UNDERSTANDING THE LAW
Nature's Sunshine Products, Inc.
Legal Department
Revised 1/1/06

LAWS

Basically, Nature's Sunshine distributors need to be aware of three types of laws:

1. Licensing codes for Medical Practitioners. These are enacted on a state level.
2. Food and drug laws. The basic food and drug law of the United States is the Federal Food, Drug, and Cosmetic Act, passed in 1938. This law has been revised many times over the years and constantly changes. State laws generally cover the same subjects, but most are not aggressively enforced.
3. Advertising laws. State and federal laws that obligate advertisers to use only claims that are truthful and do not misrepresent the value or benefit of a product.

LICENSING CODES

Generally, these codes forbid a person from practicing medicine without a license. Therefore, unless you have a license to practice medicine issued by the state, you may not diagnose, prescribe, or hold yourself out as capable of doing so.

To a health-minded person, it seems very natural to offer friendly advice to others concerning their health. But if you happen to be a sales representative for herbs and vitamins, you cannot offer any advice that could be construed as diagnosing or prescribing for diseases or other physical or mental problems.

FOOD AND DRUG LAWS

The Federal Food, Drug, and Cosmetic Act governs the following:

- Foods: Vitamins, minerals, amino acids, extracts and herbs are dietary supplements, which are classified as foods under the Act. Conventional foods like drinks, shakes and candy bars are also included.
- Drugs: These are products sold with specific disease- or symptom-treatment claims. These products can be sold without a prescription if offered for a minor problem that can be identified and treated by a lay person. Homeopathic products sold by NSP fall under this legal category.
- Cosmetics: This category obviously includes company cosmetic lines.

You should be most familiar with the law as it regards the sale of herbs.

Claiming that food or dietary supplements can cure, treat or prevent diseases makes them "drugs" that are subject to special legal requirements and often must be pre-approved by the FDA.

ADVERTISING LAWS

Truth-in-advertising laws have been enacted by both the federal and state governments. Even private organizations like the Better Business Bureau are involved in ensuring that advertisers make truthful claims so that consumers get accurate information and can make informed decisions about the products they buy.

All advertisers are required to use only claims that are truthful and not misleading. Advertisers must have adequate substantiation or "proof" for all claims before they make them.

SELLING HERBS

First of all, it is perfectly legal to sell herbs. They must be presented as dietary supplements, which is the classification determined by the Federal Food and Cosmetic Act. Labeling claims that dietary supplements affect certain bodily structures and functions are permitted as long as they are supported by scientific research. They should not be represented as “drugs” to treat or prevent diseases, because this could influence their legal status.

According to the law, foods are "articles used for food or drink." Drugs are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in man or other animals."

Even though you may be convinced that certain herbs have curative powers, the law does not permit such claims to be made without prior FDA approval. And proving the efficacy of herbs to the government would takes millions of dollars and years of testing. It is simply not feasible to do that.

So...you can sell herbs as dietary supplements, but not as drugs.

FOODS VS. DRUGS

The law uses words with great precision, and subtle distinctions are crucial. People in the herb business, therefore, need to understand how to talk about their products without putting them in the category of drugs. The law does not recognize the healing powers of herbs, nor does it give much credence to individual testimonials, especially testimonials about how herbs and other dietary supplements may have helped someone overcome a disease or sickness.

COSMETICS

Laws regarding cosmetics are much more straightforward and easy to understand. Cosmetics are defined as articles intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or applied on the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. They must be safe, sanitary, and truthfully labeled.

THE POTENTIAL FOR LEGAL PROBLEMS

To summarize, you must be careful in these three areas. You can be found guilty of breaking the law when you:

1. Present herbs or vitamins as drugs rather than dietary supplements.
2. Make outrageous or untruthful claims for any product.
3. Take the role of a licensed medical doctor by diagnosing or prescribing.

ENFORCEMENT OF LAWS

Licensing laws are enforced by state government officials. They may be notified by a dissatisfied herb customer, family member, insurance carrier, or by a medical doctor.

Food and drug laws are enforced on a national level by the Food and Drug Administration (the FDA). State agencies enforce state laws.

Because herbs and vitamins are classified as dietary supplements, manufacturers and suppliers are subject to FDA inspections in the same way that state and local health officials inspect bakeries or restaurants.

Penalties for violating the law can be severe, especially for practicing without a medical license.

LEGAL PROBLEMS

Should you be nervous about legal problems? Yes and no. Yes, if you are unaware of the law and are careless and unwise in your sales approach. No, if you keep abreast of the law and stay within the law. Very few NSP distributors experience legal problems. But we are concerned about our people and don't want any unpleasantness.

Remember: You are running a legitimate business and you have rights as such. Be prudent and stay within the law.

HOW TO STAY WITHIN THE LAW

It's critical that you understand legal limits. The chart below summarizes clearly what you can and cannot do. Read it carefully.

WHAT YOU CAN'T DO	EXPLANATION
Diagnose (without a license)	This means telling a particular person what is physically or mentally wrong with him/her. "To examine in any manner another person...to determine source, nature, kind, or extent of a disease or other physical or mental condition."
Prescribe (without a license)	This means telling a person what he/she should take for a specific malfunction or problem.
Advertise "Doctor" services (without a license)	This means do not use signs, ads, business cards that include the word "doctor" "physician" Dr." or "M.D." when representing your business or services.
Misrepresent a product	This means telling a person what he/she should take for a specific disease, illness or problem. This also means telling an individual something that is false or misleading about a product, its use, content, action, or expected performance.
Represent herbs or vitamins as drugs	This means presenting an herb or vitamin as a cure or treatment for a specific disease rather than a purely nutritional or dietary aid.
Sell or display herbs at purely educational meetings	If the meeting is for educational purposes only and may include some discussion of the medicinal value of one or more herbs, anything said can be construed by the law as representing herbs you sell as drugs.

WHAT YOU CAN DO	EXPLANATION
Talk about herbs and vitamins as dietary supplements	Discuss how they contribute to health and nutrition, and how they affect bodily structure and function.
Talk not about diseases or symptoms and more about health	Emphasize good nutrition and sound dietary practices, including supplementation.
Discuss herbs within their non-therapeutic historical setting	Explain how herbs have benefited mankind historically in general terms rather than discussing the specific effects of a given herb on a specific person.
Learn the facts	Refer to responsible sources for your information. Don't be influenced by quackery.
Inform people that you don't prescribe or diagnose	Do this at all meetings.
Find out and who is attending your meeting	Ask if there are any government health officials or FDA representatives at your meeting. Be careful because government agents have been known to pose as health professionals or customers without disclosing their government affiliations.

LEGAL GUIDELINES FOR ADVERTISING

You may find it beneficial to your business to run an advertisement in a newspaper or make up an advertising flyer.

When you plan your copy, observe the same precautions you observed in presenting information verbally.

Don't say anything that would represent an herb as a drug. Limit claims to those in approved NSP literature.

WRONG: Alfalfa...for nervousness
RIGHT: Alfalfa...Purest available supply--Only $8.95

Don't make misleading statements.

WRONG: JNT-A will add 20 years to your life.
RIGHT: JNT-A will help support the body's nutritional endurance.

Always state that you are an independent distributor. Don't imply that you are a company representative or an agent of Nature’s Sunshine Products. (This is a company policy.)

YOUR RIGHTS IN THE EVENT OF AN FDA INSPECTION

Rarely, a Nature's Sunshine Distributor will receive a visit from an FDA or State Department of Health inspector. Originally, such inspections were authorized by Congress for investigation of sanitary conditions under which products might be held. The scope of these "sanitary" inspections has expanded, and the FDA too frequently employs them as a wedge to exceed its authority under the statute.

A visit from such an inspector is a rare thing, however, and should be no cause for alarm.

YOUR RIGHTS AND RESPONSIBILITIES

The FDA is authorized to do ONLY the following for dietary supplements. No more!

- To inspect the establishment for sanitary conditions.
- To visually inspect the products on hand, either in raw or finished state.
- To visually inspect the product labels and literature actually employed in the sale of such products (to see if you are making drug claims).
- To collect samples of products and/or literature.

The FDA is NOT authorized to:

- Examine records, except for a limited inspection of certain shipping records, after submitting a request in writing. (Some state investigators have greater authority.)
- Ask for, demand, or obtain signed affidavits.
- Ask any questions about the nature of the business, customers, etc.
- Carry out an inspection when you are absent.
- Tell your employees to consent to an inspection.
- Inspect any time he pleases. It must be a "reasonable time" for you as well as him.

If you should receive a visit:

- Be polite but firm.
- Telephone Home Office immediately to alert legal department and receive advice.

ACTIVITY: WHAT ARE YOUR RIGHTS?

How well do you understand your rights in case of an inspection? Read the situations below and decide the proper response.

IF THIS HAPPENS	THEN YOU SHOULD . . .
An FDA inspector arrives for a surprise visit at your place of business.	Let him in, unless the timing is bad for you. Be polite, but insist that your rights not be violated. Ask to see an inspection notice.
An FDA inspector appears at your warehouse and presents a notice of inspection. No one else is present, the facility is locked and you are on your way to a dental appointment.	If the time of the inspection is inconvenient for you, insist on a postponement. The statute states that inspections may be made only at "reasonable" times. That means reasonable to you as well as the inspector.
Inspector requests samples of the product.	Sell him what he asks for at retail price. Ask for a receipt.
Inspector asks to look at shipping records.	Refuse unless he gives you a written request.
Inspector asks to look at customer records.	Politely refuse.
Inspector asks you to sign something	Politely refuse.
The Inspector asks you some friendly questions about your business.	Don't answer. Change the subject.
Inspector takes out a camera or tape recorder to take pictures or tape record conversations.	Do not allow photographs or recordings. If he insists, ask for a written request for permission.

LEGAL HELP

Sometimes it is difficult to understand all the implications of the law, particularly since it changes so often, and since laws vary from state to state. For this reason, the company has provided some help:

Legal Services

The company legal department can provide information on topics such as:

- Marketing of products
- Proposed publications or advertisements
- Interviews with the media
- Relations with government authorities

Call the Legal department at Home Office during work hours, 8:30 a.m. to 5:00 p.m. Mountain Standard Time. In case of an inspection, call the Legal department when the inspector arrives.

SUMMARY OF FDA LAW
Nature's Sunshine Products, Inc.
Legal Department
Revised 8/15/05

KEY ACTS [i]

I. Pure Food and Drug Act (1906)

Primarily concerned with the sanitation of food and drug manufacturing facilities and the purity of their products, this law was pushed through Congress by President Theodore Roosevelt in reaction to his reading Upton Sinclair's *The Jungle*, a landmark work about the abuses in the meat packing industry.

II. Food, Drug and Cosmetic Act (1938)

Extended the scope of the 1906 Act to include cosmetics, therapeutic devices, and animal drugs and feeds. Enumerated 19 prohibited acts, including adulteration and misbranding, whose definitions were greatly expanded over their earlier identification under the Pure Food and Drug Act. Deems products adulterated or misbranded if their composition, production, or labeling fails to meet statutory standards. Granted explicit inspection authority to FDA.

A. Pesticides Chemical Amendment (1954)
Required prior approval of tolerances for pesticide residues on raw agricultural commodities.

B. Food Additives Amendment (1958)
Authorized FDA to require pre-market approval of food additives before they may be used in food.

C. Color Additives Amendment (1960)
Authorized FDA to require pre-market approval of color additives before they may be used in food.

D. The Proxmire Amendment--Vitamins and Minerals (1976)
Prohibits the Secretary of Health and Human Services from imposing maximum limits on the potency of safe vitamins and minerals. Prohibits the Secretary from classifying as a drug a natural or synthetic mineral solely because it exceeds the nutritionally useful level of potency. Precludes the Secretary from limiting the combination or number of any safe vitamins or minerals. Restrictions do not apply to vitamin and mineral products if they are claimed as having any therapeutic purpose or if intended for use by children or pregnant women.

E. Infant Formula Amendment (1980)
Infant Formula defined as a food that is represented as being for special dietary use solely for infants on the basis of its simulation of human milk or its suitability as a partial or complete substitute for human milk.

F. Nutrition Labeling and Education Act (NLEA) (1991)
The legislation requiring new labeling on foods and permitting health and nutrient content claims on foods. The FDA subsequently purposed two sets of regulations pertaining to the labeling of dietary supplements: (1) nutrition labeling requirements; and (2) nutrient content claims. Due to subsequent passage of other laws, nutritional labeling requirements have been replaced with final regulations under DSHEA.

III. Federal Trade Commission Act (1914)
Makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices. (Includes prohibitions against false or misleading advertising.)

IV. Fair Packaging and Labeling Act (1966)
Enumerates specific requirements for the labeling of all consumer commodities (specifically excluding meat and meat products; poultry; tobacco products; commodities subject to the Federal Insecticide, Fungicide and Rodenticide Act; veterinary biological products; prescriptions; antibiotics; alcoholic beverages; and commodities subject to the Federal Seed Act). Administration lies with FDA and FTC. Mandates certain placement, form and content of quantity statements for labeling of consumer commodities subject to the Act. Specifies that the label must identify the product, the name and place of business of the manufacturer, packer, or distributor, and the net quantity of contents.

Does not apply to wholesalers or retail distributors except to the extent that such persons are engaged in the packaging or labeling of such commodities.

V. Poison Prevention Packaging Act (1970)
Applies to all household substances. Special packaging must be reasonably convenient for adults and be designed or constructed so that children under the age of five cannot, within a reasonable amount of time, obtain a harmful amount of contents from within.

Administrative authority for the Act passed from the Department of Health and Human Services to the Consumer Product Safety Commission on May 14, 1973.

The Secretary of the Commission must determine whether there is a need for special packaging based on the degree or nature of the hazard to children and the availability of such substances, by reason of the packaging. The Secretary must also consider whether special packaging would be feasible.

VI. Safe Drinking Water Act (1974)
Establishes a statutory framework for the regulation of primary drinking water supplies. Gives FDA jurisdiction over bottled drinking water and EPA authority to establish national drinking water standards.

KEY FEDERAL AGENCIES [ii]

I. Food and Drug Administration--FDA
Insures that wholesome food products travel through interstate commerce and prescribes standards of safety and performance for food and food products. Authority ranges from premarket approval of food additives to policing and regulating food, drug, cosmetic and medical device manufacture, distribution, labeling and importation.

II. United States Department of Agriculture--USDA
Authorizes the inspection and regulation of meat, poultry, dairy products and eggs. Branches of USDA administer nutrition programs and extensive inspection programs--Agricultural Research Services conducts nutrition research, human research on nutrient requirements, food consumption surveys, and maintains a national nutrient data bank in conjunction with FDA. Requires Food Handlers Permit for "food service establishments."

III. Federal Trade Commission--FTC
Its only federal authority over foods is in the area of advertising. The definition of "advertising," as used in the FTC Act, technically excludes "labeling." However, jurisdiction over “unfair trade practices” can include food labeling, but the FTC usually lets the FDA handle labeling issues.

Enforcement mechanisms of the FTC include cease-and-desist orders against parties responsible for false advertising, consumer redress (refunds), and the issuance of injunctions against violators or the FTC Act.

IV. Environmental Protection Agency--EPA

Has general statutory authority to control contaminants in drinking water. (FDA is responsible for water and substances in water used in food and for food processing, as well as bottled drinking water.)

I. DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

1. Broadly defines "dietary supplements" to include vitamins, minerals, herbs or other botanicals, amino acids, and extracts or concentrates of those items.

2. Excludes all dietary supplements from the "food additive" definition.

3. Requires FDA to prove that a supplement poses a significant or unreasonable risk of injury or illness when used as directed on its labeling in order for it to be declared "adulterated" and stop its sale.

4. Allows the use of structure/function claims on the labels of dietary supplements provided they are truthful and not misleading. Permitted statements include those that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body, that characterize a documented mechanism by which the supplement acts to maintain such structure or function, or that describe the general well-being that results from consumption. Claims of a benefit for the supplement that is related to a classic nutrient deficiency disease can be used but are not popular because you are required to disclose the actual prevalence of the deficiency disease in the U.S. Claims may not state that the supplement can mitigate, treat, cure or prevent a specific disease or class of diseases. The FDA may not require premarket or approval of nutrition support statements. A disclaimer and FDA notification are required for these claims.

   Examples of permitted claims include: Calcium helps build strong bones; Vitamin C is essential in maintaining immune system response and integrity. The RDA Handbook, 10th Edition, is a valuable source of recognized "health related information." However, permissible claims have not been limited to statements involving essential nutrients only. Claims for herbs and other important dietary ingredients are being made and their use has resulted in an explosion of nutrition support claims on supplement labels and advertising and valuable health information being made available to consumers.

5. Reprinted scientific publications and studies can be used in connection with the sale of dietary supplements to consumers under the so-called "third party literature" provision.

   In order to qualify for use as permitted "third party literature" and used to sell products to consumers, the publication:

   A. Must be reprinted in its entirety.
   B. Must not be false or misleading.
   C. Cannot promote a particular manufacturer or brand of dietary supplement.
   D. Must be displayed to present a balanced view of the available scientific information on a dietary supplement.
   E. If displayed in an establishment, it must be physically separate from the dietary supplement.
   F. Must not have appended to it any information by sticker or any other method.

   Examples of qualifying publications include articles, chapters in books, and official abstracts of peer-reviewed scientific publications that appear in an article and were prepared by the author or editors of the publication.

   Provided publications meet the forgoing criteria, a wealth of new opportunities are presented. Third party literature can have a major impact on sales of dietary supplements and the credibility of claims used to promote them.

II. PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

In 2002, Congress enacted a comprehensive legislative initiative to increase the preparedness of state and federal government responses to terrorist acts. A number of changes were put in place in order to increase government oversight and protection of the U.S. food supply (including dietary supplements). Some of the key changes include the following:

1. Requiring that both domestic and foreign food manufacturers, processors and storage facilities "register" with the FDA.

2. Obligating food facilities to maintain records of manufacturing, processing, distributing, storing and importing foods.

3. Granting FDA the right to inspect certain business records when it has a reasonable belief that the food presents the threat of a serious health consequence or death.

4. Requiring food importers to notify the FDA before a shipment arrives to permit increased scrutiny over imports; and

5. Permitting the FDA to order a detention of any food based upon credible evidence or information that the food presents a threat of serious adverse health consequences or death.