

# Supplements in Practice:

## Quality Assessment Tools

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IFM AIC - June 2022



# What does quality mean to you as a provider?

Ask yourself these questions:

- Why is quality important to me?
- Why is quality important to my practice?
- Why might my patients care about quality?
- How are patient healthcare and outcomes affected by supplement quality?
- What am I currently using as benchmarks for supplement quality?

# The story of your supplements: A timeline of quality

*“Quality = trust and transparency”*



## Sourcing standards

*Building trust in the origin*



## Manufacturer standards

*Building trust in the brand*



## Product integrity

*Building trust in the finished product*

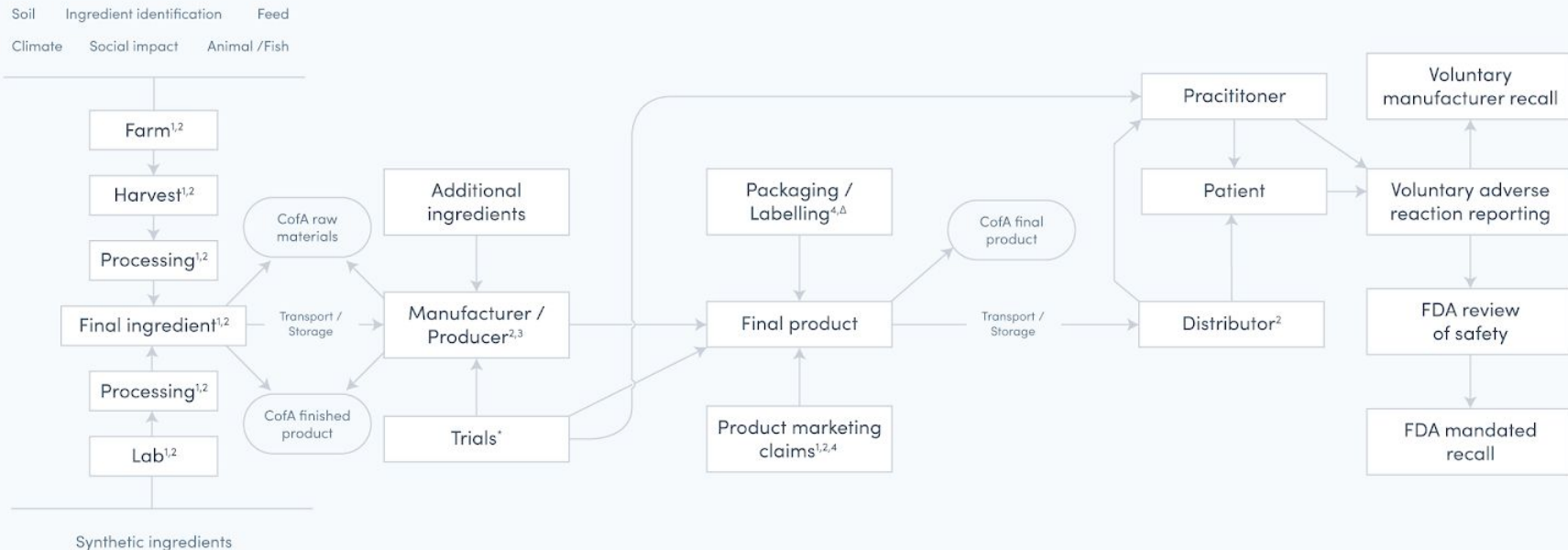


## Distributor standards

*Building Trust in our brand*

# Dietary supplement supply chain

An overview of dietary supplement origin, manufacturing, labeling and distribution from source to consumer.



\*Optional pre-clinical and clinical trials to improve safety, efficiency, and effectiveness <sup>Δ</sup>Allergens, source claims, excipients

<sup>1</sup>3rd party certification <sup>2</sup>Mandatory FDA GMP post-market <sup>3</sup>Mandatory serious adverse reaction reporting to FDA post-marketing <sup>4</sup>FDA post-market monitoring





# Assessing the source

Trust in the origin

# Ingredient sourcing

Optimal safety and efficacy relies on accurate sourcing, identification, validation, and processing.

Ingredient quality and safety considerations include:

- Origin, location, and environmental stewardship
- Derivation and processing of the ingredients
- Ingredient analysis and certification
- Other operational considerations



# Origin

## Ingredients of plant origin

- **Growing/harvest:** affected by the environment and plant's stage of growth
- **Drying:** avoids damage from microbes and mold
- **Processing:** may improve purity, remove toxins, protect against microorganisms, and improve efficacy
- **Recording:** parts of plant used, ingredient scientific names, common names, cultivar name, ecotype, chemotype, and phenotype

## Ingredients of non-plant origin

- **Sourcing:** various animal tissue sources or synthetic processes
- **Raising (animals):** differences can lead to variation in bioavailability and specific activity efficacy
- **Extraction and purification** protocols



# Examples of raw material identity/potency challenges

Ingredient	Common adulterants	Primary analytical method of choice	Methods that are not acceptable	Other comments
<b>Bilberry</b>	Amaranth dye, black soy hull	USP <b>HPLC</b> method covers both identity and potency	FTIR/NIR for identity; UV spectrophotometric for potency	The product may meet "total anthocyanin" content, but this does not mean the material is in fact bilberry
<b>5-HTP</b>	Unidentified	<b>Specific HPLC</b> methods with a primary standard	HPLC methods not traceable to an authentic <b>primary standard</b>	Market shortage of 5-HTP causes price increases which leads to economic adulteration

# Troublesome ingredients: Concerns and solutions

Ingredient	Quality Concerns	Quality Solutions
<b>Probiotics</b>	<ul style="list-style-type: none"><li>• Misidentified bacterial species and strains</li><li>• Inadvertent inclusion of pathogenic bacteria</li><li>• Inclusion of non-viable strains</li></ul>	<ul style="list-style-type: none"><li>• Bacterial identification based upon DNA fingerprinting</li><li>• Finished product potency with cell enumeration studies and microbiological contaminant testing</li><li>• Strain-specific human viability data</li></ul>
<b>Omega-3</b>	<ul style="list-style-type: none"><li>• Contamination with excessive levels of PCB, anisidine, and dioxins</li><li>• Oxidative rancidity (peroxide, anisidine: used to calculate totox value)</li><li>• Excessive heavy metals (Hg)</li><li>• EPA and DHA potency</li></ul>	<ul style="list-style-type: none"><li>• Low heat, chemical-free extraction process</li><li>• Heavy metal testing using ICP-MS or AA methodology</li><li>• Full peroxide, PCB, dioxin, anisidine screening</li><li>• Finished product potency testing using GOED GC methodology</li></ul>

# Blockchain sourcing

A secure, step-by-step verification of ingredient supply, handling, distribution, and sale

- Maps the product journey as it progresses from the original source (e.g., farmer, lab, etc.) to the consumer
- **Decentralizes** the supply chain as each “block” involves time stamping transactions for a particular batch, which then becomes unalterable
- Can reduce the time it takes to **track the origin** of a food/ingredient from days to seconds



Enter Your Herb ID Q




CAN'T FIND YOUR HERB ID?

Your herb ID# can be found on the back of your product. Or, enter A571201042 to trace a batch of our Adrenal Health Daily Support.

- Locate your Herb ID on the product's packaging
- Enter an Herb ID to search for your product's batch
- Discover Industry-leading Herbal Transparency



[E140601035](#)



ID #E140601035

## Vitex Berry

Traditionally for maintaining a healthy hormone balance & keeping your cycle regular\*

MASTER ID	E140601035
MANUFACTURE DATE	4/4/2019
BEST BY DATE	4/4/2022

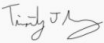
[Shop This Product](#)

### Testing Results for Vitex Berry


We believe you deserve to know exactly what's in your supplements—and what's not. At [Vitality](#), every ingredient and finished product is tested in our state-of-the-art laboratory to ensure Purity, Integrity, and Potency.

MICROBIAL TESTING	✓ Passed
HEAVY METAL TESTING	✓ Passed
IDENTITY TESTING	✓ Passed
PESTICIDE TESTING	✓ Passed
STRENGTH TESTING	✓ Passed

Quality Assurance Approvals



Director of Quality



Data Reviewer



# Assessing manufacturing

Trust in the brand

# Supplement manufacturing: Quality elements

	Raw material ingredients	Manufacturing processes	Finished product
<b>Scope of quality control</b>	Raw material sourcing and specifications: identity, potency, purity	current Good Manufacturing Practices (cGMPs)	Finished goods testing: potency, stability, contaminants
<b>Methods</b>	NIR, TLC, UV-Spec, HPLC, GC, mass spec, organoleptic, macro- and microscopic	QC unit, written SOPs, quality training, process controls, self-audits, plant sanitation, adverse event reporting	TLC, UV-Spec, HPLC, GC, mass spec, retained samples, lot number identification, real time stability program
<b>Considerations</b>	<ul style="list-style-type: none"><li>• Supplier qualification</li><li>• Specifications</li><li>• Testing methodology</li><li>• Testing frequency (every batch vs. skip-lot)</li></ul>	<ul style="list-style-type: none"><li>• Process validation (cGMP compliance)</li><li>• In-process sampling</li><li>• Self-audits</li><li>• Third-party cGMP certification</li></ul>	<ul style="list-style-type: none"><li>• Testing methodology</li><li>• <b>Frequency (every batch vs. skip-lot)</b></li></ul>

# Contamination

- Heavy Metals
- Microbial Contaminants
- Pesticides/Herbicides
- Pharmaceuticals
- Solvents



## U.S. FDA warns of hidden drug ingredients in certain supplements products

By Syndicated Content  
© Apr 20, 2022 | 2:39 PM

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2 WANTS TO KNOW

## Hidden drugs in supplements found on Amazon & eBay

Consumer Reports and the FDA are warning consumers & helping them find the list of tainted supplements.



By  
C. Michael  
White, The  
Conversation

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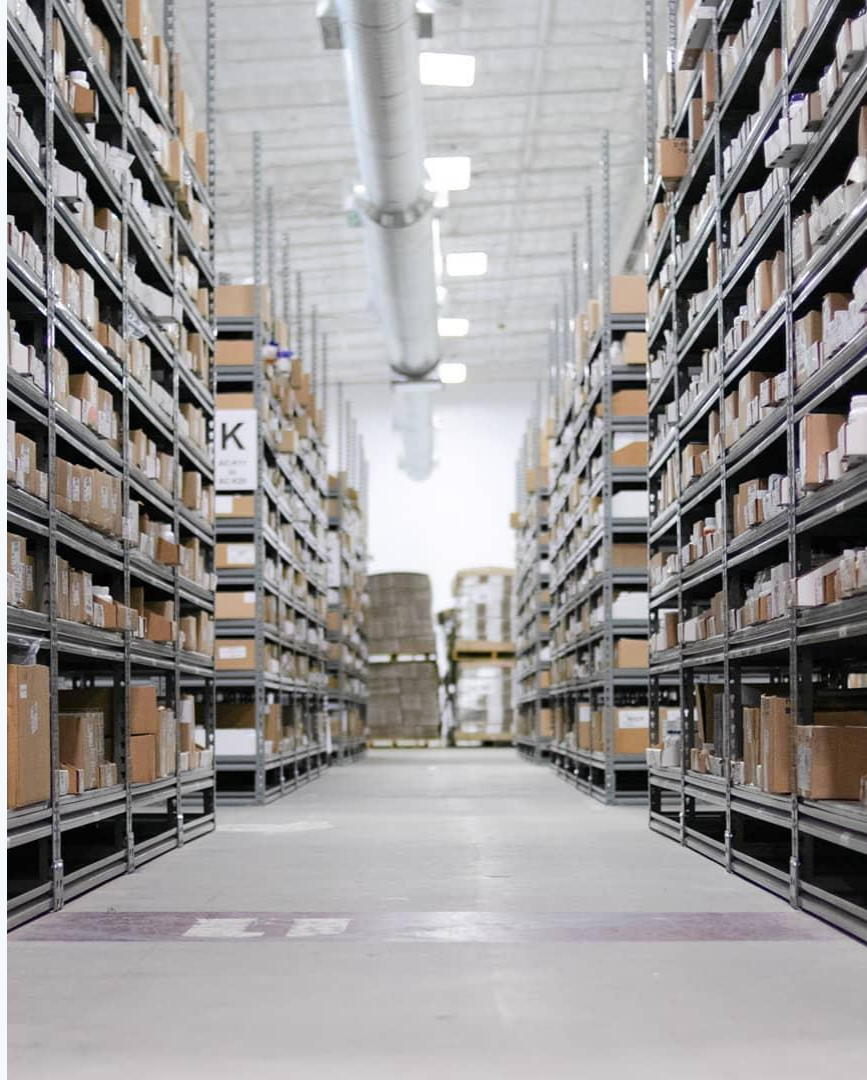


## Analysis: Some natural supplements can be dangerously contaminated

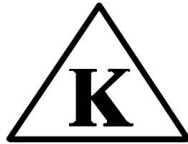
Health Feb 19, 2020 11:13 AM EST

# Testing

- The FDA requires companies to conduct identity testing; however, these standards can be chosen and developed by the companies themselves with no obligation to publicize their standards.
- **Third-party certification** companies are independent auditing agencies that inspect and verify ingredient sourcing, product manufacturing standards, distribution channels, and accurate labeling.



# Third-party certifications



# What is NSF®?

The National Sanitation Foundation (NSF): Third-party certification programs



## NSF®

- Impartial review to industry guidelines
- Verifies labeling and claims
- Provides market advantage
- Demonstrates quality, safety, and compliance
- 180+ countries



## NSF Certified for Sport®

- Used by athletes, coaches, and dietitians when choosing sports supplements to reduce the risk of doping sanctions
- Screens for 280+ substances
- Only third-party certification recognized by the USADA, MLB, NHL, and CFL



# Questions to ask the manufacturer directly

- Do you test all raw materials? Which tests? How frequently?
- Do you test finished products?
- Do you test every batch or do skip lot testing? How is the frequency determined?
- Do you conduct research on your full products?
- For herbs, how are they sourced?
- What test methods do you use?
- Do you use a third-party lab or in-house lab?
- Can you provide a Certificate of Analysis (CoA)?
- How to you ensure stability? How long do you monitor for?



# Assessing integrity

Trust in the finished product

# Defining product quality

Discerning quality requires a multi-faceted, often individualized approach.

Compliance with regulations and **current Good Manufacturing Practices** (cGMPs)

**Accurate** ingredient sourcing, identification, validation, and processing

Labeling of **allergens, source claims,** and **excipient ingredients**

Ethical implications and **third-party certifications**

Relevant **scientific evidence** supporting ingredient effectiveness

Manufacturer **transparency** at every step of the supply chain

**Professional-grade** is a marketing term used to describe product lines sold exclusively to or through medical professionals. This term is often used interchangeably with **quality**.

# Identifying needs

## How Do Naturopathic Doctors Define the Quality of Natural Health Products? An Inductive Approach to Establish North American Standards

Daniella Remy, MSc<sup>(1)</sup>, Dr. Adam Gratton, ND<sup>(1)</sup>, Dr. Kieran Cooley, ND<sup>(1,2,3,4)</sup>

1. Canadian College of Naturopathic Medicine, ON, Canada; 2. University of Technology Sydney, Ultimo, Australia; 3. Pacific College of Health Sciences, San Diego, USA; 4. National Centre for Naturopathic Medicine, Southern Cross University, Lismore, Australia



### Introduction

- Despite the regulations established by Health Canada and the FDA, issues with natural health product (NHP) manufacturing and batch-to-batch variability remain.
- Third party labs will examine the purity and chemical quality of single-ingredient products, but multi-ingredient products have inadequate objective evaluation.
- The assessment of NHP quality throughout North America remains relatively subjective and is prone to personal biases, marketing exposure and convenience.

### Objectives

- Identify what subjective and empirical attributes NDs use to define quality NHPs to ultimately develop a measure of NHP quality comparison.

### Methods and Sample

- Mixed-methods approach

#### Data Collection & Participants

- | Phase 1  | Phase 2  |
|--|--|
| <ul style="list-style-type: none"> <li>Interviews with NDs who had a minimum of 5 years of experience, using an inductive approach in grounded theory.</li> <li>Out of 67 willing participants, eight interviews were needed to obtain data saturation.</li> </ul> | <ul style="list-style-type: none"> <li>Anonymous online survey based on Phase 1 results using rank-ordering of themes.</li> <li>Out of 322 participants, 309 licensed and practicing naturopathic doctors/physicians in either Canada or the US completed the survey.</li> </ul> |

Figure 1: Geographic location of participants



### Results

- Sourcing, labelling, monographs, and third-party testing emerged as the four main themes to assess quality NHPs, with several sub-themes for each of these.
- For sourcing, participants placed the most importance on adherence to GMP, followed by the inclusion of details of the manufacturing process (ie: cold-pressed, hydrolyzed, etc.) provided on the product label or in the product monograph.
- For labelling, most importance was placed on the inclusion of the active constituents and/or standardized compounds in addition to the amount per capsule/serving, with 47.0% of participants ranking it topmost.
- For monographs, it was deemed important to provide evidence of therapeutic efficacy, including its magnitude of benefit, followed by evidence on dosing, with a clear rationale for the amounts included in the product's formula.
- For third-party testing, verifying that the ingredients match the product label was deemed the most important, with 44.5% of participants ranking it in first place.
- Though nearly half of participants did not feel the geographic location of ingredients or the manufacturer were important, Canada, Australia and Germany were deemed the best countries from which to source natural health products.

### Discussion and Conclusion

#### Strengths:

- Rank-order helps distinguish most important from less important factors that define quality.

#### Limitations:

- Distribution of participating NDs may not be representative of all provinces and states.
- Rank-order surveys can be challenging for respondents.

#### Future Considerations:

- Using a Delphi technique to refine the findings and develop a quality scoring system through consensus.

#### Conclusion:

- The ND's selection of NHPs relies heavily on the manufacturing company's reputation and its ability to adhere to GMP and high caliber extraction processes.
- The more transparent an NHP company can be, the more likely the product will be considered of high quality.

Table 1: Ranking of Items that Define Quality Sourcing

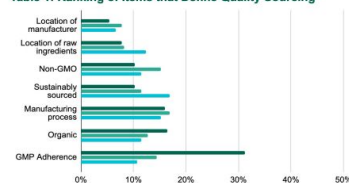
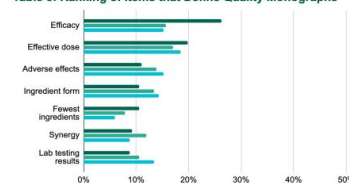


Table 3: Ranking of Items that Define Quality Monographs



#### Legend

- % of participants who ranked the item First
- % of participants who ranked the item Second
- % of participants who ranked the item Third

#### Ethics approval:

- Approved by CCNM's REB, including advertising, consent forms, and assurance of confidentiality.

#### Funding:

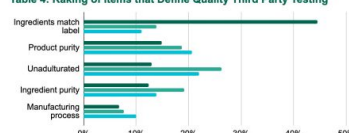
- CCNM Student Innovation Fund supported by Biotics Research Inc.

For references or further questions, please email: [dremy@ndnet.com.au](mailto:dremy@ndnet.com.au)

Table 2: Ranking of Items that Define Quality Labelling



Table 4: Ranking of Items that Define Quality Third Party Testing



# Discerning quality when comparing products

Discerning quality requires a multi-faceted, often individualized approach.

## Product example #1

- Safety
- Research
- Environment
- Uniqueness/access
- Vegan
- Gluten-free
- Glyphosate-free

## Product example #2

- Safety
- 1% for the Planet
- Research
- Cost-effective
- Transparency

## Product example #3

- Safety
- USP-certified
- Research

# How to read a supplement label

Supplement Facts		
Serving Size 2 Capsules Servings Per Container 30		
	Amount Per Serving	% Daily Value
Vitamin C	500mg	834%*
Zinc	20mg	199%*
Beta Glucans	300mg	†
Echinacea purpurea	100mg	†
Standardized to 4% alkylamides (4 mg)		
Proprietary blend	500mg	
Echinacea angustifolia (leaf)		†
Allium sativum (bulb)		†
Withania somnifera (root)		†
Ganoderma lucidum (aerial parts)		†
Rhodiola rosea (root)		†
Andrographis paniculata (aerial parts)		†
* Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.		

The "Supplement Facts" title is an indicator that the product is marketed for sale in the U.S. and is an FDA standard.

The serving size, and sometimes the number of servings per container, will be included to help you compare more easily between products.

Make sure the serving sizes match when comparing supplements to get an accurate comparison between the products.

Vitamins and minerals will always show the dose in both weight and % daily value to help you understand how you're hitting your dietary requirements.

Many supplements will have doses that exceed the recommended daily value.

Dietary supplement ingredients that are not vitamins or minerals will not have a % daily value as they are not essential ingredients in the diet.

Supplement Facts		
Serving Size 2 Capsules Servings Per Container 30		
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Vitamin C	500mg	834%*
Zinc	20mg	199%*
Beta Glucans	300mg	†
Echinacea purpurea	100mg	†
Standardized to 4% alkylamides (4 mg)		
Proprietary blend	500mg	
Echinacea angustifolia (leaf)		†
Allium sativum (bulb)		†
Withania somnifera (root)		†
Ganoderma lucidum (aerial parts)		†
Rhodiola rosea (root)		†
Andrographis paniculata (aerial parts)		†
* Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.		

Herbs will sometimes have additional information listed in the supplement facts panel. You might see ratio numbers (i.e. 4:1) that designate how much raw material of the herb (fresh or dried herb) went into making the supplement version of the herb.

Herbs might have a standardization amount that corresponds to how much of an active ingredient is present in the herbal supplement. The dose of the active ingredient is often listed, but not always.

Proprietary blends are common in dietary supplements. Only the total amount of the proprietary blend in a serving needs to be listed on a supplement, which means that you don't get all of the information about every ingredient that is in the blend.

Ingredients in a proprietary blend are listed in order from most to least. This is similar to how food ingredients are listed on nutrition facts panels that you find on prepared foods.

The daily value percent is established against a 2,000 calorie diet. While this is the standard calorie amount across most labels, it's always important to scale your requirements based on the calorie intake that you need to reach your health goals.



# Allergens and source claims

Labeling reduces allergic reactions and unintentional consumption of ingredients.

100% plant source

Corn

Dairy

Egg

Fish

Gluten (certified)

Gluten (non-certified)

Glyphosate  
residue-free

Lactose

Peanut

Sesame seed

Shellfish

Soy

Starch

Sugar

Sulphite

Tree nuts

Wheat

Yeast

Vegan

Vegetarian

# Excipients

Additional ingredients used to improve the manufacturing process; maintain or enhance product stability, acceptability, safety, pharmacokinetic and pharmacodynamic profile; or aid in product identification

α-tocopherol  
Ascorbic acid  
Ascorbyl palmitate  
Aspartame  
Benzalkonium chloride  
Boric acid  
Calcium carbonate  
Carrageenan

Castor oil  
Citric acid  
Ethanol  
Gelatin  
Glycerin  
Hydroxypropyl  
methylcellulose (HPMC)  
Lanolin

Lactose  
Lecithin  
Macrogols  
*(polyethylene glycols)*  
Magnesium stearate  
Modified cellulose  
*(microcrystalline)*  
Modified cellulose gum  
*(croscarmellose sodium)*

Potassium sorbate  
Propyl gallate  
Sesame oil  
Silicon dioxide  
Sodium metabisulphite  
Soybean oil

\*Must be **Generally Recognized as Safe** (GRAS) by the FDA

\*May be derived from animal, plant, biotechnological, or mineral sources

# Why are formulations, patents, and trademarks important?

Generally, intellectual property rights protect the **supplement manufacturer**.

- Protect **innovations** from market competitors
- Make their company more attractive to investors
- Novel formulas differentiate products in the market and drive **sales**

However, researchers develop strategies to enhance product **safety** and **effectiveness**.

- Improve ingredient solubility and permeability
- Extend ingredient metabolism and half-life



# FDA Health Fraud Database and The BAPP

## Health Fraud Product Database

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This list includes unapproved products that have been subject to FDA health fraud\* related violations. These products have been cited in [warning letters](#), [online advisory letters](#), [recalls](#), [public notifications](#), and [press announcements](#) for issues varying from products marketed as dietary supplements claiming to cure, mitigate, treat or prevent disease, to the use of undeclared ingredients or new dietary ingredients.

This list only includes a small fraction of the potentially hazardous products marketed to consumers online and in retail establishments. Even if a product is not included in this list, consumers should exercise caution before using certain products.

For more information, see the [Medication Health Fraud](#) and [Health Fraud Scams](#) webpages.

### Search Database

(Table results update automatically as you type)

Search:

[Export Excel](#) Show  entries

Date	Product <sup>1</sup>	Firm	Firm Address	Source/URL(s)	Subject	Action	Program Area(s)	Additional Outcome
04/25/2022	Kingdom Honey Royal Honey VIP	n/a	n/a	shopaax.com	Undeclared sildenafil	<a href="#">Public Notification</a>	Drugs	
04/25/2022	Cougar Secret Honey VIP	n/a	n/a	greenvalleyshops.com	Undeclared sildenafil	<a href="#">Public Notification</a>	Drugs	

Content current as of:  
04/26/2022

If the company has had a warning letter, look at what was involved:

- Sanitation
- Ingredient qualification
- Employee qualification
- Claims

Has the company remedied the findings?





# Assessing the distributor

Trust in Fullscript and Emerson Ecologics

# Distribution

**Packaging:** timing, preservatives, moisture mitigation, spoilage prevention methods

**Labeling:** details including ingredient identity, source, quantity, and quality labeling requirements

**Segmentation:** organic and non-organic ingredients are separated during storage and transport

**Storage:** temperatures for fresh and frozen products, containers, light exposure

**Transportation:** conveyances should be cleaned between deliveries and measures are taken to avoid moisture

**Documentation:** records and dating of adopted standard operating procedures should be maintained



## Raising the Standard on Quality

Ensuring the highest level of quality is in our DNA. With all of our brands meeting cGMP standards, we have taken our commitment a step further with the Emerson Quality Program<sup>SM</sup> (EQP).



### Gold

Emerson's Gold Partner Brands test every lot of every ingredient in the products they manufacture, far exceeding FDA requirements.



### Silver

Emerson's Silver Partner Brands perform enhanced testing that exceeds FDA requirements.

# Quality programs offered by distributors

**Beware** of third-party distributors that do not have quality assurance programs.

**Fullscript and Emerson Ecologics** have NSF-certified distribution centers.

We are currently in development of additional elements of quality assurances for providers.

**Our goal** is for you to have extra assurances that the supplements we carry are safe and effective for you and your patients.

# Emerson's Supplement Quality Checklist/Guide

Factors that help ensure patient safety and lead to better health outcomes.

- ❑ This guide provides information on what distinguishes a high quality supplement manufacturer from the rest, and how to choose the right brands and products for your patients.
- ❑ Ingredients: parts of botanicals used, forms, dosages, and clinical evidence
- ❑ Labelling: fully disclosed ingredients (allergens, excipients) & serving size, along with claims in line with regulations
- ❑ Brand: compliant with cGMP and third party certifications
  - ❑ How does this brand test for purity, potency and identity of ingredients?
  - ❑ How often do they perform these tests?
  - ❑ Has the brand undergone any FDA audits?



## Dietary Supplement Quality Guide



## Ingredients Quality Checklist

When it comes to finding good quality supplements for your patients, there are some key questions you should be asking.

