VENABLE® LLP

cGMPs: Understanding the Private Label Distributor's Responsibilities under the Act and Regulations

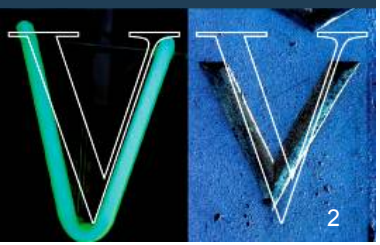
Todd A. Harrison, Esq., Partner

Claudia A. Lewis, Esq., Partner

VENABLE® LLP

Agenda

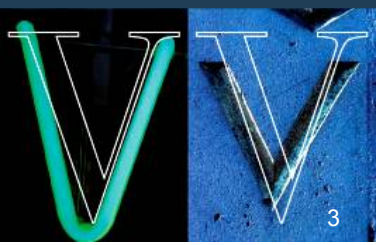
- Basic cGMP Requirements
- Standard Operating Procedures (SOPs)
  - Oversight SOPs
  - Direct SOPs



VENABLE® LLP

cGMP Requirements

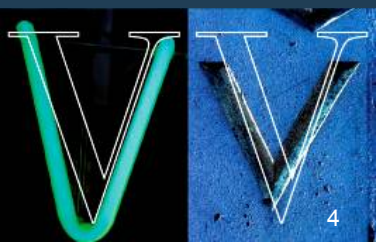
The federal Food, Drug, and Cosmetic Act (FDCA) prohibits a person from introducing or delivering for introduction, or causing the delivery for introduction, into interstate commerce a dietary supplement that is adulterated for failure to comply with dietary supplement cGMP requirements. (FDCA § 402(g))



VENABLE LLP

cGMP Requirements Applied to Private Label Distributors

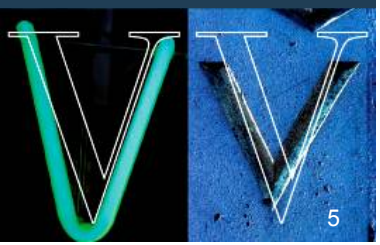
- cGMPs apply to companies who use contract manufacturers to package or label the products that they distribute under their own name.
- FDA identifies these companies as private label distributors and holds the private label distributor responsible for the products they introduced into interstate commerce.
- The private label distributor is responsible for making sure that all their products are in compliance with FDCA requirements and cGMP regulations.



VENABLE LLP

Recent FDA Enforcement Trend

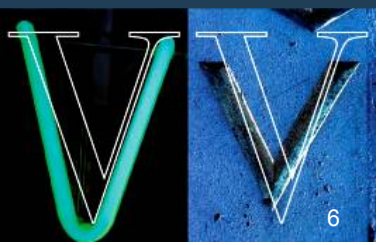
- Over the past few years FDA has placed a great deal of emphasis on cGMPs when inspecting dietary supplement firms.
- Fiscal Year 2013 statistics from Natural Products Insider:
  - 65% of dietary supplement firms inspected received a Form 483 that alleged violations of cGMPs
  - Average of 7.1 alleged cGMPs infractions per firm
  - Most common violation: failure to verify a finished batch of dietary supplements met product specifications like identity, purity, strength, and composition



VENABLE® LLP

SOPs Basics

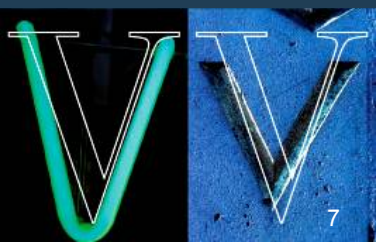
- SOPs are step-by-step instructions and detailed explanations of how the company will implement cGMP requirements
- Oversight versus Direct: Private label distributors should have SOPs that they will implement directly and oversight SOPs to ensure that contract manufacturers and fulfillment companies are in compliance
- Oversight SOPs should cover not just manufacturing of the product but further distribution to the extent that other firms are involved in distribution of the product



VENABLE® LLP

Oversight SOPs

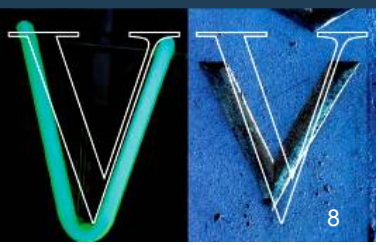
- In-Process Manufacturing Controls
  - SOPs to oversee quality control personnel to ensure that products are packaged and labeled in accordance with established specifications
  - Need to know about the manufacturing activities of the contract and fulfillment companies so you can determine if the products meet established specifications before releasing the product
- Incoming and Returned Product Quarantine, Review, and Release (includes labels, packaging, container/closure systems, product)
  - SOPs for overseeing quality control responsibilities and written procedures regarding disposition of returned products, approving for release or rejecting of any packaged and labeled dietary supplement
  - Lot traceability



VENABLE LLP

Oversight SOPs (continued…)

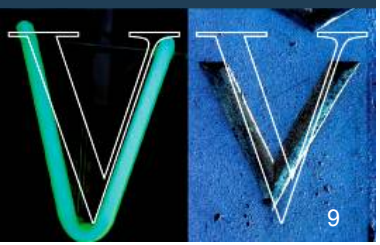
- Product Storage
  - Need to monitor written procedures for holding and distributing operations
  - SOPs for temperature, humidity, light, etc… so that identity, purity, strength, and composition of the products are not affected
- Product Expiration Dating and Stability Program
- Sample Approval and Shipping of Product
- Finished Product Quarantine, Review, and Release
- Product Rework



VENABLE LLP

Oversight SOPs (continued…)

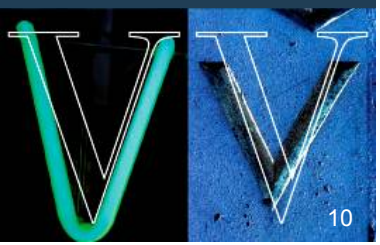
- Employee Hygiene Standards
- Facility Audits
- Inventory Control
- Change Control
- General Laboratory Testing Requirements
- Testing Specifications
  - In-process specifications for any point in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the product



VENABLE LLP

Oversight SOPs (continued…)

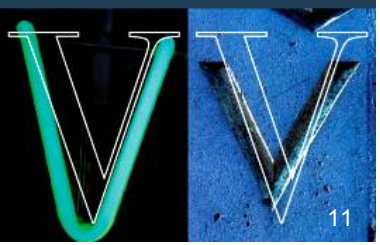
- Certificate of Analysis
- Independent Testing Program
- Information Technology Systems and Controls
  - SOP must oversee the written master manufacturing record for each unique formulation.
- Facility Design, Maintenance, and Security
- Cleaning and Sanitation
- Equipment Qualification, Use, and Maintenance
- Pest Control
- BSE Recordkeeping



VENABLE® LLP

Direct SOPs

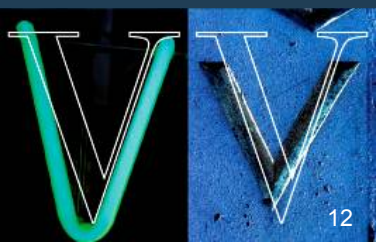
- Introduction and Responsibilities
- Employee Orientation and Training
- Intake of Product Complaints
- Investigation of Complaints
- Reporting Serious Adverse Events to FDA (Form 3500A)
- Product Recalls and Market Withdrawals
- Annual Review of Product Quality Standards
- Vendor Selection
- Labeling Definitions and Standards



VENABLE® LLP

Top Ten Recommended SOPs

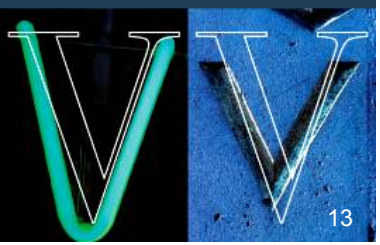
1. Oversight: In-Process Manufacturing Controls
2. Oversight: General Laboratory and Testing Requirements
3. Oversight: Finished Product Quarantine, Review, and Release
4. Oversight: Incoming and Returned Product Quarantine, Review, and Release (Includes Labels, Packaging, Container/Closure Systems, Product)
5. Direct: Product Recalls and Market Withdrawals



VENABLE LLP

Top Ten Recommended SOPs (continued…)

6. Direct: Investigation of Complaints
7. Oversight: Product Storage
8. Label Control Procedures
9. Oversight: Product Expiration Dating and Stability Program
10. Oversight: Sample Approval and Shipping of Product



VENABLE LLP

Contact Information

Todd A. Harrison
taharrison@Venable.com
t 202.344.4724

Claudia A. Lewis
calewis@Venable.com
t 202.344.4359

www.Venable.com

VENABLE® LLP