Supplements

Navigating Amazon's Supplements Category

How To Avoid Roadblocks

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Overview

Selling dietary supplements on Amazon Marketplace can be a lucrative and rewarding business opportunity. However, it's essential to ensure that all requirements and regulations are met to maintain a successful operation. One of the critical aspects of selling supplements on Amazon is having the necessary documentation readily available.

This documentation includes, but is not limited to:

- Certificate of Analysis (COA)
- Good Manufacturing Practices (GMP) certificate
- Supplement Facts Panel (SFP)
- An invoice from the manufacturer
- Product photos

These documents provide Amazon and its customers with transparency and reassurance that the product is legitimate, safe, and compliant with regulations. The availability of these documents also enables brands to build trust with customers and foster a positive reputation on Amazon.

Cartograph

Cartograph is an eCommerce-focused agency that helps CPG brands sell on Amazon. Our mission is to help brands grow products that are better for people and the planet. We support brands end-to-end with strategy, pricing, SEO, advertising, and operations and logistics.

Section 1

Documentation

One of the critical aspects of selling supplements on Amazon is having the necessary documentation readily available. These documents provide Amazon and its customers with transparency and reassurance that the product is legitimate, safe, and compliant with regulations.

In this section, we will provide an in-depth analysis of each of these documents & their importance.

Certificate of Analysis (COA)

Good Manufacturing Practices (GMP)

Supplement Facts Panel (SFP)

Invoice from Manufacturer

Live Photos

Certificate of Analysis (COA)

As a brand selling supplements on Amazon, it is essential to obtain a Certificate of Analysis (COA) to comply with Amazon's requirements.

The COA must be up-to-date and contain:

- The lot number
- Manufacture date
- Expiration date must **not** be in the past
- Include the name and address of the manufacturer or distributor
- Be issued by an ISO/IEC 17025-certified laboratory

It must be issued within the last six months and contain quantitative analysis to support the active ingredient concentration as claimed on the supplement facts panel. The COA must also include the product name.

It's important to note that Amazon requests COAs to test all ingredients, not just a few to spot-check, which consequently increases the cost of obtaining a COA. If an ingredient can't be quantitatively tested and uses the "by input" method on the COA, you need an additional COA for the ingredient.

In The Absence of a COA

Some brands may have the luxury of obtaining their COA from their manufacturer since manufacturers typically already have the qualifications to provide COAs. However, many manufacturers have the right to refuse providing a COA simply due to the cost and how time-consuming testing can be. If your manufacturer can not provide a COA, third party certification labs are the way to go.

Specific COA requirements for different kinds of supplements:

Herbal Supplements

 COAs must be submitted for each dietary ingredient

Sports Nutrition (Additional):

- Selective Androgen Receptor Modulators (SARMs)
- Ostarine (Enobosarm)
- Ligandrol (LGD-4033)
- Anabolic steroids 4-DHEA
- Stimulants Sibutramine
- · Analogs desmethylsibutramine
- Sesmethylsibutramine
- DMAA

Sexual Enhancements (Additional):

- Sildenafil
- Tadalafil
- Vardenafil
- Sulfoaildenafil
- Desmethyl carbodenafil

Weight Loss and Weight Management (Additional):

- Sibutramine
- Desmethylsibutramine
- Phenolphthalein
- Fluoxetine

Good Manufactoring Practices (GMP)



Providing Amazon with a valid Good Manufacturing Practices (GMP) certificate is essential for selling supplements on Amazon.

The GMP certificate should be issued by an accredited third-party certification body in compliance with 21 CFR 111 and 21 CFR 117.

Amazon accepts GMP certificates from several third-party programs, including:

- NSF/ANSI 455-2
- GRMA 455-2
- USP GMP

Without a valid GMP certificate, Amazon may not allow sellers to sell their products on their platform, resulting in lost sales and revenue.

GMP certifications help ensure the safety and quality of supplements, build trust and credibility with customers, and comply with Amazon's policies.

Therefore, obtaining a valid GMP certificate and providing it to Amazon is highly recommended for selling supplements on Amazon.

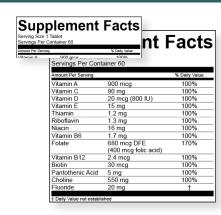
Without a valid GMP certificate, Amazon may not allow sellers to sell their products on their platform, resulting in lost sales and revenue.

It is important to note that obtaining a GMP certificate can be a complex and time-consuming process, and it may require significant investment in your manufacturing facility and processes. However, the benefits of having a GMP certificate, including complying with Amazon's requirements and building trust with your customers, make it a worthwhile investment for brands selling supplements on Amazon.

Supplement Facts Panel (SFP)

The Supplying Amazon with a SFP (Supplement Facts Panel) provides customers with important information about the contents of the supplement, including the active ingredients, the amount of each ingredient per serving, and any other important details. The SFP must comply with the regulations outlined in 21 CFR 101.36 – Nutritional Labeling of Dietary Supplements. This includes providing accurate and truthful information about the supplement's contents, following the formatting requirements, and ensuring that the label is not misleading. Failing to provide a compliant SFP can result in legal and financial consequences.

Therefore, it is important to work with a reputable and accredited certification body to ensure that your SFP complies with the regulations and to provide it to Amazon to ensure the safety and quality of your products and to comply with Amazon's policies.



Invoice from Manufacturer

Obtaining an invoice from the manufacturer is crucial for brands to gain credibility and earn customer trust on Amazon. The importance of obtaining this invoice lies in the fact that it serves as proof that the supplement brand is legitimate and that the products are sourced from a reputable manufacturer. It also verifies that the supplements comply with FDA regulations and that the seller is authorized to sell them on Amazon.

What should be included in the invoice?

- Dated within 180 days of submitting the application
- · Must include specific details, such as the seller's name and address, matching the information in the seller's account
- The manufacturer's or distributor's name and address
- Show the combined purchase of the minimum order quanity of at least 10

Pro Tip: Ensure you highlight your brand's name. If you are a DBA, provide a paper trail link between the purchasing name and your Seller Central account name.



Live Photos



Amazon has specific requirements to provide live photos of your products to sell on their platform. These photos serve as a proof of the product's quality, authenticity, and accuracy of the product's description. These must be 'live' photos of all sides of the packaging. They cannot be 3D renders and are for internal verification purposes only.

What must the photos contain?

- Name and address of the manufacturer
- Product name
- Product trademark or model number
- Clear image of the supplemental or nutritional fact panel and ingredient list
- No stock images
- Clearly display all sides of the product or its packaging

Not complying with these requirements may result in listing removal or suspension, and thus brands must ensure they meet all of Amazon's photo requirements.

Section 2

Submission

Once you have gathered all documentation, it's time to submit to Amazon. These documents are necessary to ensure that your products are compliant with Amazon's policies and regulations and to ensure the safety and quality of your products. In this section, we will walk through the steps of submitting as well as provide an example of the ideal timeline of a prepared client.

How to Submit Documentation

It is important to ensure that all required documentation is provided to comply with Amazon's policies and ensure the safety and quality of your supplement products.

To submit documentation to Amazon for supplement products:

- 1. Log in to your Seller Central account
- 2. Select the Performance tab, and choose Account Health
- 3. Scroll down to the Product Compliance Requests section in the bottom right corner of the page and click Documentation requests (Figure 1).
- 4. Find the product you need to provide documentation for and click Provide Documentation or Appeal next to it (Figure 2).

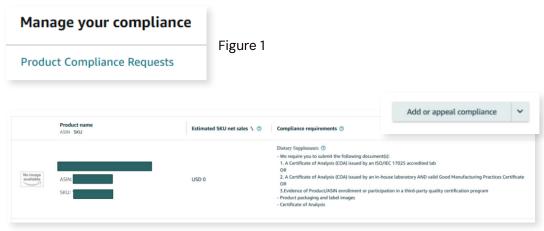


Figure 2

If Documentation Isn't Submitted

If you have not yet uploaded any documents, select "No" and follow the steps in the Submit required documents section.

This will guide you through the process of uploading the necessary documentation, such as your GMP certificate, to Amazon for review.

Real Life Example

Amazon has become a ubiquitous platform for buying and selling products of all kinds. However, one issue that has emerged is the lack of clear regulations in place for certain ingredients, which can lead to product suppression and significant headaches for sellers. This has been the case for one of our clients, who recently had their hero product removed from Amazon due to an ingredient being flagged as illegal. By having all the necessary documents readily available, the client was able save weeks or even months of lost sales and speed up Amazon's tedious review process and prove product legality. This serves as a reminder that being prepared and organized can save you time, money, the opportunity cost of lost sales, and potential legal troubles in the future.

Section 3

Maintenance & Guidelines

Documentation is necessary to ensure that your products are compliant with Amazon's policies and regulations and to ensure the safety and quality of your products. However, even if a brand acquires and supplies all necessary documentation, staying live on Amazon and avoiding suppressions are another battle brands must consider.

In this section, we aim to guide you through the most important principles of these various regulations and provide simple guidelines, examples, and explanations into some of the common reasons Amazon may flag your supplement ASINs.

General Guidelines

We've taken the time to summarize a litany of legislation and Amazon policy into <u>four general rules</u>. When writing copy, or designing product labels, these guidelines will help you avoid the majority of pitfalls that befall most companies. Or, if already facing a suspension, they may lead you to the underlying cause.

4 Rules to Avoid Common Pitfalls

- 1. Do not make disease claims, which are claims that a product can diagnose, cure, mitigate, treat, or prevent a specific disease or medical condition.
- 2. Use structure/function claims instead, which refer to a product's ability to affect the structure or function of the body in a certain way without making specific reference to a disease, medical condition, medication, or class of medications.
 - An example of a structure/function claim is "supports healthy bones" or "promotes joint flexibility."
 - By contrast, you cannot say "Supports the body's ability to fight cancer", as this is now a disease claim.
- 3. Structure/function claims must be truthful, not misleading, and must be backed by competent, reliable, relevant, and human-based scientific evidence (no animal studies).
- 4. Claims cannot be made with respect to anything that can be prescribed medication for or the symptoms of any medical condition. This includes comparing your product to medication.

| X Don't | ✓ Do |
|--|--|
| "Sleep aid" While fine for ZzzQuil to say, as they are regulated as a drug, your Melatonin product doesn't quite qualify. | "Sleep Support" "Supports Circadian Rhythm" |
| "Brain fog" A common claim in Instagram ads for the latest nootropics, but absolutely not allowed under the current FDA or FTC guidelines. | "Supports Mental Clarity" "Support Memory" |
| "Anti-inflammatory" As inflammation is something a medication can be prescribed for, and anti-inflammatories are a class of medication, this term is a trigger word for Amazon's filters. | "Promotes Joint Comfort" "Supports Healthy Inflammatory Response" |
| "Anti-Anxiety" Another term that commonly leads to suspensions, and for the same reason as "anti-inflammatory" | "Promotes Relaxation" "Supports a Calm Mind" |
| "Cures hangovers" The mandatory statement on all supplement labels states the product cannot "cure" a health condition, and a hangover is considered one. | "Helps Rehydrate and Replenish" Supports Natural Recovery Processes" |

My Product Is Suppressed: Now What?

What To Do As of 2023

Understanding the regulations imposed by these government agencies, and echoed by Amazon, is crucial for ensuring the long-term and uninterrupted success of your business on the marketplace. An FDA warning letter can leave a lasting scar on your reputation among consumers, and a product suspension can have an immediate and jarring impact on sales velocity.



Review Suppression Notification

Carefully read the notification from Amazon regarding the suppression. This will usually provide specific details about why your product was suppressed.

Be aware: sometimes Amazon will not issue a flag in Account Health, so it is imperative to be reviewing your Performance Notifications daily as well as Compliance Health to ensure you're capturing suppressions as soon as they occur.



Contact Amazon Seller Support

Use the Seller Central platform to communicate with Amazon's Seller Support team. Provide clear and concise information about the steps you've taken to address the issue.



Identify the Issue

Understand exactly the reason for the suppression. It could be due to various factors such as **product listing issues**, **compliance documentation needed for Amazon policy**, or safety concerns.



Submit an Appeal

If your product was suppressed due to a policy violation, you may need to submit an appeal. The appeal should include a detailed explanation of the steps you've taken to rectify the problem and prevent it from happening again.



Address the Issue

Based on the reason for the suppression, take appropriate steps to rectify the problem. This may include:

- Product listing issues: Update the product listing with accurate information, including titles, descriptions, images, and other relevant details.
- Policy violations: If the product violates Amazon's policies, make necessary changes to bring it in compliance
- Safety or Quality concerns: Ensure that your product meets all safety and quality standards. This may involve working with your third-party testing agency to provide necessary documentation.



Provide Necessary Documentation

If requested, provide any documentation or evidence that supports your appeal. This could include safety certificates, lab reports, or any other relevant documentation.



Monitor Seller account

Keep a close eye on your account for updates and messages from Amazon. They may request further information or provide additional instructions.

Other Claims

Outside of the aforementioned guidelines, dietary supplement brands may encounter specific phrases and claims governed by both the FDA and FTC. These regulations require careful attention and understanding. In the following section, we will explore examples that shed light on these specific aspects, enabling brands to effectively navigate these regulatory nuances.

A key point that merits emphasis is the recent focus on the requirement for human data. This standard, enforced by both the FTC and FDA and underscored by the hundreds of warning letters already issued, is something we anticipate will continue to see enforcement. While Amazon has not yet enforced this themselves, it should still be considered in your compliance strategy. As we've seen with instances involving claims about glutamine and muscle recovery, violations could also potentially lead to civil lawsuits.

| Claim | Potential Issue |
|--|---|
| "Contains", "packed with", "powerhouse", etc | Must have a research confirmed, measurable dose in each serving. Where applicable, the product must meet the FDA Excellent Source Standard. |
| Image of Any Natural Flavor Ingredient: ex. Vanilla beans next to Vanilla Protein | Must contain the actual natural flavor being claimed. Ex. must actually contain vanilla extract (not artificial flavor). |
| | *The same applies with other fruits and vegetables. |
| Any Claims About One Specific Ingredient | Any claims about a specific ingredient must match the amount in the research supporting that claim. There must be enough research to support the claim, and the research must be based on human data. |
| FDA Approved | Supplements cannot be FDA approved – you cannot claim they are in either copy or images. You also cannot use the FDA logo. |
| "Natural" | The word "natural" should not be used to imply that the product is more effective or safer than other similar products. It also cannot be used if the product contains artificial or synthetic ingredients. |
| "Healthy" | To use the term "healthy" the product must meet specific nutritional criteria established by the FDA. |



To conclude, providing Amazon with the required documentation for supplement sales is of utmost importance. Maintaining a healthy listing not only safeguards the reputation of the seller but also fosters a positive shopping experience for customers, ultimately leading to increased sales and long-term success on the Amazon platform.



Helping brands grow products that are better for people and our planet.

We are an eCommerce focused agency that helps better-for-you brands sell their products on Amazon. We support brands with strategy, pricing, SEO, advertising, and operations and logistics.



Schedule a <u>free consultation</u> and let us help grow your business on Amazon.



Resources

<u>Amazon Compliance - Dietary Supplements</u>

Amazon Restricted Products - Dietary Supplements

Health Products Compliance Guidance (ftc.gov)

Supplement Connect | U.S. Anti-Doping Agency (USADA)

How To Get Approved To Sell Dietary Supplements On Amazon - The Selling Family

New Requirements for Amazon Sellers of Supplements - AMAZON SELLERS ATTORNEY

Amazon's New Compliance Requirements for Dietary Supplement Listings to Ensure Greater Transparency and Quality for Consumers | Harris Beach PLLC - JDSupra

How to Get Approved to Sell Supplements on Amazon (New Rules Q4 2021) - Amazing Marketing Co.

Prohibited Product Claims

FDA - Nutrient Content Claims

FDA - Structure/Function Claims

FDA - Qualified Health Claims

FDA - Authorized Health Claims

FTC - Health Products Compliance Guidance

FTC - Dietary Supplement Advertising Compliance Guide