"Amazon Ready"?

Larisa Pavlick, VP, Global Regulatory & Compliance
United Natural Products Alliance

September 10, 2021

Introduction

1. Amazon seller central, Dietary Supplements, Policy V2
    - *Key issues and concerns*
    - *How can UNPA help?*

2. Amazon Untitled Letter
    - *“Spiked” products*
    - *What is an FDA Untitled Letter?*
    - *How does it fit into the FDA model?*

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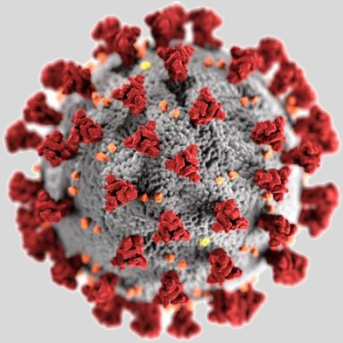
Influences and Amazon

COVID and shopping behaviors?



- 2020 DS sales = $56 billion (14.5% growth)*
  1. Highest sales* Cold/Flu/Immunity
  2. Sleep,
  3. Mental health/mood and stress.*

*Data per NBJ Summit (Clair Morton Reynolds 7/27/21)

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Influences and Amazon

Amazon sales alone for Immune products:

- Increased 165% (2019-2020)*
- $623 million in 2020 revenue*

As of 9/1/2021, I found 20,000 products on Amazon for “immune support”.

*Immune health supplement sales on Amazon. Natural Products Insider, Dan Harari, March 30, 2021

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Influences and Amazon?

- NBJ Summit audience poll: 44% buy their supplements from Amazon

- NOW Foods testing of Amazon products
  - December 2020, *Amazon issues sweeping quality specs for supplements sold on its site*
  - August 09, 2021, *NOW Tests Curcumin Prods on Amazon, Identifies "Egregious Problems"*

Setting the Amazon Stage: DS Quality Policy

- Version 1 (V1)
  - UNPA/Amazon interaction
  - ~March 2021
- V2
  - ~June 2021
- V3
  - On hold.
  - Release was planned as August 2.

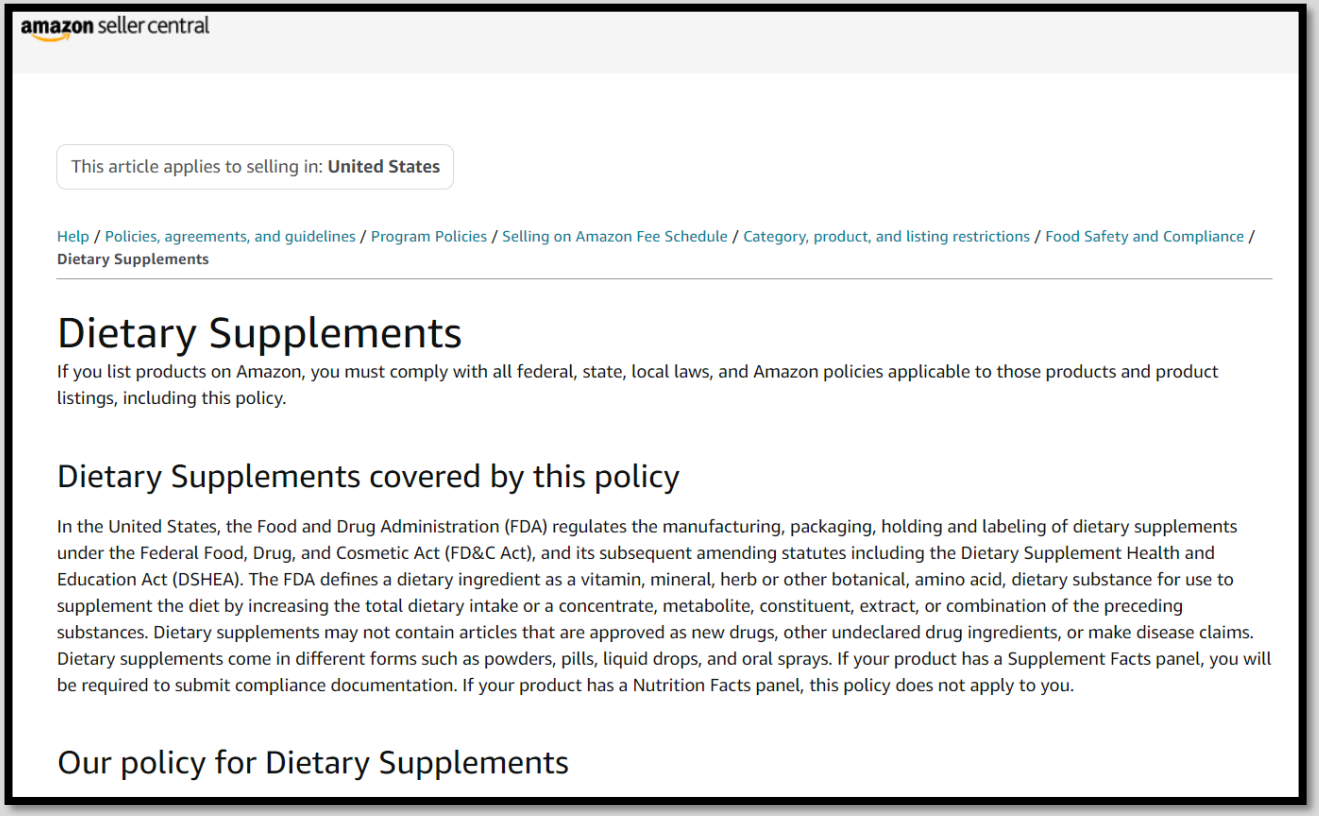
Setting the Amazon stage

UNPA Amazon Committee

Concerns and interactions:

1. NAC (~April 2021)
2. Meltable policy
3. Brand Protection Team
    - Counterfeit and diverted product
    - Amazon to UNPA Member presentation om 5/13/2021

Amazon Seller Central, Dietary Supplement Policy V2



amazon seller central

This article applies to selling in: **United States**

Help / Policies, agreements, and guidelines / Program Policies / Selling on Amazon Fee Schedule / Category, product, and listing restrictions / Food Safety and Compliance / **Dietary Supplements**

Dietary Supplements

If you list products on Amazon, you must comply with all federal, state, local laws, and Amazon policies applicable to those products and product listings, including this policy.

Dietary Supplements covered by this policy

In the United States, the Food and Drug Administration (FDA) regulates the manufacturing, packaging, holding and labeling of dietary supplements under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and its subsequent amending statutes including the Dietary Supplement Health and Education Act (DSHEA). The FDA defines a dietary ingredient as a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use to supplement the diet by increasing the total dietary intake or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Dietary supplements may not contain articles that are approved as new drugs, other undeclared drug ingredients, or make disease claims. Dietary supplements come in different forms such as powders, pills, liquid drops, and oral sprays. If your product has a Supplement Facts panel, you will be required to submit compliance documentation. If your product has a Nutrition Facts panel, this policy does not apply to you.

Our policy for Dietary Supplements

https://sellercentral.amazon.com/gp/help/external/help.html?itemID=55N3JF2WQS7RVNE&language=en_US

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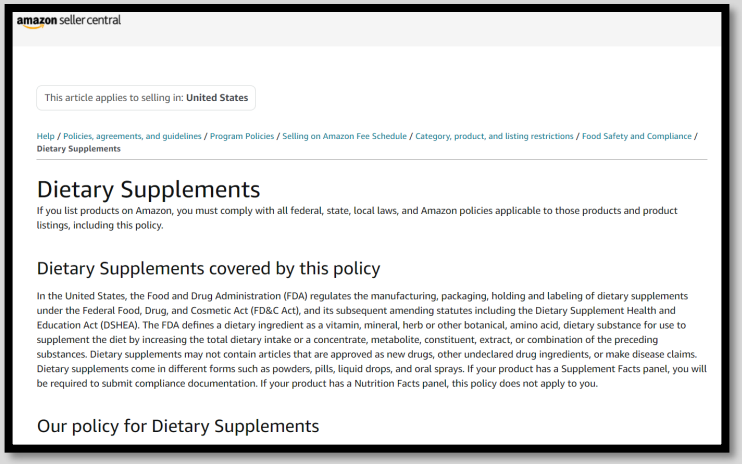
Amazon Seller Central, Dietary Supplement Policy V2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Our policy for Dietary Supplements

Four full pages including:

1. Products covered by this policy
2. **Applicable Regulations**
3. **Required Documentation**
4. **Requirements for the Certificate of Analysis (COA)**
5. Requirements for Product images
6. How to submit information
7. FAQ
8. Policy violations
9. Additional Resources

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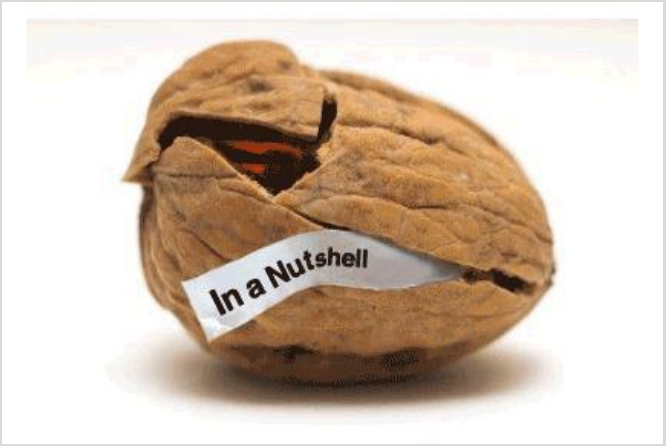
Dietary Supplements (DS) Covered by Policy

- FDA regulates manufacturing, packing, holding, labeling of DS
- DSHEA amends FD&C
- FDA defines a dietary ingredient
- DS may not contain new drugs, undeclared drug ingredients, or disease claims
- Delivery forms: “powders, pills liquid, drops and oral spray”
- Supplement Facts panel = required to submit compliance documentation



https://scratch.mit.edu/studios/5020168/activity/

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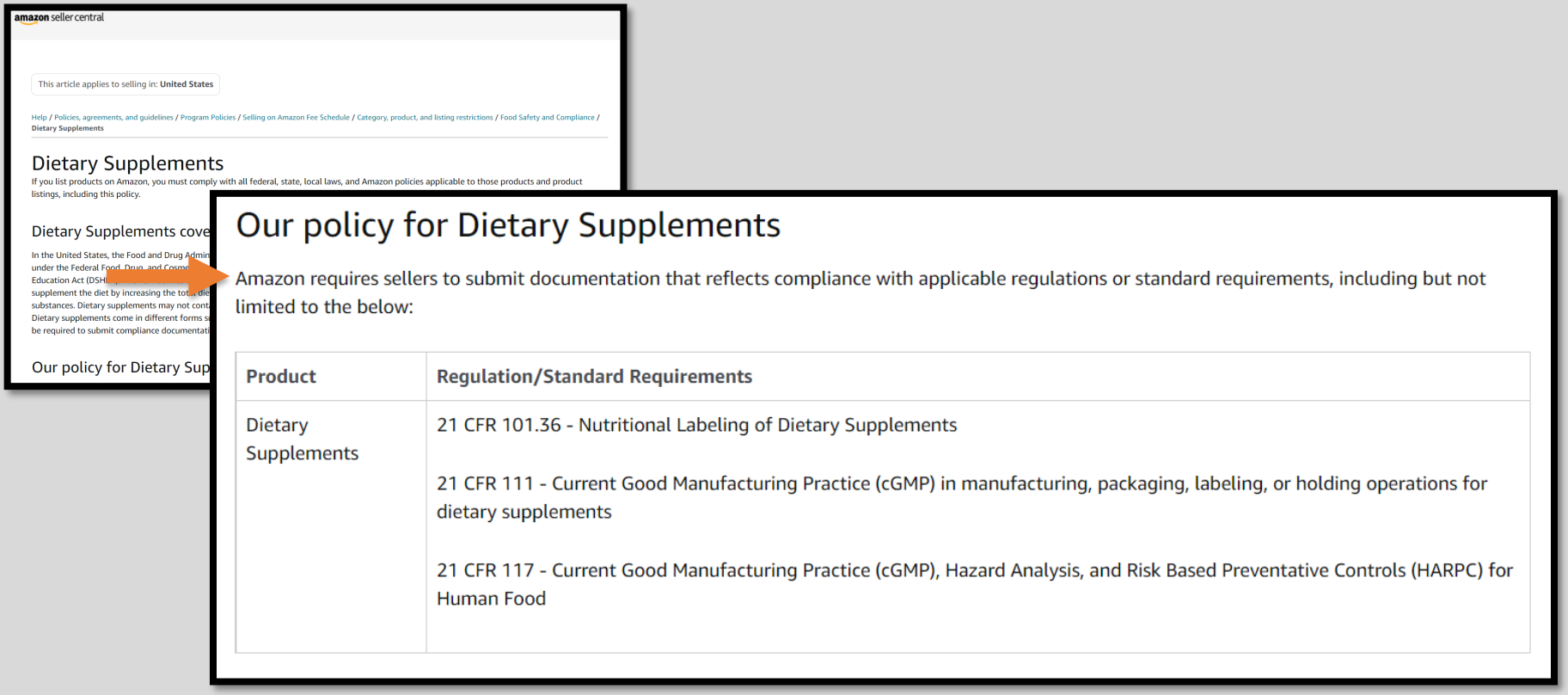
Applicable Regulations



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25 years

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Promoting safety, science and quality since 1992

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UNPA Training

In House or Public/Virtual

September 21-23 | December, 2021

October 6-7, 2021

October 20-21, 2021

November 9-11, 2021

Questions or to register contact Linda O'Dea at linda@unpa.com.

https://www.unpa.com/2021-training-schedule.html

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DS GMPs Compliance
21 CFR Part 111.70 (b) and (e)

(b) Component and (e) Finished Product

Specifications must Including:

- Identity [111.70(b)(1)]
- Purity
- Strength
- Composition
- Limits for potential contaminants or adulterants [111.70(b)(3)]

111.70(b)(2)

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Sec. 111.75
Verification via Testing and Monitoring

ALKEMIST LABS

Flora Research Laboratories, LLC

UNPA Science and Technology Partners:

- Industry Attorneys
- Laboratories, Third Party Certifying Bodies
- Consultants
- Equipment Suppliers

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Waters THE SCIENCE OF WHAT'S POSSIBLE.™

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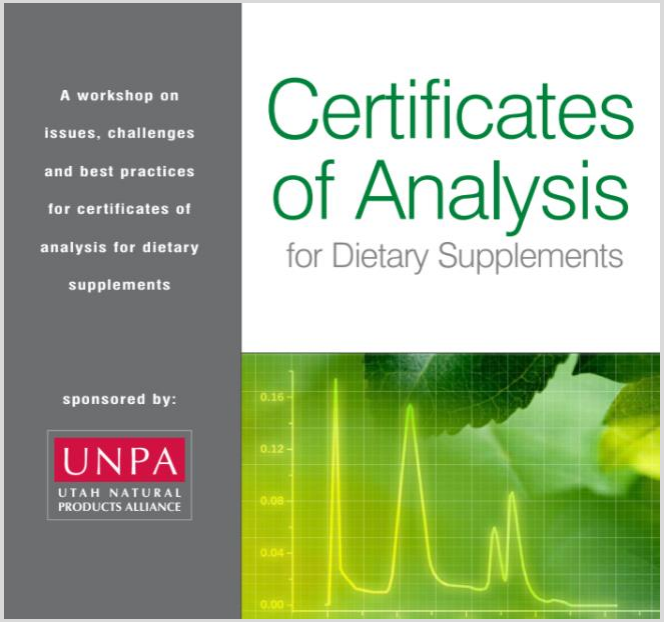
Required Documentation



1. Finished product Certificate of Analysis (COA)
   - Issued by and ISO/IEC 17025 accredited lab
   - ✓ Valid ISO certificate of lab with accreditation body and number

Concern: ISO

- Misuse of ISO in advertising
- Scope of accreditation to the specific test
- Amazon FAQ

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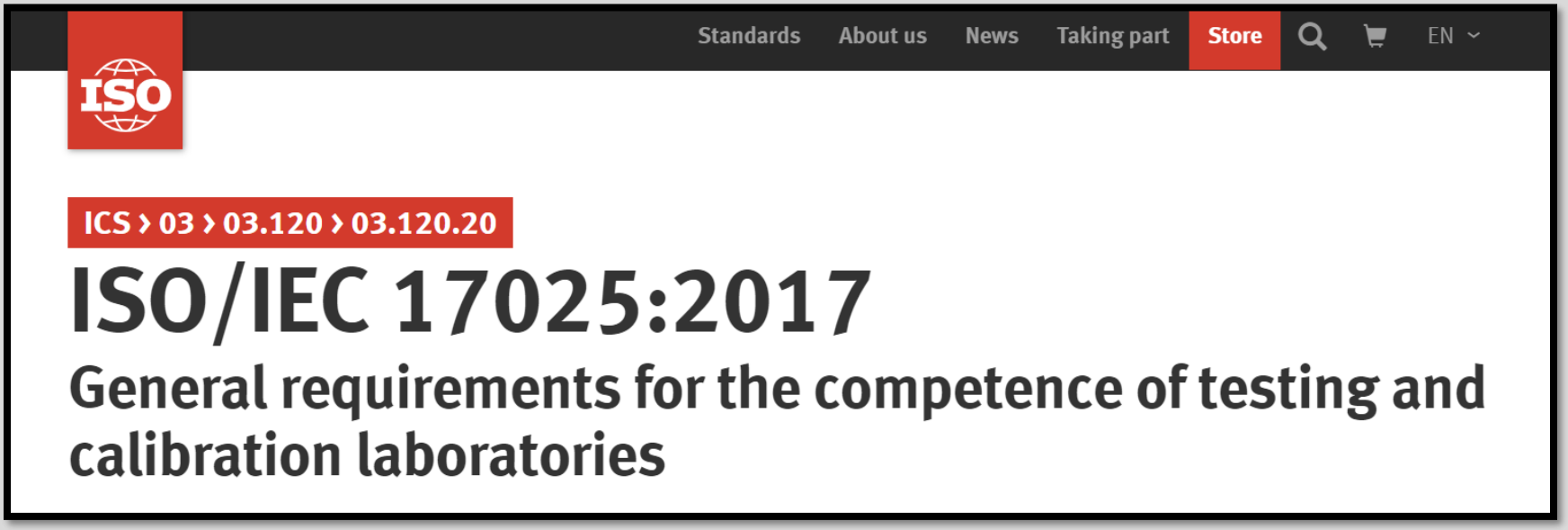
Sec. 111.75
Testing and Monitoring



Abstract, General Requirements: https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:ed-3:v1:en

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Required Documentation

Or

2. Finished product COA issued by an in-house lab
   - Compliant with current Good Manufacturing Practices (cGMP) per 21 CFR part 111 or part 117
   - ✓ Valid GMP certificate from one of ten 3rd party programs including:
     - GRMA
     - NSF/ANSI
     - UL GMP
     - USP GMP
     - Eurofins
     - SAI Global
     - SGS
     - Intertek
     - TGA
     - SSCI

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Required Documentation

Or

3. Evidence of Product/ASIN enrollment in a 3rd party quality certification program including:

- NSF/ANSI 173 Product Certification
- NSF Certified for Sport
- BSCG Certified Drug Free
- Informed-Choice/Informed-Sport Program,
- USP Dietary Supplement Verification Program
- UL Brand Certification Program

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Amazon FDA Untitled Letter

FDA U.S. FOOD & DRUG ADMINISTRATION

July 26, 2021

CMS # 608717

Andy Jassy, CEO
Amazon.com, Inc.
2021 7th Ave
Seattle, WA 98121-2601 US
Regulatory-inquiries@amazon.com

Dear Mr. Jassy:

This letter concerns your firm's distribution of products that violate the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"). As explained below, the United States Food and Drug Administration (FDA) purchased on your website, www.amazon.com, dozens of products intended for sexual enhancement and weight loss and, after subsequent laboratory analysis, determined that all tested products contain undeclared and potentially harmful drug ingredients.[1] As discussed further below, your firm is responsible for introducing, delivering, or causing the introduction or delivery into interstate commerce of products that are unapproved new drugs under section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and/or misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352, and for introducing or delivering for introduction into interstate commerce a food which is prohibited under section 301(ll) of the FD&C Act.

December 2019 to February 2020 Purchases from Amazon

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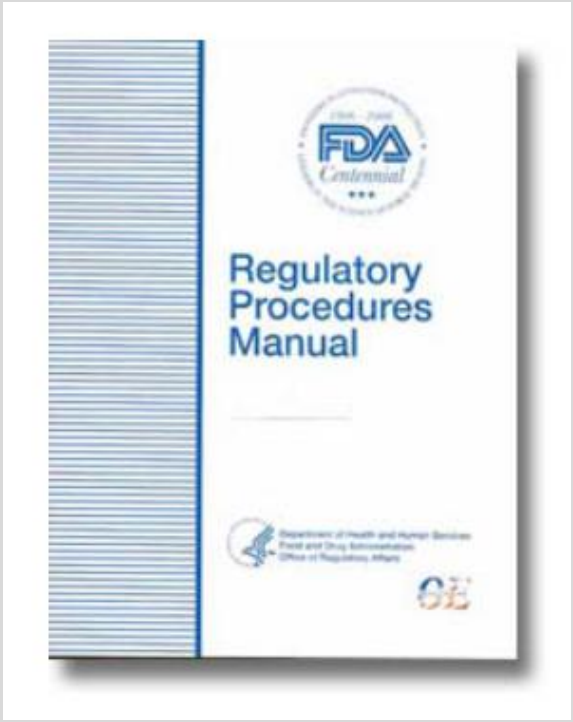
FDA Untitled Letter

What is an untitled letter?
What is the process of regulatory action?



compliance with the Act.

b. An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter. Untitled Letters are intended to cover those circumstances where the Agency has a need to communicate with regulated industry about violations that do not meet the threshold of regulatory significance as described above. The three types of letters related to licensed products that are issued by CBER and CDER, pursuant to subsection 6.3 of Exhibit 4-1 do not necessarily fall within this definition of an Untitled Letter; however, they are still Untitled Letters that are covered by the scope of these procedures.

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Amazon FDA Untitled Letter

Issued July 26, 2021

- Eight pages long!!!
- Two-page table in Appendix including 29 "Tainted Products"
- To: CEO Andy Jassy
- From: Director of Compliance for FDA-Center for Drug Evaluation and Research

U.S. FOOD & DRUG ADMINISTRATION

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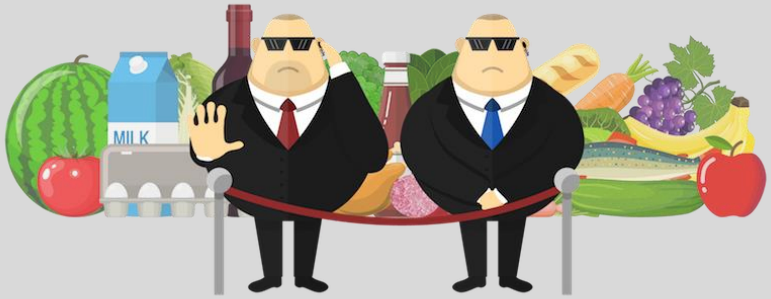
Amazon FDA Untitled Letter

As a result of at least three "*Undercover Buys*" by FDA staff…

- Initial buys were between December 2019 and February 2020 (pre-COVID)
    - Purchased 26 Sexual Enhancement Products
    - 25/26 marketed/sold as DS, one labeled as a food (coffee)
    - 26/26 test positive for ED pharmaceuticals



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Amazon FDA Untitled Letter

- December 17, 2020, FDA issued public notice
- FDA communicated “several times” in Dec and January
- Amazon, “restricted” the sale of products and sellers

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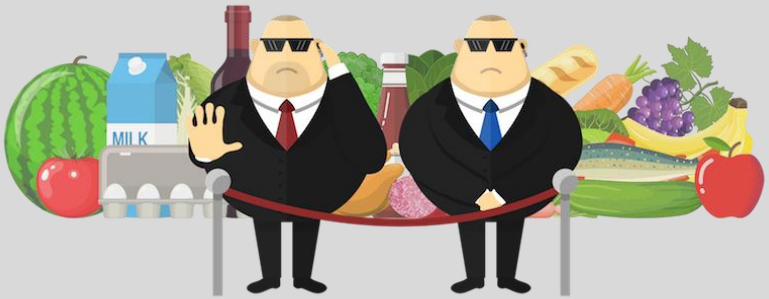
Amazon FDA Untitled Letter

2. January 2021
   - "*Compliance follow up*"?
   - FDA purchases one of the 26 violative products from the same seller (Jan 15, 2021)
   - "...you acknowledged...you previously failed to detect this product by the identified seller."



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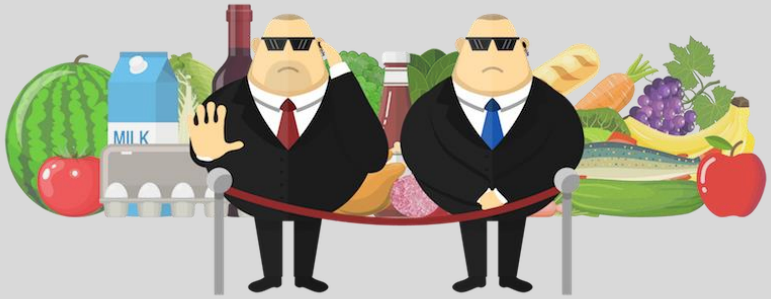
Amazon FDA Untitled Letter

3. March 2021
   - Two additional and different ED products (positive for tadalafil, an ED drug)
   - One weight loss (positive for sibutramine, weight loss drug, withdrawn from U.S. market due to risk)
     - ✓ Delivered into interstate commerce by Amazon Fulfillment by Amazon services.



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Amazon FDA Untitled Letter Now What?

Amazon's response to prior FDA communications about such unapproved new drugs, misbranded drugs with undeclared drug ingredients, and/or foods to which have been added an approved drug has not been sufficient to protect the public from the serious and continuing risk of harm posed by such products sold on www.amazon.com. Generally, Amazon has responded by making efforts to restrict the sale of specific

"Amazon's response to prior FDA communications….has not been sufficient to protect the public from the serious and continuing risk of harm posed by such products sold on www.Amazon.com."

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Amazon FDA Untitled Letter Now What?

- "Repeat Violations"
  1. May 2018 FDA purchases Rhino
     - Positive for ED drugs
     - Results in a regulatory meeting (October 2018)
  2. May 2019 FDA purchases Man Fuel
     - Positive for ED drugs

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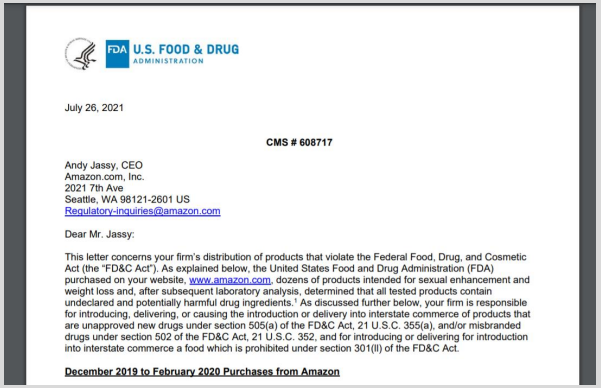
Amazon FDA Untitled Letter



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December 2019 to February 2020 Purchases from Amazon

Request for written response…

- 15 days (~August 16)

This letter notifies you of our concerns and provides you an opportunity to address them. Please submit a written response to this letter within fifteen working days from the date of receipt, explaining the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, including steps you will take to ensure that Amazon will no longer introduce, deliver, or cause the introduction or delivery into interstate commerce of, unapproved new drugs and/or misbranded products with undeclared drug ingredients, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within fifteen working days from the date of receipt of this letter.

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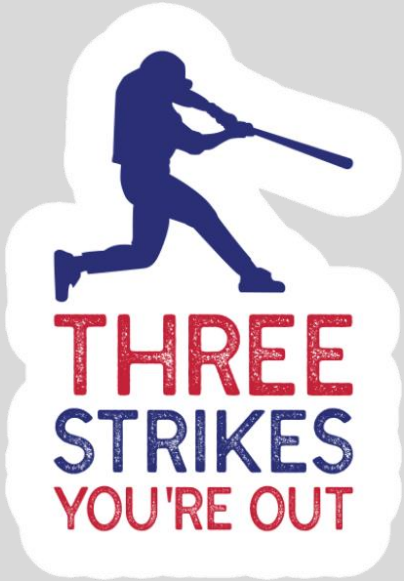
Amazon FDA Untitled Letter Now What?

FDA



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Questions?

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Conclusion

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For More Information

- **Regulatory and Compliance**
  (member support, training, consulting)
  Larisa Pavlick, larisa@unpa.com

- **Regulatory and Training Coordinator**
  (Training: Public, Private, Virtual or Onsite)
  Linda O'Dea, linda@unpa.com

- **UNPA membership or member service**
  Kira Olsen, kira@unpa.com

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Thank You

Larisa E. Pavlick
VP, Regulations and Compliance
United Natural Products Alliance

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