

Amazon Dietary Supplement Compliance: What Sellers Need to Know

Frequently Asked Questions (FAQ)

Below are the questions raised during the webinar, along with responses based on the discussion from our technical experts.

1. What are the reasons dietary supplement listings are removed or suspended by Amazon?

Common reasons product listings may be removed or suspended include:

- The product needs manufactory cGMP verification
- Testing results that do not support ingredient claims listed on the Supplement Facts panel
- Unauthorized therapeutic or disease claims on labels
- Presence of dangerous substances, contaminants, or undeclared active pharmaceutical ingredients (APIs)

Label claims such as disease treatment, prevention, or cure statements may also lead to listing removal and require artwork updates and resubmission.

2. How often does Amazon update its dietary supplement requirements?

Amazon requirements may evolve as marketplace risks, regulations, or best practices change.

In general:

- Sellers should maintain a current cGMP certificate
- Requirements are reviewed annually
- The best source for updates is Amazon Seller Central, where policy updates are communicated

3. I've heard many TICs are being flooded as Amazon starts requiring more supplements to be TIC assessed. What are your turnaround times for quote requests?

Intertek aims to:

- Turn around quote requests within approximately 2 business days
- Complete testing and compliance review within approximately 2 weeks

This includes:

- Testing review
- cGMP evaluation
- Label review
- Final report preparation for Amazon

Turnaround times are dependent on receiving required documentation and samples.

4. How long would it take for a small facility to get cGMP certified?

Timing depends on facility readiness and the certification pathway selected.

Generally:

- Audits may be scheduled within 90 days and often sooner
- On-site audits typically last 1-3 days, depending on factors like facility size and number of employees.
- The auditor submits the audit report within at least 10 business days after the audit.
- The report undergoes a review process, and corrective actions must be submitted within 10 business days of receiving the report.
- The certification decision is made after the report is issued, reviewed, and corrective actions are completed
- Certification can often be completed within approximately 4-8 weeks after the audit, depending on CAPA closure and evaluation timelines

5. Does this apply to third-party fulfillment or just Fulfilled by Amazon (FBA)?

The Amazon dietary supplement compliance requirements discussed during the webinar are intended to help keep products active and available on the Amazon marketplace.

In many cases, Amazon compliance requirements closely align with FDA dietary supplement regulations.

6. Is pesticide testing required for all products?

Not always.

Pesticide testing is typically required when:

- The product contains botanical ingredients
- The daily intake exceeds 5 grams of botanical material

7. Did you say that a Health Canada Site License would be sufficient GMP evidence?

Yes.

A Health Canada Site License is considered acceptable evidence of GMP compliance under Amazon's current dietary supplement requirements.

8. How do we export our products from the UK? Does Intertek review documents before sending them to Amazon? Does Amazon order the import permit to export products to the USA?

This topic falls outside the core Amazon dietary supplement compliance process covered in the webinar.

Importing dietary supplements into the U.S. may involve additional regulatory, documentation, and import requirements depending on product type and market.

Intertek can help connect companies with the appropriate regulatory specialists to better understand applicable requirements and next steps.

9. Are there any particular guidelines or requirements for OTCs?

OTC (Over-the-Counter) products were outside the scope of this webinar and follow a different regulatory pathway than dietary supplements.

Generally:

- OTC products follow 21 CFR Parts 210 and 211
- Amazon may apply separate requirements for OTC compliance
- Standards such as NSF/ANSI 455-4 may apply depending on product category

For OTC-specific questions, Intertek can connect companies with the appropriate specialists.

10. Other TICs are requiring additional fees if CAPAs are required during TIC review. Is that the case with Intertek?

Not for the initial review.

If corrective actions can be completed without reformulation or retesting, additional fees are generally not required.

However, if CAPAs involve:

- Reformulation
- Retesting
- Product rework

A new TRF (Testing Request Form) may be required and standard fees may apply.

11. Once an ASIN has passed the testing requirement, is there an annual retest?

No annual retesting is currently required if the product has successfully passed testing requirements.

However:

- Products are subject to annual review
- cGMP certificates must remain current and renewed annually

12. How should companies respond if a dietary supplement listing is flagged or removed?

Amazon generally sends a notification if a product listing is flagged or removed.

Companies should:

1. Create a TRF in Seller Central
2. Assign an approved Third-Party Inspection & Certification (TIC) provider
3. Submit required documentation and testing materials
4. Complete compliance review and testing as required

Once compliance requirements are met, reinstatement may be initiated.

13. Can lack of cGMP compliance lead to Amazon listing restrictions or suspensions?

Yes.

Lack of cGMP compliance may result in p

roduct listing restrictions or suspension from Amazon.

Maintaining a valid and recognized cGMP certification can help reduce disruptions and support continued marketplace access.

14. What documentation should companies maintain to demonstrate cGMP compliance?

Companies should maintain documentation related to:

- Manufacturing processes
- cGMP certificates
- Testing reports
- Product specifications and quality systems

Intertek can provide a cGMP checklist and technical guidance to help companies understand requirements.

15. Is it okay if a contract manufacturer satisfies all requirements? Does the brand need to provide extra information?

Yes.

If a contract manufacturer satisfies requirements, additional documentation from the brand may not be necessary.

However, documentation must still be verified, including:

- Current cGMP certificates
- Testing reports
- Product verification
- Label and product information

The manufacturer may also need to be contacted as part of the verification process.

For more questions, reach out to us!

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