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FDA Label Compliance

Top Five Points for Manufacturers

The United States Food and Drug Administration (FDA) is an agency in the United States Department of Health and Human Services. One of the major goals of the administration is to protect and promote public health through the regulation and supervision of various industries such as, food safety, tobacco products, dietary supplements, prescriptions, pharmaceutical drugs, and vaccines. In order to ensure that such products are safe the FDA has regulations concerning proper labeling of products. Navigating the complex statute addressing what constitutes a proper label can often be overwhelming and confusing to the inexperienced. The following are the five things you need to know about FDA label compliance.

1. The Product Matters

When it comes to label compliance what a product is matters. Each product falls within a category defined by the FDA. Generally, a product falls into one of three categories; food (such as a cereal or produce), cosmetic product, or drug. Dietary Supplements are a specific category within food that has unique requirements and is worth mentioning separately. The Federal Food, Drug, and Cosmetic Act defines each of these categories.

Food means 1) articles used for food or drink for man or other animals, 2) chewing gum, or 3) articles used for components of any such article.

Dietary supplements are defined as products (other than tobacco) intended to supplement the diet. The definition specifically includes a vitamin; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or a combination of any ingredients mentioned above.

Cosmetics are products, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

Drugs are articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component

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of any article specified in clause. A dietary supplement can be a "drug" under certain circumstances.

Each category has specific labeling criteria that must be established in order to comply with FDA regulations. Knowing which category the product or good falls into can make the difference between compliance and non-compliance.

2. Understanding the Principal Display Panel

Every label, in every category, has a Principal Display Panel (PDP). It is the portion of the package label that is most likely seen by the consumer at the time of the purchase. Usually, this means the PDP is the portion facing the customer as they walk through the isle of a supermarket. For example, to the right is an illustration of the PDP on a cereal box. The PDP actually serves a very important purpose other than advertisement for a particular product. It is a place where a consumer can immediately identify the product, understand the quantity included in the product and know the type of food. In fact, those are the minimum requirements a product must have on the PDP. There must be: a statement of identity, name of the food, and a net quantity statement (or amount of product). Unfortunately, it isn't as simple as merely having the required information on the PDP. The FDA regulates the size, font and location of how the three requirements are displayed.

3. Location Matters

Location, location, location. When determining whether a label is in compliance with FDA regulations location matters. One of the most obvious examples is the three requirements needed on a PDP, but there are more. A common mistake is the location of an ingredient section on a label. Placement of an ingredient list on a label needs to be immediately below the nutrition label. If there is insufficient space below the nutrition label, it must be placed immediately contiguous and to the right of the nutrition label. Knowing where certain information needs to be placed can make the difference between being in or out of compliance with FDA standards. Location and information requirements can change between categories of product and type of label used.

4. What Is An Identity Statement

Simply put, the identity statement is the name of the food and must be located on the front label, or PDP, as well as any alternative PDP if applicable. Sound simple? Well, it is a little more complicated than merely identifying the product. The name used to identify the product must be established by law or regulation, or in the absence thereof, the common or usual name of the food. If there is no name established by law, regulation, or common usage, then an appropriate descriptive name, that is not misleading should be used. It is important to note that brand names are not an identity statement. Instead the identity statement

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merely identifies the food, not the company selling the food. To the lower right is an illustration detailing the identity statement for a can of ANTON'S pasta sauce. It is important to note that the requirements of an identity statement change depending on which category the product falls into. What may be an appropriate identity statement for a food may not be appropriate for a dietary supplement, drug, or cosmetic.

Another important illustration in this example is the size, font and prominence of *Pasta Sauce* when compared to the rest of the font on the PDP. A statement of identity must use prominent, bold type font. The font must be *reasonably related* to the most prominent printed matter on the front panel and should be one of the most important features on the PDP. *Reasonably related* is a debatable term, but it is at least ½ the size of the largest print on the label. Here the size of *Pasta Sauce* is reasonably related to the most prominent printed matter on the PDP.

5. Claiming

There are a lot of criteria that go into what can be claimed and how it can be claimed on the label. An entire article could discuss various methods of claiming for different products and still not cover everything. Don't panic, even a general understanding will help in navigating what is an appropriate claim. Generally there are four different types of claims that can appear on a label: Nutrient Content Claims, Health Claims, Qualified Health Claims, and Structure/Function Claims.

Nutrient Content Claims is a claim that, either directly or by implication, characterizes the level of a nutrient in food. A statement such as "low fat" is considered to be a Nutrient Content Claim. The FDA provides specific wording that must be used in relation to a predefined amount of the nutrient. For example, the use of the word "low" is an approved word relating to a predefined amount. In contrast, saying something has "tons" or "loads" would be an improper claim as these terms are not defined by the FDA.

A Health Claim is any claim made on the label or in the labeling of a food that expressly, or by implication, characterizes the relationship of any substance to a disease or health-related condition. The statement can be implied through brand name, symbols, or even vignettes. These claims must be limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation or treatment of disease. Any Health Claim must be evaluated by the FDA prior to use. Health Claims require Significant Scientific Agreement based on the totality of publically available scientific evidence.

Qualified Health Claims are claims based on less scientific evidence than Health Claims.

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The FDA began considering these claims on September 1, 2003. In contrast to Health Claims, a Qualified Health Claim must be established based upon the totality of publicly available evidence, but the scientific support does not have to be as strong. A petition must be filed with the FDA in order to use a Qualified Health Claim. A response to the petition will be given on or before 270 days after receipt.

Structure/Function Claims were created from the Dietary Supplement Health and Education Act of 1994 (DSHEA). It allows a dietary supplement to bear certain statements on its label as long as certain criteria are met. More specifically, statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function are considered to be Structure/ Function Claims. An example of a Structure/ Function claim would be the statement "helps you gain energy."

When making a structure/function claim there must be:

1. Substantiation that such a statement is truthful and not misleading;
2. Inclusion of a disclaimer; and
3. Notification to the FDA no later than 30 days after the first marketing of the product that you are making the statement.

The disclaimer must provide:

> "***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.***"

This list should help to provide a general overview of key concepts when labeling your product. It is by no means all inclusive, but provides a starting point from which the label can be created.

For more information or to have your proposed labels evaluated for compliance contact Smith & Hopen, P.A. at 800-807-3531.

Author: David Jacobs is a U.S. Registered Patent Attorney with Smith & Hopen, P.A. He is graduate of Stetson College of Law graduating in the top 10 of his class. He obtained his Bachelor of Science from Arizona State University's Barrett Honors College with a focus on biology.