



IS SNAKE OIL AN UNAPPROVED DRUG?

What NJ Registered Environmental Health Inspectors/Specialists Need to Know About Imported Herbal Remedies, Dietary Supplements, and Cosmetics

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What Is Snake Oil?

A pain reliever that originates from China, and was popularized in classic American film. “Snake oil” has become a generic name for many compounds marketed as miraculous remedies.

In US, ingredients were usually secret, unidentified, or mis-characterized — and mostly ineffective.

Modern Snake Oil?

Roghan Badam Shirin Sweet Almond Oil label claims:

- relieves tension
- strengthens brain power
- good for heart
- relieves constipation
- fights dandruff
- keeps body warm in winter
- nourishes skin
- prenatal/postnatal care
- helps build stronger bones
- good for infants



Objective

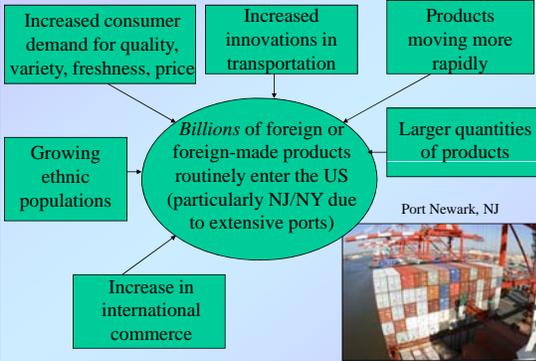
After viewing this presentation, you will gain a better understanding of:

- Popularity of imported herbal remedies, dietary supplements, and cosmetics
- Cultural roots
- Significant health issues
- Routes of entry into the US
- Where to find the products
- FDA regulation, NJ statutes and rules, limitations
- Steps to take when you find such products during an inspection



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Globalization



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Uses of Herbal and Dietary Products

- Prevent illness/disease or manage symptoms
- Weight control
- Boost energy and increase vitality
- Increase longevity
- Improve mental or physical performance
- Alternative to more expensive treatments



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Cultural Roots

Deep roots in mystical/spiritual beliefs and ancient traditions:

- In India, *Ayurvedic*, or “knowledge of life” medicine is stated to be a divine revelation of the ancient Indian creator, Brahma. (Also, Unani, Siddha)



- In China, holistic medicine includes the theory of *Ying-Yang*, the vital force of life *Qi*, and the five elements of natural energies Metal, Wood, Water, Fire, and Earth.

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Some Interesting Facts

- >50% of Europeans, North Americans, and people from other industrialized countries have used herbal remedies at least once
- In China, herbal preparations account for 30%-50% of the total medicinal consumption
- Herbal products used by 70-80% of India’s population
- 60% of children with malaria-induced fever receive herbal treatment at home in some African countries

Source: World Health Organization

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Some Interesting Facts (continued)

- 75% of people living with HIV/AIDS use herbal remedies as treatment in San Francisco, London, and South Africa



- 158 million adults use herbal remedies

- Herbal supplements for pets gaining popularity



The global market for herbal remedies stands at over \$60 billion annually and is growing steadily!

Source: World Health Organization

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Popularity

- Cheaper than going to a doctor
- “Natural,” so perceived as safe/better
- Available for retail sale without prescription
- “Proven” to work because product or ingredients have been around for centuries
- Distrust of modern medicine
- Harsh treatments for life-threatening diseases



But many products HAVE NOT BEEN PROVEN TO WORK and ARE NOT SAFE!!!

Issues

- 1) May cause harmful, even fatal effects
 - 2) Pre-market safety and efficacy testing NOT required
 - 3) Can reduce the effectiveness of medications
 - 4) Quality control standards to ensure consistent amount of active ingredients and purity *not* required
- UPDATE!** as of June 2007, quality control standards now required



Issues

According to a recent study many people:

- Have no idea whether herbal remedies are effective
- Are largely ignorant of the potential health risks



More than 2/3 of supplements have NEVER been clinically proven to be effective for the specific conditions they're advertised to ease or cure!!!

....SNAKE OIL???

Source: Mayo Clinic, June 2007

Safety Issues: Cosmetics

RECETA DE LA FARMACIA – skin lightening cream from the Dominican Republic found in NY

- Also for acne, skin blemishes, freckles
- Contains 6,000 parts per million of mercury (FDA allows 1 ppm)
- Caused at least one case of mercury poisoning that lead to hospitalization



Safety Issues: Cosmetics

KOHL, KAJAL, AL-KAHL, or SURMA – often contains high lead levels; found in NJ in April-May 2007

- In some cultures, used as eye makeup for both children and adults

★ **NOTE:** “kohl” is often used to describe a shade of black; not an ingredient in the product. Check ingredient list.

- Directly linked to blood lead poisoning

- Unapproved color additive; illegal to sell in the US!



Safety Issues: Supplements

EPHEDRA (aka, ma huang) - Banned for sale since 2004 as an ingredient in remedies and herbal supplements

- Derived from an Asian shrub
- For energy and weight loss
- Presents unreasonable risk, especially to those with heart disease, high BP
- Caused 16,000 adverse health events including 150 deaths



2003: 23-year old Baltimore Orioles' pitcher, Steve Bechler, died from Ephedra-related complications.



NEWS RELEASE

11/5/07: Metabolife International founder Michael Ellis pleaded guilty to making false statements when he told FDA in 1999 that his firm had not received any reports of adverse events linked to ephedra.

Michael Ellis

In fact, Metabolife had received **THOUSANDS** of such reports. Not revealed until 2002, this led to the ban of ephedra and mandatory adverse event reporting.



Source: Food Chemical News, 2007

Safety Issues: Supplements

SAFI BLOOD PURIFIER – Indian herbal product found in NJ in April-May 2007

- Promoted for acne, boils, rashes, blemishes
- Claims to cure constipation, check nose bleeding, correct indigestion, improve complexion
- Confusing wordage “builds sturdy babies” is actually an ad for another product



BUT...IT CONTAINS MORE THAN 40 TIMES THE ALLOWABLE AMOUNT OF ARSENIC!!!

Safety Issues: Supplements

LU SHEN WAN – Chinese herbal medicine found for OTC sale in NJ in June 2007

- Claims to treat respiratory conditions and various “toxic heat” problems
- Contains *chan su*, herbal ingredient that has caused cardiac arrhythmia, breathlessness, seizure, coma, one death
- *Chan su* not listed on label



Are ALL Herbal Remedies/Dietary Supplements Bad?

NO! In fact, 25% of modern medicines are made from plants first used traditionally.

- *Artemisia annua*, a Chinese herbal remedy, proven to be an effective malaria treatment
- In South Africa, a plant used to treat AIDS patients may increase patients' energy, appetite, body mass
- Folic acid known to reduce birth defects when taken by pregnant women



Are ALL Herbal Remedies/Dietary Supplements Bad?

- Mistletoe proven to kill cancer cells, stimulate immune system*
- Hawthorn leaf and flower safe and effective for mild heart failure*
- Grape seed prevents cell damage caused by free radicals*



*Source: National Center for Complementary and Alternative Medicine, NIH, 2007

How Are Products Getting Here?

- Internet sales, air mail shipments, smuggling
- Weak US regulation
- Grey markets – “a disease to be eradicated”

brand competition and maintain distributor margins. Gray market activity—that is, the sale of genuine trademarked products through distribution channels unauthorized by the manufacturer or brand owner—poses a direct and significant threat to manufacturers' deployed resale restrictions.

the bane of brand owners and gray markets — in which a

firm's products are sold or resold through unauthorized dealers — have become so prevalent that one trade publication called them a “disease to be eradicated.”¹ In response to this increasing threat, manufacturers in a variety of industries have been waging a pitched battle against gray market sales around the world.

Sources: MIT Sloan Management Review, 2004; Journal of Marketing, 2006

FDA Regulation: DSHEA

Until 1994, FDA regulated dietary supplements as food under the Food, Drug, & Cosmetic Act.

In 1994, new legislation was passed...

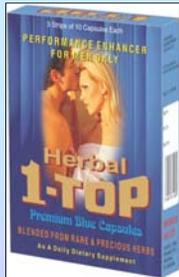
THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA)

SIGNIFICANCE: unlike new food ingredients and drugs, dietary supplements and their ingredients are no longer pre-approved by the FDA....

FDA's role is reactive, not pro-active

Gaps in DSHEA Regulation

- Manufacturers are responsible for ensuring:
 - product safety and efficacy
 - truthful labeling
 - reporting of adverse events
- Onus on FDA to prove product is unsafe



UPDATE!

FDA Regulation: CGMPs

Effective August 24, 2007:

FDA announced Interim Final Rule (IFM), establishing regulations to require CGMPs for dietary supplements. The rule ensures that they:

- are produced in a consistent, quality manner
- do not contain contaminants or impurities
- are accurately labeled

Let's go into more detail...

UPDATE! **FDA Regulation: CGMPs**

Intended to prevent:

- inaccurate amounts of ingredients
- wrong ingredients
- contaminants
- improper packaging
- improper labeling



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UPDATE! **FDA Regulation: CGMPs**

Applies to:

- All domestic and foreign companies that manufacture, package, label, or hold dietary supplements



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UPDATE! **FDA Regulation: CGMPs**

The rule establishes CGMPs that require dietary supplements to be manufactured consistently as to:

- identity
- purity
- strength
- composition



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UPDATE! **FDA Regulation: CGMPs**

Provisions:

- design and construction of plants
- cleaning
- proper manufacturing operations
- quality control procedures
- testing final product or ingredients
- handling consumer complaints
- maintaining records



UPDATE! **FDA Regulation: CGMPs**

Three-year phase-in:

- June 2008: large companies
- June 2009: medium-sized companies with <500 employees
- June 2010: small companies with <20 employees

June 2008  June 2009  June 2010 

UPDATE! **FDA Regulation: CGMPs**

Manufacturer requirements:

- qualified employees
- plant design protects product from adulteration
- equipment/utensils are appropriate for intended use
- manufacturing and batch production records are established and maintained
- quality control established
- product and ingredients held/distributed under good environmental and sanitary conditions
- record of complaints
- file of records (1 year past shelf life or 2 years past last batch distribution date)

So What?

- The burden of proof regarding safety and efficacy of a product is *still* on the manufacturer
- Numerous products manufactured cheaply in other countries where conditions may be questionable
- Such products enter into the US everyday
- Demand is increasing

FDA inspects LESS THAN 1% of all imported products under its jurisdiction!!!



So What?

- Many products that enter into the US market contain active ingredients not listed on label (concern: allergens, drug interactions)
- Products safe for healthy persons may not be safe for pregnant women or someone with serious illness



Medimix soap (India)

The FDA banned these products in the US because they have drug ingredients that are not listed on the label.



Kelly Pearl cream (China)

So What?

- Sweeping claims that are false, unproven, and/or not approved by the FDA (i.e., “controls diabetes”)
- Give false hope to desperate people; may delay necessary treatment
- Exclusive reliance on herbal medicine

NJDHSS inspectors recently embargoed Dia-Slim Tumbler, a diabetes control treatment made in India. It is an unapproved product.



***CLAIMS:**

- controls diabetes
- reduces excessive fat
- controls blood sugar
- purifies blood

*These claims are not approved by the FDA, so the product is unapproved.

So What?

- Numerous imported products have non-English labels*
- Consumers who do not read the language miss out on important health information



*Labels must be written in English. Foreign language translations are permissible, as long as all required labeling is in English.

So What?

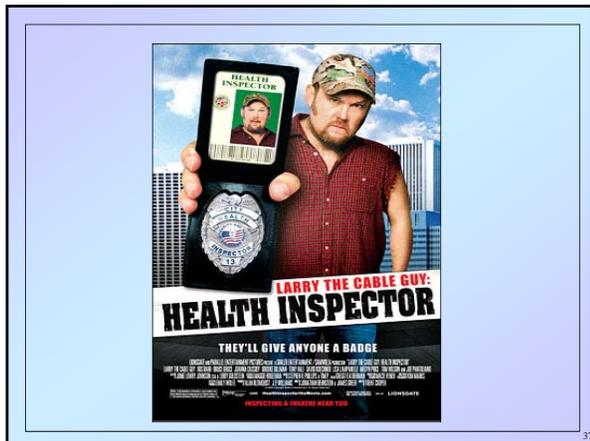
- Lack of adequate oversight = potential for environmental contaminants
- Contaminants from cultivation, formulation, contaminated machinery
- Found in numerous herbal products from China and India:
 - pesticides
 - heavy metals (cadmium, mercury, lead, arsenic)
 - highly toxic alkaloids



If industry self-regulates and FDA inspects <1% of imported products...



...who's the REAL watch dog?



If YOU found these products during an inspection...

...would YOU know what to do?

FDA Regulation

Under the Food, Drug, & Cosmetic Act, all imported products must be:

- pure, wholesome, safe to eat (food)
- produced under sanitary conditions
- safe and effective (drugs and devices)
- safe and made from approved ingredients (cosmetics)

...and must contain informative and truthful labeling in English.

Products that DO NOT conform to these standards are either *adulterated* or *misbranded*.

What's the Difference?

As defined in the US FD&C Act:

Adulteration refers to the content of a product (such as the addition of a substance which makes a product inferior, impure, not genuine, etc.)

Misbranding refers to statements on labels or labeling that are false or misleading

How Does NJ Regulate Herbal Medicine/Dietary Supplements and Cosmetics?

It's simple.

Our rules reference FDA regulations and we follow FDA guidance.



What to Look For

PREVENT, TREAT, CURE, REMEDY

Prevent ringworm



Remedy common cold

HEALTH CONDITION
(or contains an active ingredient)

**PRODUCT MAY BE CONSIDERED AN
UNAPPROVED DRUG***

*Under N.J.A.C. 8:21, New Jersey references FDA regulatory requirements for labeling. Use these citations for violations:

- For dietary supplements and **unapproved drugs**, N.J.S.A. 24:1-1 and N.J.A.C. 8:21-1.2, 1.3, and 1.4
- For cosmetics, N.J.S.A 24:1-1 and N.J.A.C. 8:21-1.2 and 1.5

Actual Claims Refused by FDA

“Used for dyspnea with shortness of breath, acute and chronic tracheitis, and for patients in bronchial asthma”

“Used for chest pain, headache, coronary heart disease, angina pectoris, hypertension”

“Indication: dizziness due to tinnitus and otalgia, dysuria”

“It is usually used to treat cystitis, urethritis, kidney stone and syndrome of strangury”
(painful urination)

Source: FDA Cyber Warning Letter - April 8, 2004

What to Look For

Definition of a “drug” per FD&C Act 201(g):

★ ALL drugs MUST be pre-approved for sale by the FDA! ★

- (a) a product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- (b) a product (other than food) intended to affect the structure or any function of the body
- (c) a product that is not a cosmetic

What to Look For

What’s the difference between a “drug” and an “herbal/dietary supplement?”

Definition of a “dietary supplement” per FD&C Act 201(ff)(1):

A dietary supplement is composed only of essential nutrients, such as vitamins, minerals, and proteins, herbs, or similar nutritional substances to include ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these.

What to Look For

A “dietary supplement” can be classified as an unapproved “drug” if it 1) makes an unsubstantiated medical claim, and/or 2) contains an active ingredient.

TREATS
DIABETES

PREVENTS
DANDRUFF

HEALS
ABRASIONS

INDICATED FOR
HYPERTENSION

CURES COLD
SYMPTOMS

WHITENS
TEETH

REMEDY FOR
RHINITIS



What is NOT a Medical Claim?

It's OK to say: MAINTAIN, HELP, SUPPORT, PROMOTE, MAY

- “promotes good health and vitality”
- “for immune system support”
- “diets low in saturated fat and cholesterol may reduce the risk of heart disease”
- “helps to maintain cell integrity”
- “studies suggest that regular consumption of calcium may reduce the risk of osteoporosis”



What Does A Correct Label* Look Like? CORRECT LABEL

- Statement of identity
- Net quantity of contents
- Proper structure-function claim
- Directions for use
- Supplement facts panel
- List of ingredients
- Name/address of manufacturer
- Info above MUST be in English



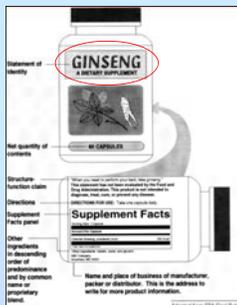
* Cosmetic labeling requirements are similar, except that supplement facts panel is not included

Statement of Identity

A product label must display a common language statement of identity.

NOT OK	OK
“Karela”	Bitter Melon
“Olibanum”	Frankincense

CORRECT LABEL



Net Quantity of Contents

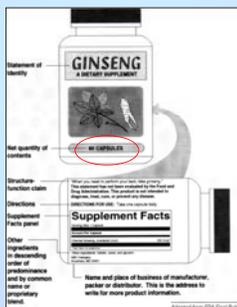
The label must include the net quantity of contents for all ingredients. Quantities must be listed in:

- pounds and ounces

OR

- U.S. gallons, quarts, pints, or fluid ounces

CORRECT LABEL



Structure-Function Claim

Certain claims must include this disclaimer:

“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

Without this statement, it is an unapproved drug.

★ No label is permitted to claim “APPROVED BY THE FDA.”



Supplement (Nutrition) Facts Panel

This is an easy way to identify a correctly labeled dietary supplement. Should include:

- suggested serving size
- nutrients (vitamin A, iron, etc.)
- Percent Daily Value
- all other dietary ingredients in common language



List of Ingredients

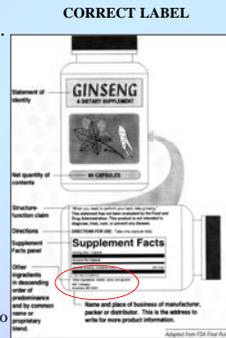
Label must have ingredients in descending order of predominance.

FDA identifies certain Generally Recognized As Safe (GRAS) ingredients. Examples:

- Niacin
- Vitamin A
- Zinc oxide

For a complete list, refer to Title 21, Chapter 1, Subpart F:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=582>



Name/Address of Manufacturer

Name/address of manufacturer must include street address.

- Exception: if firm is easily located in telephone directory, street address not necessary
- If manufacturer is outside US, must display the name/address of distributor in US



Inspection Procedure

Use "Inspection Checklist For Herbal/Dietary Supplements," (see next page). If you suspect the product is **ADULTERATED** or **MISBRANDED**:

- 1) Take samples.
- 2) Get addresses of the firm's suppliers, buyers in the US. For traceback/traceforward purposes, ask if they sell to other firms or if sales are limited to retail consumers.
- 3) Embargo and/or voluntarily destroy.
- 4) Contact: Virginia Wheatley
 NJDHSS, P.O. Box 369, Trenton, NJ 08625
 virginia.wheatley@doh.state.nj.us
 Tel: (609)588-3123 Fax: (609)588-3135

INSPECTION CHECKLIST FOR HERBAL/DIETARY SUPPLEMENTS

NAME OF PRODUCT: _____ DATE: _____
 LOCATION OF PRODUCT: _____
 QUANTITY OF PRODUCT: _____
 QUOTE FOR NAME: _____

	YES	NO	N/A
1. Is the packaging clear, sealed, and tamper-evident so that the contents are adequately protected?			
2. Is all writing in common language?			
3. Is the print large enough to be easily readable?			
4. Does the label indicate the product is an herbal or dietary supplement?			
5. Does the label indicate that the product is an herbal or dietary supplement in an herbal or dietary supplement? (e.g., herbs, roots, fruits, or leaf extracts)?			
6. If a medical claim is made, is it followed by a statement that the FDA has not evaluated the claim?			
7. If a medical claim is made, is there a disclaimer that the product is not intended to diagnose, treat, cure, or prevent any disease?			
8. Does the label include directions for use?			
9. Does the label include information on serving size, nutrient/diagnostic percent?			
10. Does the label list other ingredients in common language?			
11. Does the label list other ingredients in common language?			
12. Does the label list the name(s) of the manufacturer on the label?			
13. If the product is manufactured outside the US, are the name and address of the manufacturer listed?			
14. If product is questionable, has the firm given you the name(s) and address(es) of the manufacturer?			
15. If product is questionable, has the firm given you the name(s) and address(es) of their distributor?			

Any NO answers may necessitate further evaluation or action (i.e., embargo).

More Information

- NJDHSS, Food and Drug Safety Program:
<http://nj.gov/health/eoh/foodweb/>
- FDA-CFSAN: <http://www.cfsan.fda.gov/list.html>
- IBIDS: http://ods.od.nih.gov/Health_Information/IBIDS.aspx
- Medwatch: <http://www.fda.gov/medwatch/safety.htm>
- National Drug Code Query:
<http://www.fda.gov/cder/ndc/database/docs/queryndcno.htm>
- NIH-NCCAM: <http://nccam.nih.gov/>
- Nutrition.gov: www.nutrition.gov
- WHO: <http://www.who.int/en>



Great Articles

(all available on-line or from Virginia)

Antia, K, et al. (2004) "Competing With Gray Markets." *MIT Sloan Management Review*, Fall.

Morris, C. (2003) "Internet Marketing of Herbal Products." *Journal of the American Medical Association*, vol. 290, no. 11.

Saper, R, et al. (2004) "Heavy Metal Content of Ayurvedic Herbal Medicine Products." *Journal of the American Medical Association*, vol. 292, no. 23.

Trotter, R. (1990) "The Cultural Parameters of Lead Poisoning: A Medical Anthropologist's View of Intervention in Environmental Lead Exposure." *Environmental Health Perspectives*, vol. 89.



So Is Snake Oil an Unapproved Drug?

Relieves and Cures:

- Headache
- Neuralgia
- Toothache
- Backache
- Swelling
- Sprains
- Sore chest, stiff joints, dislocations, cuts, and bruises and more...



YOU DECIDE!!!!
