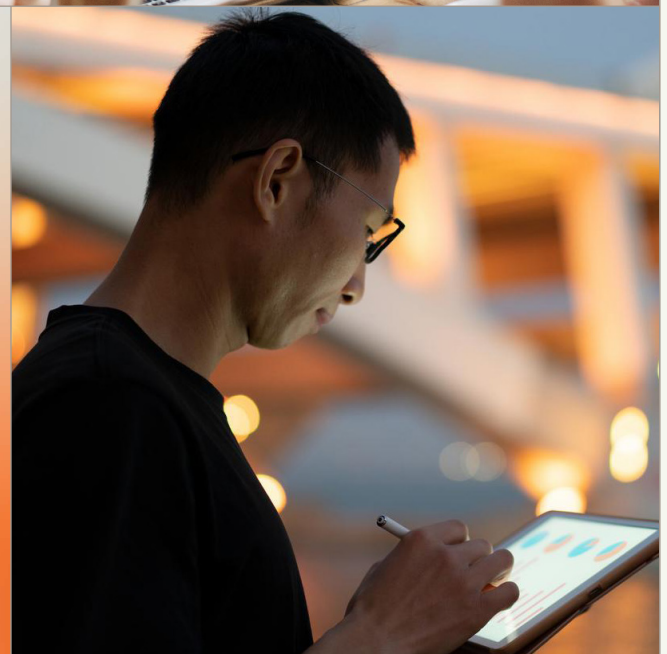

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Dietary supplements

Overview

US dietary supplements are governed by a framework established under the Dietary Supplement Health and Education Act (DSHEA) of 1994 and subsequent regulations, including the 2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act. The FDA dietary supplement regulations include 21 CFR Part 190 Dietary Supplements and 21 CFR 111 Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Current Good Manufacturing Practices (cGMPs) under 21 CFR 111 require documented quality management systems, sanitary and controlled production processes and consistent batch quality. Manufacturers must also ensure labels are accurate and not misleading and report serious adverse events to the FDA.

This framework places primary responsibility on manufacturers to ensure product safety, substantiation of claims and compliance with labeling requirements. FDA does not approve products prior to marketing, but it retains authority to take enforcement action against unsafe or noncompliant supplements, making regulatory oversight largely reactive and dependent on manufacturer compliance.

Dietary supplement regulations vary by country. In contrast to US regulations, the European Union dietary supplements regulations, European Foos Safety Authority (EFSA) Directive 2002/46/EC (Food Supplements Directive), require approved ingredients and scientific substantiation of safety and health claims to be reviewed by EFSA before products can be marketed. The United Kingdom Food Standards Agency has similar regulatory requirements.

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Litigation

Dietary supplement litigation

The dietary supplement industry has experienced litigation and regulatory scrutiny involving a range of issues related to product formulation, labeling, marketing, and compliance practices. These matters can lead to legal actions and associated reputational and financial impacts.

OxyElite Pro cases alleged use of synthetic stimulants, false "natural" labeling, and liver injury events, following FDA enforcement actions. The company also faced criminal charges. A 2014 settlement totaling $4.2M to a 24-year-old who developed acute liver and kidney failure and had to undergo emergency liver and kidney transplant surgery linked to Epio-Plex, a product recalled after the FDA suspected it contained unlabeled synthetic steroids.

More recent matters include kratom litigation alleging design, manufacturing, and labeling defects, including an $11M award for one wrongful death case. False advertising cases such as Balance of Nature, for misleading health claims which settled for $9.95M, Prevagen over allegedly misleading cognitive benefit claims with a settlement of over $36M and a $70.8M settlement by Premier Nutrition for false advertising of Joint Juice glucosamine supplements as products that could support joint health.

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Product liability exposures

Dietary supplement product liability exposure

Product liability exposures are driven by a combination of company experience, regulatory compliance history, and the inherent risk profile of certain product types. Additional risk is introduced through the use of problem ingredients, quality control deficiencies across sourcing and manufacturing, and labeling or marketing practices that may lead to misleading claims or failure to warn. These elements contribute to elevated litigation risk, regulatory scrutiny, and the potential for bodily injury claims.

Additional information | Cannabinoids

Per FDA, tetrahydrocannabinol (THC) and cannabidiol (CBD) cannot be legally marketed as dietary supplements because both are active ingredients in FDA-approved drugs and there are concerns around contaminants, dosage limits, labeling clarity and risk of unintended ingestion (especially children). Regulations vary by country. Some countries have similar restrictions or require approval prior to marketing.

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Risk evaluation

Evaluating the risk

Because the regulatory framework places primary responsibility for safety, quality and compliance with the manufacturer, loss exposure is related to how well a company manages its internal controls rather than regulatory oversight. How a company manages internal controls related to supplier oversight, quality management, labeling and marketing and post market monitoring may adversely impact risk.

Information that helps our team evaluate an account:

- Supplier contracts
- Raw material testing process
- Quality management program
- Finished product testing process
- Label and marketing material review process
- Recall program
- Complaint handling program
- Third-party verifications or certifications

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Dietary supplements

Conclusion

Risk within the dietary supplement sector is driven by manufacturer practices rather than regulatory oversight. Risk differentiation is based on the effectiveness of quality systems, supplier controls and labeling and marketing practices. Additionally, limitations in contractual risk transfer can increase exposure where liability is not effectively allocated or enforceable.

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