

Catalog SOP: Disease, Medical & Pathogens Claims of USA

10/09/2024 1:24 pm CDT



Who is this for: This is intended for sellers operating in the USA Amazon marketplace who offer products that make disease, medical, or pathogens claims. This includes but is not limited to, manufacturers, distributors, and resellers of dietary supplements, herbal remedies, and other products marketed for health or medical purposes.



Objective: To provide guidance for sellers operating in the USA Amazon marketplace regarding the restrictions and limitations on disease, medical, and pathogens claims. This aims to ensure that all product claims are compliant with federal laws and Amazon's policies, particularly those related to the Dietary Supplement Health and Education Act of 1994.

The USA Amazon marketplace has stricter policies than other marketplaces when it comes to disease, medical & pathogens claims because of its federal laws.

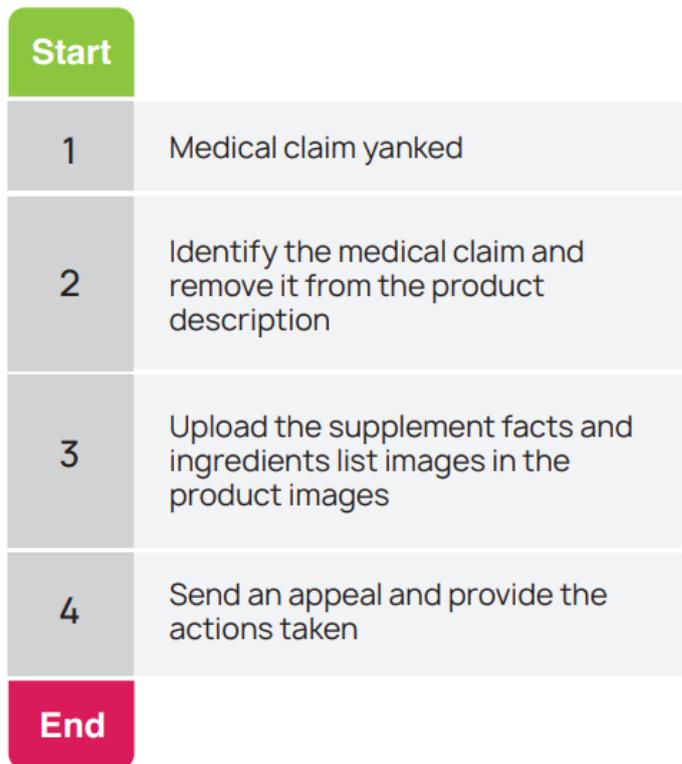
Section 6 of the Dietary Supplement Health and Education Act of 1994, titled Statements of Nutritional Support, states that *"A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."*^[1]

In compliance with this law, Amazon's legal team put restrictions on any products that have such claims.

Documents You May Need

- 1. Real-world product packaging images (Often asked by Amazon).** Amazon may need to review the product packaging if it's compliant and does not have disease, medical, and pathogens claims.
- 2. Certificate of Analysis (CoA) (Rarely asked by Amazon).** If the violation states that the product contains an ingredient or drug for the treatment, cure, mitigation, or remedy of a disease, then, you'll need a CoA.
- 3. Certificate of Good Manufacturing Practices (cGMP) (Rarely asked by Amazon).** In a very rare case if the ASIN needs selling application approval and at the same time received a disease, medical, and pathogens violation, then, you'll need GMP along with the 2 documents above to clear it from the selling application.
- 4. Manufacturer Link of the Product (Rarely asked by Amazon).** Amazon may specify that there are claims present from the manufacturer's website link of the product. If that's the case, ask the seller to edit their website and remove the prohibited claims.
- 5. Test Reports (Rarely asked by Amazon).** If the response from Amazon states that the product isn't fit for human consumption or poses safety concerns, then you'll need a test report from the manufacturer.

At a Glance



Restricted Product Policy Violations Details

The violation details are located under “Reason” in Restricted Product Policy Violations in Account Health Performance.

Diabetes

- *This product has been identified as claiming to be a treatment, cure, or remedy for Diabetes or Diabetic Neuropathy symptoms. Products marketed as Diabetes treatments, remedies, cures, or similar Diabetes related products are prohibited from listing or selling on Amazon unless they have been approved by the FDA. For more information, please see our Help Pages: https://sellercentral.amazon.com/gp/help/external/help.html?itemID=200164490&language=en-US&ref=efph_200164490_cont_200164330 For reinstatement, please remove the prohibited disease claim from the detail page and appeal the restriction. **Please note that if the disease claim is on the product labeling, there may not be a path to reinstatement.** For additional guidance, please see: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm361487.htm>*

Diabetes Claims (not limited to):

- Diabetes/Diabetic
- Blood sugar support
- Sugar support
- Sugar Balance
- Glucose
- Insulin/Insulina

Arthritis

- *This product has been identified as claiming to be a treatment, cure, or remedy for arthritis. Products marketed as arthritis treatments, remedies, cures, or similar arthritis-related products are prohibited unless they have been approved by the FDA. To be considered for reinstatement, please remove the prohibited disease claim from the detail page and appeal the restriction. **Please note that if the disease claim is on the product labeling, there may not be a path to reinstatement.** For more information please see https://sellercentral.amazon.com/gp/help/external/help.html?itemID=200164490&language=en-US&ref=efph_200164490_relt_202115120 and <https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm100228.htm>.*

Arthritis Claims (not limited to):

- Arthritis

- Joint support
- Cartilage support
- Knee remedy
- Joint pain

Cancer

- *This product has been identified as claiming to be a treatment, cure, or remedy for cancer. Products marketed as cancer treatments, remedies, cures, or similar cancer-related products are prohibited unless they have been approved by the FDA.*

Cancer Claims (not limited to):

- Free radicals
- Chemo
- Tumor

Pathogens

- *This product has been identified as a dietary supplement that makes prohibited disease claims about pathogens such as bacteria, fungi, viruses, yeast, protozoa, or microbes. Dietary supplements that make disease claims are prohibited from sale and listing on Amazon. For additional guidance, please see: https://sellercentral.amazon.com/gp/help/help.html?itemID=201829010&language=en_US&ref=su_201829010_cont_200164330 and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>. To be considered for reinstatement, you must (1) remove the prohibited disease claims from the detail page before appealing the restriction, and (2) upload a picture of the product's ingredient list to the detail page (such as the "Drug Facts" or "Supplement Facts" table). **Please note that if the disease claim is on the product labeling, there may not be a path to reinstatement.***

Pathogens Claims (not limited to):

- Microbe
- Bacteria/Bacterial
- Virus/Viral
- Toxin
- Candida
- Fungi/Fungal
- Any form/type of bacteria
- Any form/type of fungi

Other Claims (not limited to):

- Any disease with the 'itis' suffix (eg. tonsillitis, gingivitis, appendicitis, etc)
- Any description that may mitigate illnesses (eg. relief, relieve)

Remember:

1. The 4 violations above are the most common yank reasons for some dietary supplements. There is more disease, medical and pathogens violations in the US Amazon marketplace. If ever you run into other violations, please search in Google about the disease, medical, and pathogens claims of that particular "condition".
2. If the medical and disease claims are present on the product packaging, ask the seller to create a new label. If the seller wanted the listing to get reinstated immediately, ask a designer to remove the claims from the packaging.

How to Fix?

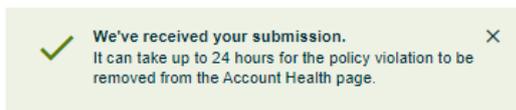
Document the changes/actions you will take.

1. Check the product images and remove the prohibited claims from infographics.
2. Download a category listing report (CLR) and remove all prohibited claims from the following attributes.
 - a. Title

- b. Description
 - c. Bullet points
 - d. Search terms
 - e. Intended Use
 - f. Other Attributes
3. Upload the updated CLR and take the batch ID.
 4. Go to A+ contents and look for the ASIN. Remove the prohibited claims from the description, images, and alt-text keywords.
 5. If you're confident that everything is set, go to Performance > Account Health > Restricted Product Policy Violations > Look for the ASIN > Appeal > Check the 2 boxes and Submit. Wait 24 hours before the listing gets reinstated.

Address your listing violation

ASIN:



Things you can do

- Monitor the performance of your account on [Account Health](#).

History

Submission

- ✓ Reviewed the original notification in Performance Notifications to confirm modifications required on the details page to be compliant.
- ✓ Read the Restricted Products policy. Products offered for sale on Amazon must comply with all laws and regulations and with Amazon's policies.

What if the listing remained yanked?

1. Send a ticket. Follow this pathway Help > Get Support > Selling on Amazon > Or, browse for your issue in the menu > Products, Listings, or Inventory > Inventory file upload issue.
2. Title/Reason: "US - Restricted Products - Appeal - ASIN: B0xx"
3. Body (the following is just an example, please don't copy but tweak it depending on the actions you took).

Case Template

Greetings,

ASIN B0xxxxxxx was yanked because it was classified/falsely classified as a product claiming to be a treatment, cure, or remedy for [enter the medical or disease claim]

We thoroughly checked the listing and removed the following claims (batch ID: xxx).

Title:

- Blood Sugar Support

Description:

- Diabetes

Bullet 1:

- *Insulin*

Search Terms:

- *Glucose*

Please see the supplement facts and ingredient list in the product images.

Please reinstate the listing. Send this to the internal team for further review and reinstatement.

1. Get the case ID and monitor the updates. Follow the instructions from the support if they give a clear one, if not, insist on the request until the listing gets reinstated.

Note:

- **Supplement Facts/Ingredients List** of the product should be present in the product images for faster reinstatement.

1. https://ods.od.nih.gov/About/DSHEA_Wording.aspx ↑
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