WEBINAR #1 [eBook contains all text from the Webinar Slides.]

Link to the special PEL Forum
http://groups.yahoo.com/group/PEL-Webinars/

[1] P.E.L. Webinars …™
Practical, Ethical & Legal™
Standard Operating Procedures – SOPs
Introductory Webinar
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DSHEA Regulated Companies
Employee GMP / SOP Certification Program
Dietary Supplement Industry cGMPs - Includes SOP Training & Certification
Quick-Start Guide to Best Operating Practices
[2] Presenter: Ralph Fucetola JD - The Vitamin Lawyer
This Webinar is a Vitamin Lawyer Consultancy Educational Program

Designed for Dietary Supplement
Label-Owners & Marketers

Ten Hour Certification Course
1. Preparatory Reading, SOP Format . . . . . 3 hrs
2. Introductory Webinar . . . . . 2 hrs *

3. SOPs in Detail Webinar 1 . . . . . 2 hrs
4. SOPs in Detail Webinar 2 . . . . . 2 hrs
5. SOP Certification Conclusion Test (Open Book) . . 1 hr
6. Optional Bonus Webinars

Including Special Record-Keeping Webinar

* This is the Introductory Webinar

[3] P.E.L. Webinar

Presenter & Certification
Webinar presented by Ralph Fucetola JD
36 Years Practicing Attorney
Minister and Notary Public
Expertise: Dietary Supplement Health and Education Act
Focus: Standard Operating Procedures (SOPs)

This is the Introductory Webinar for the
Certification of Completion Course
Includes

- eBook with all Slide Contents
- Certificate of Completion

[4] Webinar Overview

This Webinar will teach you about:
Structuring Your Company for GMP Regulatory Compliance
The Contents and Terms of the SOP Document
Company Positions that Implement the SOPs
Best Practices for Labels, Claims, Manufacturer and Marketing
Defendable Record Keeping
The Company Core Data Sheet & Substantiation Note Book

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under

the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

[5] Index of Slides

Please Note: all slide text is in the eBook.

Webinar # 1 : Introduction to cGMPs and SOPs

Index:

[6] Index of the SOPs

The SOP Manual consists of the following individual Procedures:

Standards, Complaints and Policy Coordination
8. Contract Manufacturer Agreement GMP Enforcement Terms
9. Order Processing Procedure
10. Bookkeeping and Account Management
11. Order Record Keeping and Retrieval; AER Reporting
12. Emergency Planning and Crisis Management
13. Payment Card Industry Data Security System
14. Private Labeling
15. Receiving & Storage of Inventory and Returns
16. Returns and Recalls
17. Complaint Form
18. Change Controls / New SOPs
19. CAPA SOP
20. CCDS (Company Core Data Sheets) SOP
21. New Employee Qualification and Training

[7] Introduction

My personal perspective:
BA with Distinction – Rutgers College – 1967
JD – Rutgers Law School – 1971
Attorney at law 1971 - 2006
Holistic minister practitioner since 1974
Notary Public in NJ #23-98815

www.VitaminLawyer.com
www.LifeSpirit.org
www.NaturalHealthOptions.net

Graduate of Rutgers College (B.A. with Distinction, 1967), Rutgers Law School (J.D., 1971) and a founding Trustee of a 501(c)(3) Exempt Church established in 1974

Certified in HoloLinguistics, Basic Homeopathy and Human BioAcoustics

Until 1994 vitamin purveyors were at risk when making any claims about their food products. Concerted consumer and retailer lobbying resulted in Congress unanimously adopting the Dietary Supplement Health and Education Act of 1994

(DSHEA) which allowed truthful and not misleading claims about how dietary supplements support the normal structure and function of the body

From that moment, the modern dietary supplement / natural product market began to develop into the over one hundred billion dollar industry it is today. As the market has matured, additional restraints have been enacted or implemented by regulation. Chief among these are the cGMP (Current Good Manufacturing Practices) which Congress told FDA to pattern after food, not drug, practices. Industry compliance with DSHEA "food" GMP standards may avoid further regulatory developments that will impose stricter "drug" standards.

The cGMP regulations are permissive and suggestive, sometime compelling specific actions, but most often leaving it up to the company to develop the ways and means to market the product that meets the standards outlined in the GMPs. The regulations mandate standard operating procedures and require companies to educate the staff in cGMPs and the company SOP documents.
This webinar is the first in a series that constitute a GMP/SOP certification course.

[8] **Top Ten Warnings Received During FDA Inspection:**

CAPA procedures
Complaint procedures
Written Adverse Event Reporting procedures
Process validation
Product master record
Purchasing controls
Control of non-conforming product
Quality audit procedures
Design change procedures
SOP Training & Certification

"My goal is to help dietary supplement & natural food purveyors comply with the law and regulations in elegant, simple and inexpensive ways." rf

[9] **"Own Label" Distributor GMP Requirements Under Certain 21 CFR 111 Subparts – 1**

Subpart A – General Provisions
Registration under the Bio-Terrorism Act
Serious adverse event reporting
Food allergen (labeling)
Labeling requirements

Subpart B- Personnel
Qualified employees
GMP training for holding/distribution/complaints
Required procedures and records

Subpart C- Plant and Grounds
Maintained plant and grounds
Pest Control, trash removal
Suitable space, size, construction and design
Required procedures and records

[10] **GMP Requirements – 2**

Subpart E- production & process control system
Specifications – raw materials; packaging materials; labels; finished products; packaged, finished products
Reserve samples
Ensure contract facilities are performing operations in compliance with GMPs
Ensure documentation exists showing finished product meets specifications
Required procedures and records

Subpart F- Quality Control
Quality Control Personnel
Material Reviews and Disposition Decisions (MRDD)
Document Control
Required procedures and records

Approve/Reject all items relating to production of products-specifications, MMR, BPR
Ensure contract facility qualifications – lab, manufacturer, packager/labeler

[11] **GMP Requirements – 3**

Subpart M- Holding and Distribution
Environmental conditions
Suitable distribution conditions
Required procedures and records

Subpart N- Returned Products
MRDD- salvage, destruction, repossessing
Oversee testing required
Required procedures and records

[12] **GMP Requirements – 4**

Subpart O-product complaints
Investigation- possible product failure to meet specifications
Required procedures and records

Subpart P- record retention
Supplier Qualification records
Receiving records
Examination records
Distribution records
Complaint records
SAE report records
Returned product records
Test records
Recall Procedures

[13] The Forbidden Words & Federal Regulation

Reserved Medical terms

Med-Term	Non-Med - OK
• Diagnose	**Evaluate**
• Prescribe	**Recommend**
• Treat	**Therapy, Technique**
Prevent }	
• Mitigate }	**Harmonize, Balance**
• Cure }	

Also OK

Stimulate
Support
Regulate
Maintain

1. FDA "Structure and Function Rule"
- key to the forbidden words.

2. DSHEA Statutory Disclaimer:
"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

[14] Disclaimers: Required or Not?

By Statute (in the case of the first disclaimer below) or by market demand or industry custom, vitamin labels contain certain information. Here we give a brief overview of Disclaimers. This section does not address the formal requirements of a label. What Disclaimers are required?

> **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."** [DSHEA Statutory Disclaimer]

"Testimonial results within range of typicality."

Do you need a "Sell by" date? NO! And if you have one, FDA says you must have substantiation for it! Better is coding the manufacturing date in the batch number!

Product Warnings:

"Keep out of reach of children."
"Do not exceed recommended serving"
"Do not use if outer or inner seal is broken or damaged."
Resources
Some Useful Web Sites: www.SOPcertification.com

[15] Disclaimers: Required or Not? – 2

[NOT REQUIRED]: "If you have a serious adverse reaction to product, discontinue use immediately, seek medical attention if necessary, and contact us." [AER only requires that label include a phone or address for contact, *without* requiring the mention of "Adverse Event." [This is recommended]: "If you are undergoing treatment for a medical condition or if you are pregnant or lactating, consult your physician when taking this product."

[REQUIRED]: In addition to the above, you may need a Food Allergy Warning:

"The term "major food allergen" means any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans."

That statutory warning reads:

Contains: [list allergens].

http://www.fda.gov/food/labelingnutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm

Finally, there is a special warning for iron containing pills or capsules: "WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6.

Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately."

[16] Resources

Some Useful Web Sites: www.SOPcertification.com / www.RegulatoryComplianceNetwork.com
Natural Health Options Network: www.NaturalHealthOptions.net
Vitamin Lawyer.com Consultancy: www.VitaminLawyer.com
Site Use Statement: www.SiteUseStatement.com
Natural Solutions Foundation: www.HealthFreedomUSA.org
www.NaturalSolutionsFoundation.org
Institute for Health Research: www.inhere.org
LifeSpirit Seminary: www.LifeSpiritSeminary.org
NutraSpace: www.nutraspace.com
Roehr MicroTabs: www.BioG-MicroTabs.weebly.com

Vitamin Lawyer Web Pages:

- SOP Outline: http://tinyurl.com/2eu6yj
- Oversight Seal: http://tinyurl.com/2cfoyb

[17] eBook and Attachments

Your eBook includes:
The text of these slides
The expanded "Forbidden Words"
Link to the special PEL Forum*
http://groups.yahoo.com/group/PEL-Webinars/

Assuring the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA.

* An online forum where you ask me questions and share information and ideas with other PEL webinar graduates.

[18] Thank you… Practical, Ethical & Legal Webinars

I hope this Webinar has been useful.
You can find more information at my blogs:

http://vitaminlawyerhealthfreedom.blogspot.com
http://vitaminlawyerarchives.blogspot.com

www.vitaminlawyer.com
ralph.fucetola@usa.net

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- Dietary Supplements & Medical Foods in Physician Practice
- CAM Cautions: Alternative Practices
- The Ministry and Healing Arts

WEBINAR #2

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   Test - Open Book . . . . . 1 hr
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   Including Special Record-Keeping Webinar!

   * This presentation is SOP Details Part 1

[3] Webinar Overview
This Webinar will teach you about:

Standard Operating Procedures – Sections 1 through 11

1. Introduction / Index 01
2. Refund, Delivery & Returns Policies 02

[4] Index of Slides

Please Note: all slide text is in the eBook.
Webinar # 2 : SOP Details Part 1

1. Title
2. Presenter
3. Webinar Overview
4. Index of Slides
5. [1] Introduction
6. [2] Refund, Delivery, Returns
7. [3 & 4] Disclaimers, Waivers
8. [5 & 6] Email, Document Policy
9. [7.1] QC
10. [7.2] PSN & Claims Control
11. [8] Manufacturer Contract Control
12. [9 & 10] Orders and Accounting
13. [11] Record Keeping & Retrieval
14. Introduction
15. Resources
16. Thank You

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

[5] SOP [1] Introduction

The Introductory Page has the index and two statements:

"This Operations Manual is a confidential compilation of information regarding the operations of the company, for company use only. It is how we implement our Goal of serving our customers with good service and great value. This document is intended as the Company's Standard Operating Procedures (SOP) under cGMPs. Each SOP will be implemented as the activities of the company make it appropriate to implement that SOP. SOP requirements not implemented are waived until it is appropriate for them to be implemented, as directed by the CEO.

The following Positions in the Company are listed in these SOPs:

the CEO
the COO
Quality Control Manager (QCM)
Emergency Manager
CCDS Manager.

The COO or (where one is not designated) the CEO shall hold these Manager Positions unless the Positions are filled by appointment by the CEO.

[6] SOP [2] Refund, Delivery & Return Policies

The company is obligated, under state and federal regulations, to have a clearly articulated refund and return policy. This format meets FTC standards , but can be varied by careful revision of language.

"Refund Policy: Satisfaction Guaranteed

If for any reason you are unsatisfied with your purchase(s) within the first 60 days of receipt, please return any unused portion for an exchange or refund. We reserve the right to accept or deny any returns based on product misuse, neglect, or other "Acts of

God" beyond our control. If your product(s) arrive(s) damaged please contact our customer support department and request a return ticket.

We adhere to the standard Consumer Protection guidelines as promulgated by the Attorneys General or other competent state authorities.**"**

The company can lawfully only guarantee "satisfaction" -- which is a determination that the consumer may make in his or her subjective judgment -- but if the company were to guarantee "results" instead, it would have to have very convincing evidence of efficacy.

[7] SOP [3 & 4] Standard Disclaimers; Site Use Statement
Standard Waivers: Model – Testimonial – Clinical Study

Disclaimers ,Disclosures, Releases and the like are important legal statements or documents. The SOP formats are to be used.

Site Use Statement -- for use on the company web site, and intended to address the privacy and similar concerns of the consumers.

Standard Waivers should be used whenever appropriate.

These include:
Models
Testimonials*
Clinical Studies

* Current testimonial releases are important under FTC and FDA regulations that require all testimonials to be "typical" of what the average consumer can expect.

[8] SOP [5 & 6] Email Privacy Policy & Document Retention Policy

5. Email Privacy Policy - We have created this email privacy policy to demonstrate our firm commitment to your privacy and the protection of your information.

6. Document Retention Policy - The corporate records of the Company and its subsidiaries (hereafter the "Company") are important assets. Corporate records include essentially all records produced by or on behalf of the Company, whether paper or electronic, in the possession and control of the Company. A record may include a memorandum, an e-mail, a contract or a case study, or something not as obvious, such as a computerized desk calendar, an appointment book or an expense record.

The law requires the Company to maintain certain types of corporate records, usually for a specified period of time. Failure to retain those records for those minimum periods could subject the responsible person and the Company to penalties and fines, cause the loss of rights, obstruct justice, spoil potential evidence in a lawsuit, place the Company in contempt of court, or seriously disadvantage the Company in litigation.

The Company expects all employees to fully comply with any published records retention or destruction policies and schedules, provided that all employees should note the following general exception to any stated destruction schedule…

[9] SOP [7.1] Quality Control Procedures / Claims Controls

Index:

Introduction
Purpose and Standards
Manufacturing Standards
Review and Distribution Standards; Claims; Substantiation; Notices
Complaints, AERs and Product Recalls
Maintenance and Contamination Control
Policy Coordination

Quality Control – QC – is a major responsibility of the Company to its customers. The CEO shall appoint a Quality Control Manager - QCM (or the COO shall hold that position if none other is appointed).

The Company has adopted this QC Procedure Statement to establish Current Good Manufacturing - Marketing Practices (cGMPs) as they apply to the Company's products, under 21 USC 342(g), and subject to the final regulations issued by the FDA June 22, 2007 - http://www.cfsan.fda.gov/~dms/dscgmps6.html - http://edocket.access.gpo.gov/2007/07-3039.htm . The QCM is primarily responsible for QC.

The primary purposes of this policy are (1) to prevent claims that are not "truthful and not misleading" and (2) to prevent adulterated or misbranded dietary supplement products. The standards to which the Company's contract manufacturer(s) should adhere must ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition. The standards to which claims marketing should adhere must ensure that all claims are properly substantiated and are "truthful and not misleading"

The QCM coordinates these issues with the manufacturer and with company management through overseeing the implementation of the Contract Manufacturing Agreement as it relates to QC and communicating breaches and potential breaches to the Manufacturer and management.

The Current Quality Control Manager is: _____

[10] SOP [7.2] Product Substantiation Notebook / Claims Controls

The company shall develop over time and maintain a **Product Substantiation Notebook (PSN)** or files, as part of these SOPs that shall include, for each product:

(1) A copy of the product label and the CCDS (Company Core Data Sheet) with Spec Sheet.
(2) Copy of the Notice(s) of Structure and Function Claims
(1) Abstract pages of relevant scientific journal articles
(2) Clinical study reports, if any, about the ingredients and combinations of them
(3) Ethnographic reports on traditional uses
(4) Expert opinion articles or letters, if any

(g) The QCM shall see to the QC requirements of Sec 111.127 (packaging and labeling), oversee all required cGMP records and any Claims Notice filings.

Complaints, Adverse Reactions & Product Recalls

With regard to (1) consumer complaints and (2) serious adverse reaction reports* that come to the attention of the Company, the following policy shall apply: the Company shall establish and maintain a dated record of each such complaint or Report received by the Company and shall report any serious adverse events to the FDA as required by the Dietary Supplement and Non-Prescription Drug Consumer Protection Act -- http://www.fda.gov/cder/regulatory/public_law_109462.pdf

The Report shall include…

The Quality Control Manager shall coordinate all QC issues. QC Policy shall be coordinated with (A) Refund, Delivery & Returns Policies, (B) Standard Disclaimers, (C) Standard Testimonial Waiver, (D) Email Privacy Policy, (E) Document Retention Policy and Order Record Keeping / AER Reporting Policy.

* As defined later in the webinar series.

[11] SOP [8] Dietary Supplement Contract Manufacturer Control

During the term of this Agreement, Manufacturer will supply product that meets all assembly, test, quality and documentation requirements at a cost provided in the quotation for the product, and on a delivery schedule guided by the purchase order. Manufacturing & test, labeling and production records must meet all applicable FDA regulations. Product is manufactured, tested and labeled per customer specifications. Customer has responsibility to ensure specifications meet applicable regulatory requirements and effectively communicate requirements to Manufacturer.

Manufacturer represents that it has expertise in meeting all current Good Manufacturing Practices (GMPs), as mandated by FDA dietary supplement, medical food or device guidances. Manufacturer shall ensure compliance with GMPs as they

apply to the Company's dietary supplement products, under 21 USC 342(g), and subject to the final regulations issued by the FDA June 22, 2007 - http://www.cfsan.fda.gov/~dms/dscgmps6.html - http://edocket.access.gpo.gov/2007/07-3039.htm

The standards to which the Manufacturer adheres must ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition.

As required by Food and Drug Regulation Subpart D 111.80: the Contracting Company contracts with the Manufacturer for it to maintain " Representative samples of each lot of packaged and labeled dietary supplements to determine whether the packaging and labeling of the finished packaged and labeled dietary supplements meet specifications established in accordance with Sec. 111.70(g), and as applicable, Sec. 111.70(a)."

As required under 21 CFR 111.75 (1)(i) there shall be at least one at appropriate test per source of each nutrient ingredient as to "purity, identity, composition and strength..." Contracting Company shall keep records of such tests and provide copies to the Company which shall verify and keep copies of such records. With regard to other ingredients, the Company shall receive and keep copies of Certificates of Analysis from duly qualified suppliers.

All manufacturing, testing and labeling shall be in strict compliance with all applicable GMPs, so that all dietary supplement products are manufactured, stored and shipped so that same are consistent as to identity, purity, quality, strength, and composition.

The Contracting Company shall make available to the Company documentation of GMP compliance, permit a reasonable onsite audit of compliance on behalf of Company at Company's request, and the Company shall document the compliance documentation and audit.

[12] SOP 9 &10]

Order Processing Procedures / Bookkeeping and Account Management

9. The Company uses an automated Order Processing System. Management shall maintain the integrity of the System so that orders are accurately taken, processed and fulfilled…

The Company shall maintain sufficient computer, back-up and hard copy records to provide customer service and identify customers and product in the event of a serious Adverse Event Report … or Product Recall…

10. The Company maintains standard books of account.

The computer accounting system used by the company is: _____.

The appointed Accounting firm, if any, will assist the Company in the preparation of financial statements in accordance with professional standards, but will express no opinion or any other form of assurance on the underlying information included in them. Any financial statements produced will be used by management for making financial decisions.

[13] SOP [11]

Order Record Keeping and Retrieval For AER Reporting and Other Purposes

11 1. The Company shall maintain copies of all Order Invoices as shipped.

2. The Company, when using electronic records, shall maintain regular back-up copies of its Order database.

3. The Company shall maintain copies of records of all products ordered by the Company for resale to customers.

4. The records of products ordered shall generally include:

A. Records showing that the dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition.

B. Records showing procedures to prevent superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, glass, lead), color variation, tablet size or size variation, under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling, if any.

C. Records showing the steps taken to reduce risks associated with dietary supplements that are contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities or are not properly labeled to accurately describe what they contain.

D. Records of all claimed "adverse events" and, if required by law, the referral thereof to independent third parties to determine if such events are "serious" and should be reported; such records should include the determination whether the event was "serious" and the steps taken to report it. A "serious adverse event" is defined by law as: "The term "serious adverse even" is an adverse event that-- (A) results in-- (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A)."

[14] Resources

Some Useful Web Sites: www.SOPcertification.com

- Natural Health Options Network: www.NaturalHealthOptions.net
- Vitamin Lawyer.com Consultancy: www.VitaminLawyer.com
- Site Use Statement: www.SiteUseStatement.com
- Natural Solutions Foundation: www.HealthFreedomUSA.org
  www.NaturalSolutionsFoundation.org
- Institute for Health Research: www.inhere.org
- LifeSpirit Seminary: www.LifeSpiritSeminary.org
- NutraSpace: www.nutraspace.com
- Roehr MicroTabs: www.BioG-MicroTabs.weebly.com

Vitamin Lawyer Web Pages:

- SOP Outline: http://tinyurl.com/2eu6yj
- Oversight Seal: http://tinyurl.com/2cfoyb

[15] Thank you…

Practical, Ethical & Legal Webinars
I hope this Webinar has been useful.
You can find more information at my blogs:

http://vitaminlawyerhealthfreedom.blogspot.com
http://vitaminlawyerarchives.blogspot.com

www.vitaminlawyer.com
ralph.fucetola@usa.net

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- CAM Cautions: Alternative Practices
- The Ministry and Healing Arts

WEBINAR#3

[1] P.E.L. Webinars …™
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5. SOP Certification Conclusion
   Test - Open Book . . . . . 1 hr
   Optional Bonus Webinars
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* This presentation is SOP Details Part 2

[3] Webinar Overview

This Webinar will teach you about:

Standard Operating Procedures – Sections 12 through 21

12. Emergency Planning and Crisis Management
13. Payment Card Industry Data Security System
14. Private Labeling
15. Receiving & Storage of Inventory and Returns
16. Returns and Recalls
17. Complaint Form
18. Change Controls / New SOPs
19. CAPA SOP
20. CCDS (Company Core Data Sheets) SOP
21. New Employee Qualification and Training

[4] Index of Slides

Please Note: all slide text is in the eBook.
Webinar # 3 : SOP Details Part 2

Index:

12. [18] Changes / New SOPs
13. [19] CAPA
14. [20] CCDS
15. [21] New Employee Qual. & Training
16. Resources
17. Thank You

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

[5] SOP [12] - Emergency Planning & Crisis Management

Companies, especially in volatile industries that are subject to regulatory reversals and strong competition, need to pre-plan to deal with the unexpected. Supply, labor, equipment, electrical or computer disruptions must be considered; how to deal with a manufacturing error that might make a product dangerous; what to do if someone that everyone in the company relies upon were suddenly taken away by illness or other emergency; if a key employee is called to active duty, or arrested, or leaves for a better job; for a Product Recall. Crises take many forms, from surprise regulatory inspections to accidents and litigation, to a blizzard or other serious storm.

Management needs to have - in place - contingency plans and designated personnel who can consider contingencies, before the crisis. The President of the Company shall serve as or designate an Emergency Manager who shall plan Company response to emergencies. In the event the President is not available, the most senior Vice President available shall act as Emergency Manager.

The current Emergency Manager is: _____.

[6] SOP [13] - Payment Card Industry Data Security System

As of November 1, 2008 the Company shall be compliant with the Payment Card Industry Data Security System required by the *Fair and Accurate Credit Transactions Act*. The Company designates the IT manager as the PCIDSS Data Security Compliance Officer. Credit card service provider audit of the operation of the Company shall suffice to document compliance.

The current Data Security Compliance Officer is:
_____.

1. The Company hereby establishes this written policy for protecting the security of customer (and employee) account data…

[7] SOP [14] - Handling of Products for Private Labeling

This SOP applies if the Company provides private labeling services for the Company [or for wholesale customers]. We receive and store products that have been manufactured elsewhere under cGMP conditions and hold the products pursuant to the SOP herein, entitled "Receiving & Storage of Inventory and Returns."

1. All labeling is to be done in a clean working environment, with employees who are appropriately dressed and trained in the GMPs for the services they provide.

2. All employees shall wash hands before starting any labeling job. The employee shall ensure that the work area remains clean and orderly, so that only the correct label is affixed to the correct product.

3. No unlabeled product shall be separated from its labeled carton before the label is applied, to ensure the wrong label is not affixed to a product.

4. A supervisor shall check to see that the correct label is affixed to the product. The supervisor shall verify that the product specifications on the carton label meet the product specifications on the label being affixed to the product.

5. In-house labels are to be printed only as needed and any excess printed, except for samples and records, shall be destroyed at the completion of labeling. The labels shall have a batch code

on them, in a format that encodes the production or storage date, or duplicates existing unique batch code associated with the bottle.

6. Written shop records are to be kept of each job. Labels are to show label revision codes.

[8] SOP [15.1] - Receiving & Storage of Inventory and Returns

Receiving –

1. Upon receiving any shipment of inventory or any return product, the received materials shall be logged and dated, with the unique batch numbers associated with the product.

2. The receiving employee shall check the received materials against bills of lading or other transmittal documents to ensure that what the Company ordered is what was received.

3. The receiving employee shall check the materials receive to ensure the quantity matches what the invoice or packing list states.

4. The receiving employee shall inspect the packages for damage: i.e., dented bottles, broken caps, open seals, crooked or missing labels, water damage, and the like, and make written record of any damages, notifying a supervisor.

5. The supervisor of the receiving employee shall direct all damaged received inventory to be returned to the contract manufacturer with appropriate return documents, for credit or refund.

6. Returned product shall not be returned to inventory but shall be removed and discarded.

7. No returned or damaged product shall ever be sold to consumers.

[9] SOP [15.2] - Receiving & Storage of Inventory and Returns

Storage –

1. All product is stored in an organized manner so that the product groups are not co-mingled that could result in the wrong product being pulled to fill an order.

2. Product inventory is rotated to be sure the product is sold in order, so that product received earlier is sold before product that is received later.

3. All product shall be stored at room temperature, in a temperature and humidity controlled environment to prevent overly wet, hot or cold storage.

4. All returned product shall be handled and stored separately from inventory and new product received. Returns shall be clearly marked "RETURN" and never stored with inventory. Returned product shall be quarantined from inventory and shall be disposed of in an organized manner, after QC review.

5. The QCM shall review or cause to be reviewed all returned product for defect or irregularity.

6. If defect or irregularity is found, the QC manager shall forthwith contact the contract manufacturer, with a copy to senior management, directing the manufacturer to address any defect or irregularity.

[10] SOP [16] – Product Recall

Product Recall Procedure in the event a product:

[1] is removed from the market by government action,

[2] by manufacturer recall, or

[3] the Company becomes aware of significant risk to the public involving contaminated or adulterated ingredients (or wrong strength of ingredients used) and recalls the product, the procedure is the same.

Any such Recall shall be treated as an Emergency under the Crisis Management and Emergency Planning SOP herein.

The Emergency Manager shall direct all necessary immediate steps to communicate in the quickest practical manner with all affected customers, expediting the Recall with common carrier product return requests.

All recall procedures shall conform to Regulatory Procedure Manual (RPM) Chapter 7 - Recall Procedures:

http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177304.htm

All recalled product returned shall be processed under the *Receiving and Storage of Inventory and Returns* SOP, above.

[11] SOP [17] - Customer Complaint Sheet Form

Any employee receiving any customer complaint, including an Adverse Event Report, shall use a form Customer Complaint Sheet to report the receipt of the complaint to the employee's supervisor.

The Customer Complaint Sheet shall record the following information.

Name of Customer
Address
Phone number
Name of Product
Unique Batch Code
Date of Complaint
Nature of Complaint
Company Response

Space shall also be provided for:

QCM Form Review, with date; form to provide:

QCM determination whether the complaint may meet AER reporting threshold

QCM indication of which AER criteria, as set out in the SOP herein entitled: *Order Record Keeping and Retrieval; AER Reporting* appears to require reporting, if any

QCM decision if injury, illness, product defect or irregularity needs to be addressed with manufacturer, with date

QCM recommendation to the COO and CEO regarding a Recall under the *Product Recall* SOP, above.

QCM decision to inform Customer of findings, if defect or irregularity existed that requires an AER report, with date

QCM indication that AER report was filed. When filed.

[12] SOP [18] - Change Controls / New SOPs

Every FDA-regulated company should maintain a *state of control* for any process used to distribute, provide customer services or manufacture any regulated product. This is necessary to show that the company does the same thing the same way every time.

Over time, the company may buy better equipment, implement new technologies, adopt new materials, improve designs or service procedures. Each process still must be executed in a state of control and the Standard Operating Procedures need to reflect and document the changes implemented.

Change control forms are used to track changes and describe current states of control. The company QCM is tasked with maintaining records of changes and of previous versions of the SOPs.

1. All changes to the SOPs (including newly added SOPs) shall be implemented through a Change Control Form. The form consists of any written communication that includes the following;

a. Heading: SOP Change Control Order
b. Date of Change
c. Brief summary of change (is this a new SOP?)
d. Particular SOP effected (include page number of SOP)
e. Date prior SOP created

f. Manager(s) authorizing change
g. Text of revised SOP
h. Approval by QCM

2. All Change Control Forms shall be reviewed by the QCM and approved prior to distribution. The QCM shall maintain a record of all changes and shall integrate the changes into the SOPs, maintaining a current copy of the SOPs and maintaining copies of superseded SOPs. All such copies shall include the effective dates for the SOP.

3. The form may be distributed electronically to anyone in the company concerned with the particular change.

[13] SOP [19] – CAPA - Corrective and Preventive Analysis

CAPA PURPOSE: The purpose of CAPA is to document, correct and prevent such deviations. A CAP Analysis typically starts when an employee notifies management that something is wrong. Examples: a label is incorrect, advertising is not "truthful and not misleading" or a product appears deviant as to identity, purity, quality, strength, and composition. Deviations may also involve processes, such as maintenance, cleaning, and proper manufacturing, packing or shipping operations, quality control procedures, testing final product or incoming and in-process materials, handling consumer complaints, AERs, and maintaining records.

NOTIFICATION OF DEVIATION: When management is notified of a deviation, or becomes aware of a deviation, the President or his designated subordinate shall direct a specific individual to be responsible for the CAP Analysis, specifying that an initial written report shall be made to the President within a specific number of days; interim and follow-up reports may also be appropriate.

[14] SOP [20] - Company Core Data Sheet

The CCDS (Company Core Data Sheet) is the prime reference document for each product the Company markets. It is one of the central documents upon which employees, regulators and resellers rely regarding the labeling and management of the product. It should always be marked, "Private and Confidential …"

The CCDS is part of Standard Operating Procedures (SOPs) system, and includes the Product Substantiation Notebook (PSN = product files) maintained for all products, as part of the SOPs.

The PSN includes a section for each product, with copies of:

[1] The CCDS
[2] The product label
[3] The product sales sheet
[4] Copy of any Structure and Function Claims Notice(s) filed with the FDA
[5] Any substantiation notes including peer reviewed journal article abstracts and professional reports (such as clinical trial results).

The CCDS is a summary sheet for each product within the SOP system.

The CCDS page for a product includes the following:

Benefits claims;
Serving sized and requirements;
Directions for use;
Concerns of special consumer populations;
Packaging and storage requirements and limitations;
Safety information - including allergen and other warnings;
Formal disclosures and disclaimers.

The CCDS shall be established and maintained by the COO or by the CCDS Manager designated in writing by the COO to direct the creation and maintenance of the CCDS.

The current CCDS Manager is: _____.

[15] SOP [21] - Employee Qualifications and Training

Each employee who works with dietary ingredients shall be or become qualified in GMPs for the work that employee provides. The COO shall be tasked with overseeing the training program.

Each new employee shall be trained in the contents and use of this SOP Manual. The Company will, over time, develop a Training Manual based on these SOPs (which serves as the Training Manual until the development of a more extensive Manual). The Training Manual shall be attached to and considered a part of the SOPs. The goal of training is to have "adequate practice mimic adequate procedures."

Training in each topic and to each classification level will be dependent on the job classification based upon the training needs. Where available, commercial SOP and GMP certification training programs will be made available to the employees.

A written, dated record shall be kept of each new employee's training and the Training Manual, as it is developed and amended will take into account the learning experiences of new employees. Third Party training and certification shall be utilized when available.

[16] Resources

Some Useful Web Sites: www.SOPcertification.com

Natural Health Options Network: www.NaturalHealthOptions.net
Vitamin Lawyer.com Consultancy: www.VitaminLawyer.com
Site Use Statement: www.SiteUseStatement.com
Natural Solutions Foundation: www.HealthFreedomUSA.org
www.NaturalSolutionsFoundation.org
Institute for Health Research: www.inhere.org
LifeSpirit Seminary: www.LifeSpiritSeminary.org
Roehr MicroTabs: www.BioG-MicroTabs.weebly.com
Vitamin Lawyer Web Pages:

- SOP Outline: http://tinyurl.com/2eu6yj
- Oversight Seal: http://tinyurl.com/2cfoyb

[17] Thank you…

Practical, Ethical & Legal Webinars

I hope this Webinar has been useful.
You can find more information at my blogs:

http://vitaminlawyerhealthfreedom.blogspot.com
http://vitaminlawyerarchives.blogspot.com

www.vitaminlawyer.com
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- Dietary Supplements & Medical Foods in Physician Practice
- CAM Cautions: Alternative Practices
- The Ministry and Healing Arts

WEBINAR #4

[1] P.E.L. Webinars …™
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Standard Operating Procedures – SOPs
SOP Conclusion and Certification Test
www.SOPcertification.com

DSHEA Regulated Companies
Employee GMP / SOP Certification Program
Dietary Supplement Industry cGMPs - Includes SOP Training & Certification
Quick-Start Guide to Best Operating Practices

[2] Presenter: Ralph Fucetola JD - The Vitamin Lawyer

This Webinar is a Vitamin Lawyer Consultancy Educational Program

Designed for Dietary Supplement
Label-Owners & Marketers

Ten Hour Certification Course

1. Preparatory Reading
   SOP Format . . . . . 3 hrs
2. Introductory Webinar . . . . . 2 hrs
3. SOPs in Detail Webinar 1 . . 2 hrs
4. SOPs in Detail Webinar 2 . . 2 hrs
5. SOP Certification Conclusion
   Test - Open Book . . . . . 1 hr*
6. Optional Bonus Webinars
   Including Special Record-Keeping Webinar!

Private Certification Issued upon Completion

* This presentation is SOP Conclusion

[3] Webinar Overview

This Webinar will teach you about:

- Overview of Labeling Requirements
- Review and Conclusion
- Open Book Test for Certification
- Your Certificate - Sample

[4] Index of Slides

1. Title
2. Presenter
3. Webinar Overview
4. Index of Slides
5. Some Label Concerns
6. Review and Conclusion
7. Certification Test
8. Receiving Your Certificate
9. Resources
10. Thank You

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

[5] Some Label Considerations

Here is what a Dietary Supplement label needs to contain, at a minimum, to meet FDA standards for grandfathering under DSHEA:

1. Main panel of the label must include:

A. Name of Product: _____ (followed by the ® or TM)
B. Total number of capsules/pills in bottle
C. The term "Dietary Supplement" OR "_____ Supplement"

"You must identify a dietary supplement by use of the term "dietary supplement" as part of the statement of identity, except that you may delete the word "dietary" and replace it with the name of the dietary ingredient(s) in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredient(s) in your dietary supplement product (e.g., herbal supplement with vitamins).

If you use a Proprietary Blend - "You must identify proprietary blends by use of the term "Proprietary Blend" or an appropriately descriptive term or fanciful name. On the same line, you must list the total weight of all "other dietary ingredients" contained in the blend. Indented underneath the name of the blend, you must list the "other dietary ingredients" in the blend, either in a column or linear fashion, in descending order of predominance by weight. These ingredients should be followed by a symbol referring to the footnote "Daily Value Not Established." Dietary ingredients having RDIs or DRVs must be listed separately and the individual weights declared. 21 CFR 101.36(b)(2) and (c)"

2. Usually, the right side panel: the Supplement Facts Box, with its detailed nutritional information.

3. Usually, the left side panel: Directions, Warnings and Disclaimers.

Dietary Supplements must include Directions since such food products are deemed safe if used as directed. Standard Warnings and Disclaimers are also needed, including the Statutory Disclaimer, **"These statements have not been evaluated**

by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

[6] Review and Conclusion

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

As the market has matured, additional restraints have been enacted or implemented by regulation. Chief among these are the cGMP (Current Good Manufacturing Practices) which Congress told FDA to pattern after food, not drug, practices. Industry compliance with DSHEA "food" GMP standards may avoid further regulatory developments that will impose stricter "drug" standards. Similarly, proper compliance with the AER (Adverse Event Reporting) system will promote good customer relations.

The cGMP regulations are permissive and suggestive, sometime compelling specific actions, but most often leaving it up to the company to develop the ways and means to market the product that meets the standards outlined in the GMPs. The regulations mandate standard operating procedures and require companies to educate the staff in cGMPs and the company SOP documents.

[7] Certification Test

When you are ready to take your Certification Test, email me at ralph.fucetola@usa.net with "Certification Test" in the subject line.

I will email you to provide access to the Forum & Test.

[The PEL online Forum is where you can learn, ask questions and find answers…]

When you complete the test, you will submit it, and after review, I will email you your Certification.

[8] Your Certificate: Sample

[9] Resources

Some Useful Web Sites: www.SOPcertification.com

Natural Health Options Network: www.NaturalHealthOptions.net
Vitamin Lawyer.com Consultancy: www.VitaminLawyer.com
Site Use Statement: www.SiteUseStatement.com
Natural Solutions Foundation: www.HealthFreedomUSA.org
www.NaturalSolutionsFoundation.org
Institute for Health Research: www.inhere.org
LifeSpirit Seminary: www.LifeSpiritSeminary.org

Roehr MicroTabs: www.BioG-MicroTabs.weebly.com
Vitamin Lawyer Web Pages:

SOP Outline: http://tinyurl.com/2eu6yj
Oversight Seal: http://tinyurl.com/2cfoyb

[10] Thank you…

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APPENDIX

"Supporting Natural Marketing Compliance With FDA and FTC Regulations."

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Private and Confidential…

A Brief List of Forbidden and Allowed Terminology for Advanced Health Care Practitioners

Allowed	**Disallowed**
Stimulate	Anti-inflammatory
Support	Improve
Regulate	Restore
Maintain	Correct
Energizer	Relieves crushing chest pain
Rejuvenative	Prevents irregular heart beat
Revitalizer	Antibacterial
Adaptogen	Antimicrobial
Tonic	Antifungal
Calmative	Antiseptic, kills germs
Digestive aid	Hormone
Helps maintain intestinal flora	Sunscreen
Boosts stamina	Diagnose
	Treat
Allowed	Mitigate
[If in context no disease claim]	Prevent
	Antibiotic
Promote	Laxative
Augment	Analgesic
Strengthen	Antiviral
Reduce	Diuretic
Improve	Antidepressant
Modify	Vaccine
Inhibit	Cure
Protect	Symptom
Defend	
Supports the immune system	

Relief [Depending on what is relieved]

Also not disallowed: Optimalize / Maximize

Some Alternatives

NG	OK
Symptom	Indication
Allergies	Hyper reactivity
Spiritual Healing	Spiritual Relaxation
Treatment	Feedback / Training
Sport Therapy	Muscle Reeducation
Treatment	Therapy that may benefit
Pain	Discomfort
Addictions	Cravings

This list is a private communication to the clients of the Vitamin Lawyer.com Consultancy.
It was developed from the Commentary to the FDA Structure and Function Claim Notice Rule of 2000.

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