

EVIDENCE REVIEW 01 • REGULATION

How supplements are regulated differently from medicines

Supplements are not unregulated. The difference is that most reach the market without approval, while a new medicine must prove safety and effect first.

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BOTTOM LINE

Most dietary supplements receive no premarket approval. Companies carry the legal duty for safety, lawful ingredients, accurate labels and compliant manufacturing, while regulator inspection and enforcement usually begin after a product is already on sale.

KEY POINTS

- A new prescription medicine needs regulator review of safety and effectiveness before it can be sold.
- The FDA does not approve dietary supplements, their effectiveness or their labelling before sale.
- Supplement firms still carry duties for safety, labelling, manufacturing and adverse-event reporting.
- A structure/function claim is not evidence that a product prevents or treats disease.

“Supplements are unregulated” is the most repeated claim in this field, and it is wrong in a way that makes people worse at judging products rather than better.

There are rules. They are simply different rules, applied at a different point in a product’s life, and knowing where that point sits tells you what a label can and cannot be trusted to mean.

Premarket review is the dividing line

A company seeking to sell a new prescription medicine submits clinical and manufacturing evidence for regulator review, and cannot market the product until that review is complete. Safety and effectiveness are established before sale, by an outside body, using the company’s data.

For dietary supplements, the FDA states that it does not have the authority to approve products for safety and effectiveness, or to approve their labelling, before they are sold. Most supplements enter the market without the agency having

examined them.

There is one significant exception. A firm introducing certain new dietary ingredients must submit a safety notification beforehand. That notification is not approval of the finished product, and the distinction matters — it was exactly the gap at issue in the [2013 OxyELITE Pro liver-injury outbreak](#) ([/evidence/oxyelite-pro-liver-injury-2013/](#)), where the implicated ingredient had not been accepted through that route.

What manufacturers are still required to do

The obligations are real, and they sit with the company.

The manufacturer or distributor is responsible for ensuring a supplement is neither adulterated nor misbranded. Labels must identify the dietary ingredients and their amounts. Firms must follow dietary supplement current good manufacturing practices. A company that receives a report of a serious adverse event must forward it to the FDA within 15 days.

This is why “unregulated” is the wrong word. The accurate description is a distinct, largely post-market framework with no routine product-by-product approval before sale — which is a meaningfully different criticism, and a more useful one.

Claims can sound stronger than the evidence

A supplement may carry a structure/function claim — that it supports a normal bodily function — provided the company holds substantiation and includes the required disclaimer. These claims are not pre-approved by the FDA.

A claim to diagnose, treat, cure or prevent a disease generally makes the product a drug under federal law, and pushes it into the approval framework described above. That boundary, not the marketing vocabulary, is what separates the two categories.

The familiar disclaimer — that the FDA has not evaluated the statement — is widely misread in both directions. It does not mean the claim is false. It also does not mean anyone has checked it.

What happens after sale

The FDA can inspect facilities, review labels and websites, monitor adverse-event reports, test products, issue warnings, seek recalls and take enforcement action.

Because products can reach the market without the agency being notified, detection depends on surveillance, inspection, complaints, laboratory testing and clinical reports. That machinery works — the [2004 ephedra rule](#) ([/evidence/fda-ephedra-ban-evidence/](#)) is proof that an entire ingredient class can be removed — but it works slowly, and it works after exposure has already happened.

For a buyer, the practical conclusion is that the word “supplement” carries no quality signal on its own. What matters is the specific ingredient, the dose, the manufacturer’s quality control and the intended use. Where a seal is involved, [what a “third-party tested” seal actually proves](/evidence/third-party-tested-supplement-seals/) (/evidence/third-party-tested-supplement-seals/) covers how narrow that assurance is.

In New Zealand, the framework differs again. Supplements are regulated under the Dietary Supplements Regulations and food standards administered with FSANZ, with Medsafe taking over the moment a product makes a therapeutic claim — at which point it is treated as a medicine under the Medicines Act. The dividing principle is the same as the American one, but the agencies, the thresholds and the permitted wording are not: those are set out in [what supplement labels are allowed to claim in New Zealand](/supplements/what-supplement-labels-can-claim-in-nz/) (/supplements/what-supplement-labels-can-claim-in-nz/).

SOURCES

01. FDA 101: Dietary Supplements

US Food and Drug Administration

<https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements>

02. Questions and Answers on Dietary Supplements

US Food and Drug Administration

<https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements>

03. Small Entity Compliance Guide on Structure/Function Claims

US Food and Drug Administration

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>

Medical note. General information only. Not personalised nutrition or medical advice. This review explains published research and cannot diagnose or treat a condition. Ask a qualified clinician or pharmacist about your own health, medicines and supplement use.

Source of record. The current version of this review, with working links, is at <https://www.proteinnotes.com/evidence/supplement-regulation-vs-medicines/>