



Dietary Supplement Claims Handbook

The FDA and YOU...

This industry handbook has been prepared by the Natural Products Association as a service to its members. The information contained herein is presented as a guide and to assist you in two areas of concern:

FDA Inspections—Your Rights and Obligations

Today it is not an unusual occurrence for a Food and Drug Administration (FDA) inspector to arrive at the door of a local health food store or establishment and announce his intention to inspect the premises. More than ever before, FDA is making extensive use of inspections as a means of enforcement in its administration of the Federal Food, Drug and Cosmetic Act.

Since the inspector is instructed to ask for many things, some of which legally may not be required of you (under the theory that there is no harm in asking), you should be aware of the inspector's powers, and your rights and responsibilities during the inspection. This information is presented on pages 2-7.

Giving Nutritional Information to Your Customers

In recent years, proprietors and employees of health food stores have found themselves in a position of being faced with charges by federal and state regulatory agencies that consumers were being furnished with information in a manner that may constitute the illegal practice of medicine or the illegal dispensing of drugs without a pharmacist's license. In most instances, these charges flow from an honest attempt by the store proprietor or his employees to give truthful information about their products in response to the seemingly sincere and honest questions of customers. Unfortunately, in some instances these customers turn out to be local or federal agent inspectors.

It is important that you are aware of the kind of information, advice, or statement which should not be made in order to avoid running afoul of the law. This information is presented on pages 8-12.

If you need additional help or advice regarding your relationship with FDA, contact the Natural Products Association at (800) 966-6632.

FDA Inspections— Your Rights and Obligations

FDA's power of inspection is derived directly from the Federal Food, Drug and Cosmetics Act. Section 704 of the statute spells out the scope of these powers for foods and dietary supplements as follows:

“For purposes of enforcement of this Chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein.”

Reasonable Time

Concisely put, what this means is that the power of inspection that Congress has given to FDA is limited to an inspection at a reasonable time and in a reasonable manner of equipment, products, product materials, containers, and labeling which includes product labels and any literature or printed or graphic material accompanying the product.

This presentation is intended to provide you with a basic outline of your rights and obligations and the practicabilities of the inspection situation, and to provide a few guidelines and suggestions for some of the questions that frequently come up during the course of an inspection.

What happens when the FDA inspector arrives at your establishment? It may be that the first person who will encounter the inspector is a clerk. Your employees should be instructed that the owner or some other designated managing employee is to be called when an inspector arrives. Your

employees should be instructed not to panic merely because an inspector flashes his badge and announces his authority.

If no one of authority is present, the inspector should be firmly, but politely asked to return a little later or the next day—he should not be unreasonably delayed or stalled; and if possible, there should be more than one individual who has the authority to deal with an inspector. Even if the appropriate individual is available, if it is extraordinarily inconvenient to attend to an inspector (for instance, if the designated individual is involved in a heavy work load, or if the inspector has arrived at a busy time of the day), he can be asked to return a little later. The law says he must inspect at reasonable times. Some judgment in asking an inspector to return should be used in very unusual circumstances where he claims a serious situation, such as salmonella poisoning, is involved.

In one circumstance, the inspector cannot be refused admittance: if the inspector has a search warrant issued by a court. However, this is an unusual situation. Your basic position should be one of good faith and cooperation as long as this is demonstrated on both sides.

No inspection should take place without the presence of an establishment representative who should stay with the inspector at all times during the inspection. The inspector should be required to produce his credentials and written notice of inspection as required by the state. Ask him to state the purpose of his inspection. The inspector should be given courteous attention, but as a general rule, information should not be volunteered. Employees should be advised that they should avoid idle conversation with the inspector. Once the inspector commences his inspection, he is entitled to observe in thorough detail all parts of the establishment where products are shelved, stored, packaged and otherwise handled. In addition to such detailed observation, what else may the inspector do? The following items are among the most frequently encountered.

Records

An inspector may not require you to produce records regarding your products as part of an inspection *unless* he/she has (1) a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, *and* (2) the records are necessary to make such a determination.

The authority is new and was given to FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the

Bioterrorism Act). It is important to note that an inspector needs special authorization by the agency to request records under the Bioterrorism Act. Specifically, the inspector must contact FDA's Emergency Operations Center, communicate the cause for concern and obtain authorization to make the records request.

When this authorization is granted, the Bioterrorism Act allows FDA to access *and copy* records held by a company involved in manufacturing, processing, packing, transporting, distributing, receiving, holding or importing food (including dietary supplements). The range of records that may be requested by FDA under such circumstances can be in any format (including paper and electronic) and may be related to any aspect of the food manufacturing, production, and transporting processes. FDA is obligated to keep any requested information confidential. Importantly, the Bioterrorism Act does *not* authorize FDA to request recipes for food, financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales and records from farms and restaurants.

In other situations, FDA may not—as a matter of law—require you to produce records regarding your products. But again, the question of being practical arises. If the inspector requests to see records, such as invoices or shipping receipts, it may be desirable to be cooperative if the information in the records is available anyway, or if it is fairly clear that information sought is not intended for use against your establishment. If the inspector goes further and wants to make copies of other records, here you should draw the line. The statute does not authorize the copying of records.

There is one exception to the foregoing summary of your rights concerning the production of records. Section 703 of the statute expressly provides that records showing the movement of a product in interstate commerce must be made accessible and may be copied if the request is made in writing and specifies the nature or kind of article to which the request relates. It is unlawful to refuse such written request. But the law provides that any information obtained by way of such written request cannot be used in any criminal prosecution against the person providing the information. The significance of requiring a written request as opposed to giving information voluntarily is obvious. Even when a written request is made for records, you need not part with your original documents. The inspector must make copies at his own expense (or you can get copies for him).

Photographs

Occasionally an FDA inspector may arrive at an establishment with a camera. FDA's instructions to its inspectors specifically state that an inspector should not ask for permission to take photographs. The inspector has been told by his or her supervisors to take his camera, and if the need arises, shoot first and ask questions later. If you see an inspector with a camera, it is advisable to forbid him to take pictures. The inspector has been further instructed that if management objects to picture taking, he should tactfully explain how photographs may help to make a better presentation and offer copies. If he does this, tactfully continue your objection. If you do this, the inspector has been instructed to explain that you may request copies of his photos at your expense. You should maintain objection all the way through such a discussion. The law does not explicitly allow that inspectors be allowed to take pictures. If pictures have already been taken, you have a right to request copies from the FDA District Office at your expense. An inspector will not surrender pictures already taken, but he must stop taking pictures if you so demand. If you encounter any difficulties in connection with the taking of photographs, tell the inspector you must temporarily interrupt the inspection and call your attorney for advice.

Tape Recorders

In the past, inspectors have used concealed tape recorders in the course of an inspection. When this practice was discovered, a court case was commenced. As a result the Secretary of Health, Education and Welfare (Celbresse) issued a statement published in the House Interstate Committee Report (H.R. No 2646, Sept. 22, 1962, p.14) disapproving such use of tape recorders. Today the FDA Inspection Operations Manual expressly states that no recording devices will be used on any establishment inspection. As with photographs, the law does not explicitly permit inspectors to use tape recorders. You do not have to consent to the use of recordings. If you find that a tape recorder is being used, tell the inspector you must temporarily interrupt the inspection and call your attorney for advice.

Samples

Inspectors are authorized to collect samples during the course of an inspection. Sampling may include a product or products, product labels and labeling. Labeling includes any literature accompanying the product. You have a right to demand payment for any samples taken by the inspector.

The inspector is instructed to pay for samples at your invoice price plus 10% or the regular retail price, if not unreasonable. In any event, the law requires, and you should demand, that the inspector give a receipt for whatever samples he takes during the course of the inspection. If practical, it would be desirable to set aside and preserve a duplicate sample of everything taken by the inspector. The inspector's receipt should describe the sample taken; but in addition, for your own information you should be careful to note the date the sample was taken. Such practice is extremely desirable and important in the event it should later become necessary to make analysis of the duplicate sample to either check or counter an analysis made by the FDA of the samples taken by the inspector.

Affidavits

At the conclusion of an inspection, the inspector will usually write up a report of his observations and ask you to sign an affidavit or other statement as to what was done or said during the course of the inspection. The law does not require, and an inspector can not legally demand, that an employee or representative of the establishment sign any affidavit, statement or other writing prepared by the inspector during the course of his inspection. The inspector may be instructed to get a written statement or affidavit or at least to have someone review and initial or make written changes in a statement prepared by the inspector. This, however, does not mean you have to comply with any such request. Usually, it would not be objectionable to sign the acknowledgment that an inspection was made or that specified samples were taken by the inspector. However, with these possible exceptions, it is generally advisable to refrain from signing anything. In effect, when an inspector is looking for signatures, he is collecting evidence. If, as a matter of cooperation, you would be willing to sign an appropriate affidavit or statement, then advise the inspector that before doing so you wish to have your attorney review any such statement or affidavit.

Upon completion of an inspection, the law requires the inspector to leave a report in writing setting forth his observations that any product consists in whole or in part of any filthy, putrid or decomposed substances, or has been prepared or held under unsanitary conditions whereby it may become contaminated with filth or rendered injurious to health. However, if the inspector finds the conditions to be satisfactory, he is not required to give you a written report that he has made such a finding.

Voluntary Embargo

It may occur that the inspector will ask you to embargo or set aside and withhold from sale certain products observed by him during the course of his inspection. If this does occur, ask the inspector the reasons for his request and have him specify the manner in which the particular product violates the law. While the inspector is instructed to encourage such voluntary embargo, the law does not require it. Here, the matter is one of sound discretion. The extent of the willingness to display a cooperative attitude and the nature of the alleged violation are valid, important considerations in deciding whether you should voluntarily comply.

The foregoing guidelines should give you some idea of some of the more common problems and practices which are likely to be encountered during an establishment inspection. Always try to be cooperative and courteous, keeping in mind not only the legalities of a situation, but the practicabilities as well. Don't hesitate to check with counsel if any questions arise during the inspection, and where appropriate, don't be afraid to politely say "no."

Giving Nutritional Information to Your Customers

There is at present a very fine line between dispensing of medical advice and drugs, on one hand, and the dispensing of nutritional information and sound nutritional advice, on the other hand. Federal and state authorities have been all too quick with accusations that the line has been crossed.

It is important that you are aware of the kind of information, advice, or statement which should not be made in order to avoid running afoul of the law. At the same time, there are areas of solid nutritional advice and information under the law as it stands today, that you should be able to give to your customers.

The purpose of the following outline is to provide you with some guidelines as to the kind of information which should NOT be given and the kind of information which you should be able to give without fear or repercussion. These guidelines apply whether the information is imparted to a customer in your store, a customer (inspector) making a telephone inquiry, or to an audience at a lecture you may be giving.

What You May Not Do or Say!

1. Do Not Diagnose!

It is not uncommon for a customer or an inspector to enter the store and describe to the proprietor or an employee a variety of symptoms or conditions being experienced by the customer in the expectation that you will define these symptoms and prescribe appropriate relief. This is the practice of medicine. Although you may feel you can identify a particular disease or other condition based on the symptoms being described to you, you may not, under the law, engage in such diagnosis.

2. Do Not Prescribe!

It is also not uncommon for a customer (or an inspector) to ask the proprietor or employees of a health food store if there is any product in the store which may be effective in the treatment or cure of either a particular-named disease or a variety of symptoms described by the customer. This

again involves the practice of medicine and should be scrupulously avoided.

3. Do Not Make Claims That Your Products (or Any Specific Product) is Good For The Treatment Or Cure Of Any Disease Condition!

If a customer (or an inspector) inquires as to the particular uses or purposes of any given product, you should avoid any statements suggesting that the particular product is especially good for arthritis, high blood pressure, or any other disease condition unless the product bears an appropriate health claim. Such statements could be construed not only as the dispensing of medical advice, but may also be construed as drug claims converting the food products which you sell into drugs. This then could entail the unlicensed practice of medicine and/or pharmacy.

4. Do Not Display A Particular Book With A Particular Product!

It is one thing, and a good thing, to have a section of literature and information on nutrition in your store. It is another thing, however, to set up a display on your counter or shelves wherein a book and a product are presented side by side with the intention that your customer will associate the book and the product, even though neither you nor your employees has said anything. Indeed, even if that is not your intention, and although not a single word is said, it is likely that the book or literature will be construed as labeling for the product if there is the remotest connection between the two.

Information Which You May Give to Your Customers!

Although there is a definite list of the DO NOT's with respect to providing information to your customers, there is also an area of discretion wherein you should be able to stand up for your right to give sound and truthful nutritional information to you customers.

1. Providing Publications and Scientific Literature to Your Customers.

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), retailers are permitted to provide publications, articles, chapters on books, and scientific literature regarding the benefits of a dietary supplement or ingredient, provided that such information:

- a) is not false or misleading;
- b) does not promote a particular manufacturer or brand of dietary supplement;
- c) presents a balanced view of the available scientific information;
- d) is displayed in a store location physically separate from the supplements and;

e) does not have appended to it any information by sticker or other method.

The literature must be reprinted in its entirety, unless it is an official abstract of a peer-reviewed scientific publication. DSHEA also preserves the right of the retailers to sell books and other publications as part of their business in the book section of their store.

What the law means is that you can have scientific literature meeting the above standards on display in your store, but you still may not place it next to supplements containing the dietary ingredient discussed in the literature. Now if a customer asks “what is vitamin C for?,” you can provide a balanced piece of literature or a balance of different pieces that discuss vitamin C.

2. Talking With Your Customers.

While you should avoid talking about the treatment and cure of disease conditions, you should be able to talk about general problems in nutrition. This may include a reference to the role of vitamins, minerals, and dietary supplements in human nutrition and the physiological function of such products.

You should be able to discuss the problems associated with foods which are subjected to various additives, chemicals, sprays, and other elements foreign to the natural environment.

You should be able to truthfully discuss the fact that there are various segments of our population that may not be getting all of the vitamins, minerals and other nutrients they require, such as older people who may not wish to cook for themselves or have poor dentures, teenagers who eat on the run, and the wide variety of people who, for a variety of reasons, may not be getting the so-called well-balanced average diet. In other words, the concept of vitamins, minerals and dietary supplements as nutritional insurance is one which you may espouse without fear of reprisal.

There is, therefore, a broad spectrum of sound nutritional facts and information which the proprietor of a health food store and his employees should be able to make as part of their function in servicing their customer, as part of the right of freedom of speech guaranteed to them by the First Amendment to the Constitution, and as part of the right of the consumer to receive such information.

The following are some of the specific examples of the kind of information which the health food store proprietor and his employees should be able to give their customers:

- Most of the hard tissues of the human body, such as bones and teeth, are comprised in part of mineral elements. In the case of bones and teeth, relatively large amounts of calcium and phosphorus are needed to make up these structures, but the body also needs many other minerals, some in very minute quantities, to carry on its life processes. For instance, in order to function properly, muscles, nerves and the heart must be constantly nourished by body fluids containing the correct proportion of minerals like sodium, potassium, and calcium. Similarly, red blood cells cannot be formed or function properly unless sufficient iron is supplied to the body. The USDA has reported that the minerals in which diets are most likely to be low, or deficient, are calcium, iron, iodine and fluorine.
- Vitamins are compounds which are essential for the proper utilization of foods and for healthy functioning of the human body. The various vitamins differ greatly in their composition, and each one has specific, separate vital functions. Most vitamins must be supplied by preformed foods from outside sources such as foods or dietary supplements since the body cannot manufacture them.
- The function of the various vitamins are innumerable and a few of the more important ones are listed here. Vitamin A is essential for the maintenance of a healthy skin and mucus membranes. Vitamin D is needed to enable the body to utilize calcium and phosphorus derived from the daily food, and to build and maintain healthy bones and teeth. Vitamin B1 (thiamin) is required for proper utilization of carbohydrates to obtain energy. Without vitamin B2 (riboflavin) and niacin the body cannot utilize most food constituents properly. Vitamin C (ascorbic acid) plays an important role in normal tooth and bone formation and in wound healing.
- Good nutrition is necessary for proper development and function of the central nervous system.
- Persons who are unable to metabolize lactose find it necessary to exclude milk and many milk products in their diets. Milk is

a major dietary source of calcium. Diets without milk frequently contain less of this important mineral than is recommended by the Food and Nutrition Board of the National Research Council.

- Unless supplemented by milk or calcium therapy, the diet presently selected by the geriatric population in the U.S. is generally deficient in calcium.
- During stress periods, such as infancy and adolescence, and during the childbearing years in women, it may be difficult to select diets to meet the increased needs for iron.
- Among the nutrients likely to be deficient in certain areas of the country and segments of the population are cobalt, copper, chromium and iodine.
- Good nutrition is essential for good muscle development and maintenance.

Questions?

If you need additional help, or have questions regarding the information contained in this booklet, contact the Natural Products Association at (800) 966-6632.

About the Natural Products Association

Founded in 1936, the Natural Products Association is the nation's largest and oldest non-profit organization dedicated to the natural products industry. The Natural Products Association represents more than 10,000 retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids.

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Headquarters Office
1773 T Street, NW
Washington, DC 20009
toll-free: (800) 966-6632
phone: (202) 223-0101
fax: (202) 223-0250

www.NPAinfo.org