

The Supplement OWL

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www.SupplementOWL.org



TM

Regulators Should Know the Industry They Regulate

- ✓ Who are the companies in the industry?
- ✓ What brands are being marketed?
- ✓ What ingredients are in the marketplace?
- ✓ Which products contain which ingredients?





Retailers Want to Know the Companies & Products they Sell

- ✓ What brands are in the marketplace?
- ✓ What ingredients are in those products?
- ✓ What's on the label and how does it compare with other products?





Consumers Demand Transparency

- Consumers expect product manufacturers to be forthright about the ingredients in their products
- Consumers want to be able to educate themselves about product labeling before they buy
- ✓ Consumers want to know the retailers they shop are curating products and vetting their suppliers







THE

Supplement OWL Online Wellness Library

A single authoritative registry of dietary supplement product information where all stakeholders can find information about products, ingredients, and additional quality and safety information.



What is the **Supplement OWL**[™]?

- An industry-wide, self-regulatory initiative that promotes transparency and accountability.
- Assists regulators, retailers and other stakeholders in understanding the dietary supplement marketplace.
- Demonstrates responsibility by the industry.



What does the Supplement OWL provide?

Two Tiers of Product Information

- **Tier 1** is **FREE** to all product marketers who are willing to provide the basic information about their products.
- It includes the information that is accessible from the product label.
- It provides regulators with basic contact information about the product manufacturer and packager.
- **Tier 2** allows product marketers who want to provide additional documentation and supporting materials to specific audiences they select.
- Annual fees generated by Tier 2 will provide financial resources to support the ongoing administration of the registry.



What information will be included?

- Tier 1 information:
 - brand, product name, product category, delivery description, intended users, ingredients, Daily Values, serving size, label claims, precautionary statements, storage information, seals & certifications, allergy statements; etc.
 - Images of the product and the product label;
 - A unique alpha-numeric identifier (may be used on the product, but not required).
- Tier 2 information:
 - Product specification sheets, supporting documents for product attributes and certifications, evidence of third-party audits and GMP compliance.





SUPPLEMENT OWL

CHEWABLE VITAMIN C	
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Product Image	C Visit the supplier's site for support
Supressimmune health, Only one 10 calorie wafer daily, Great tasting. Vitamin C is an	Bookmark
stress and Vitamin C also supports immune health. This product has been	C All supplier content
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SUPPLEMENT OWL

CHEWABLE VITAMIN C	
D: DS1944597	Share
Company: Country Life	f 🛩 8° in
Fags: 🕤	☑ Visit the supplier's site for support
Supressimmune health, Only one 10 calorie wafer daily, Great tasting. Vitamin C is an	D Bookmark
stress and Vitamin C also supports immune health. This product has been manufactured at a GMP Registered facility.	C All supplier content
See label by clicking Documents General Information Product Label	Tier 2 feature. Only visible to users that manufacturer provides access. This can be, a single person, multiple people, a company, and/or an entire persona such as retailers. Users without access would only see General Information

Product Information	Label Statements	Contact Information	Supplement/Nutrition Facts Calculator	
Product Information		Tier 1 l	nformation (Continued)	
Allergen Statements / Claims		NO YEAS	T NO WHEAT NO SOY NO MILK NO PRESERVATIVES NO ARTIFICIAL COLORS NO ARTIFICIAL FLAVORS NO ARTIFICIAL SWEETENERS	
Delivery Form			Wafer	
Footnote		* Percent Daily	Values are based on a 2,000 calorie diet. ** Daily Value not established	
Intended User(s)			Adult, Male or Female	
Label Type			Supplement Facts	
Net Contents Quantity			90 Wafers	
Other Ingredients		-	Other Ingredients: Fructose, orange juice concentrate, glucose, honey, starch, stea acid, natural orange flavor, silica, magnesium stearate, cellulose, maltodext	
Product Category			Specialt	
Serving Directions		Adults chew one (wafer daily. As a reminder, discuss the supplements and medication that you take with your health care providers 	
Serving Size			1 wafe	
Servings Per Container			90	
Statement of Identity			Dietary Supplemen	
UPC			1579407233	
			View le	
Label Statements				
FDA Disclaimer Statement			nts have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease	
Precautions		-	CAUTION: If you are pregnant or nursing, taking medication or planning a surgery, cons your doctor before using this product. If any adverse reactions occur, stop taking t product and consult your doct	
Seals/ Symbols/Certifications/Related		с	ERTIFIED GLUTEN-FREE BY GFCO.ORG RECYCLABLE PACKAGING MANUFACTURING SUPPORTS WIND POWER	
Storage and Handling Information		Do not accept it	f seal is broken. Store in a dry place between 59°-86° F. Keep out of the reach of children	

Label Statements	Tier 1 Information (Continued)
FDA Disclaimer Statement	These statements have not been evaluated by the Food and Drug Administration. The product is not intended to diagnose, treat, cure or prevent any disease
Precautions	CAUTION: If you are pregnant or nursing, taking medication or planning a surgery, consu- your doctor before using this product. If any adverse reactions occur, stop taking the product and consult your doctor
Seals/ Symbols/Certifications/Related	CERTIFIED GLUTEN-FREE BY GFCO.ORG RECYCLABLE PACKAGIN MANUFACTURING SUPPORTS WIND POWE
Storage and Handling Information	Do not accept if seal is broken. Store in a dry place between 59°-86° F. Keep out of the reach of childre
Contact Information Public Contact Information	
Contact Information	Manufactured by Country Life, LLC 180 Vanderbilt Motor Parkway Hauppauge, NY 1178 (USA) CountryLifeVitamins.co
Manufacturing Facility Contact Confidential	Confidential contact Information only viewable by FDA-
Packaging Facility Contact Confidential	Manufacturing company and Packaging company or responsible senior quality professional contact information
Packaging Facility Contact Confidential Supplement/Nutrition Facts Calculator	senior quality professional contact information
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Supplement/Nutrition Facts Calculator Amount Per Serving Calories 10 Sodium (as Sodium Ascorbate) 5mg	senior quality professional contact information 1 Servings Calculate Res % Daily Value % Calculate 1
Supplement/Nutrition Facts Calculator Amount Per Serving Calories 10 Sodium (as Sodium Ascorbate) 5mg Total Carbohydrates 2g Vitamin C (as Ascorbic Acid, Calcium Ascorbate, Sodium Ascorbate, Rose Hips	senior quality professional contact information 1 Servings Calculate Res

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Link to LIVE SITE

UIC CRN®















Will a product registry build trust?

- Demonstrates pro-active self-regulation by industry.
- Strengthens the industry's relationship with the FDA, by providing FDA with relevant information about supplements and improving its ability to obtain product, ingredient and manufacturer information.
- Counters the perception (sometimes perpetuated by FDA itself) that the agency does not know, and cannot determine, the size and breadth of the industry—so we will change the landscape.
- Establishes an industry-run, voluntary registry that *could* serve as a model for a mandatory program if it should ever be imposed in the future. (NOTE: We are not proposing, recommending or supporting a mandatory registry.)



Will a product registry build trust?

- Assists retailers to more easily evaluate dietary supplements and select quality products for their customers;
- Ultimately, allows consumers to identify, examine and evaluate dietary supplements based on labeling, contents and indicia of quality, to more wisely "navigate the aisle";
- Improves the perception of all stakeholders and critics of the industry (elected officials, regulators, retailers, consumers, healthcare practitioners, media) by demonstrating increased transparency and accountability.







Developing consensus-based American National Standards for Good Manufacturing Practices (GMPs) in several industries.



- Strengthening safety, quality and trust throughout the supply chain
- Ensuring consistency and proper training of auditors
- Reducing the number of audits and financial costs associated with audits
- Combining regulatory requirements and retailer quality requirements



American National Standards Institute (ANSI) Standards

- Open and Fair Process
- Requires a consensus from a balanced group of stakeholders including industry, public health regulators and users who participate in a joint committee process.
- Designed for openness and transparency



Accreditation by ANSI signifies the procedures used by a standards development body meet essential requirements for:

- Openness
- Balance
- Consensus
- Due process (including requirements for transparency, public comment and appeals)



Comparing Public and Private Standards

Public (ANSI) Standards

- Consumers can trust ANSI standards because they are public — not created by any one special interest or private group.
- Third-party certifiers can certify to ANSI standards.
- ANSI standards are recognized by regulators and industry alike.

Private Standards

- With private standards, consumers don't know what criteria are used.
- Private standards may not hold up to the scrutiny of state or federal regulators.
- Independent certification bodies may not be able to certify to private standards.



Quality, Safety and Compliance from farm (or raw material factory) to shelf; Elevate regulator and consumer confidence on supply chain controls as well as safety and purity of dietary supplements globally.



- Enhance safety, authenticity, and compliance of dietary supplements throughout the supply chain while reducing audit redundancy.
- Management system to address the authenticity, safety, and regulatory compliance of dietary supplements through harmonized benchmarking to determine equivalency between various dietary supplement certifications and standards.
- A minimum standard of equivalence for all manufacturers to meet to be accepted into major retailers offering quality assurance from harvest to retailer shelf.



- Work to identify a set of best Quality/Compliance practices (for each segment of the supply chain) to which scheme owners must benchmark against for SSCI recognition and retailer acceptance.
- Once SSCI recognized; accepted by all.
- Global goal (harmonization with TGA, EU, China Food Safety Law)



The Benchmarking Process

- Achieved through the benchmarking of existing and future dietary supplement safety audit schemes.
- Benchmarking is the process by which various safety and compliance certifications and/or schemes are compared to the SSCI Guidance Document.
- A scheme is "SSCI recognized" once it has been verified that it meets the requirements outlined in the SSCI Guidance Document.











Thanks for listening!

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