

# NATURAL PRODUCTS EXPO – EXHIBITOR STANDARDS

From the Standards Dept. at New Hope Natural Media, Revised June 2006

All Expo exhibitors are required by contract to comply with the Exhibitor Standards (<http://newhope.com/standards>), which include U.S.A. labeling and marketing regulations, that is, compliance with Food and Drug Administration (FDA) and Federal Trade Commission (FTC) laws and regulations.

## FOODS & SUPPLEMENTS: STANDARDS for LABELS, BROCHURES & SIGNS

1. All promotional materials (brochures, sales sheets, catalogs) are considered “labeling” (<http://www.cfsan.fda.gov/~dms/ga-sup2.html>).
2. Labeling has restrictions on its direct and implied claims as to the benefits of the product (<http://www.cfsan.fda.gov/~lrd/fr000106.html>).
3. Claims for foods are limited to statements about taste, aroma, or nutritive value (e.g., High in Vitamin C, or Low Fat), The one exception is an approved health claim; see below.
4. Labeling cannot make direct or implied claims that the food or supplement or any of its ingredients is intended to treat, prevent, cure or mitigate a disease or abnormal health condition (<http://www.cfsan.fda.gov/~dms/hclaims.html>). The only exception re. disease prevention claims are several specific health claims which have been pre-approved by the FDA.
5. For supplements, only structure/function claims and U.S.-FDA-approved health claims and are allowed on labeling at Expo: (<http://www.cfsan.fda.gov/~dms/ds-faq.html>); (<http://www.cfsan.fda.gov/~dms/qhc-sum.html>); (<http://www.cfsan.fda.gov/~dms/scimguid.html>).
6. Health claims, which are pre-approved by the FDA, claim a link between a substance (usually in certain minimum amts.) and the prevention or reduced risk of a particular disease. Some health claims apply only to foods (e.g., oat bran may reduce your risk of heart disease), whereas a few also apply to supplements (e.g., calcium may reduce your risk of osteoporosis).

### ACCEPTABLE STRUCTURE/FUNCTION CLAIMS (examples)

Helps maintain a healthy cardiovascular system; Helps support a healthy immune system; Helps maintain healthy cholesterol / blood sugar / blood pressure levels already within the normal range; Assists in maintaining weight loss.

### UNACCEPTABLE DISEASE AND DRUG CLAIMS (examples)

May help prevent cancer; Helps prevent heart disease; Lowers high cholesterol; Helps relieve cold, flu, and allergy symptoms; Relieves chronic joint inflammation (implies arthritis treatment); An Herbal antibiotic; Defends against germs and infection.

### APPROVED HEALTH CLAIMS (examples)

Unqualified: Soy protein may reduce the risk of heart disease. Plant sterols may reduce the risk of heart disease.

Qualified: “Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.” [Note that the FDA’s exact language must be used—heavily qualified, and including many disclaimers.]

### UNAPPROVED HEALTH CLAIMS (examples)

Pomegranate may reduce the risk of heart disease. Cherries may reduce the risk of cancer. Cranberry may reduce the risk of cancer. [Note that the FDA may approve these claims at some time in the future, based on a substantial body of science.]

### **COSMETICS & TOPICALS: STANDARDS for LABELS, BROCHURES & SIGNS**

1. Products applied to the skin, including essential oils and “aromatherapy” sprays, are cosmetics, unless the product complies with U.S. FDA regulations for an OTC drug category (<http://www.cfsan.fda.gov/~dms/cos-218.html>). Note that prescription drugs are not exhibited at Natural Product Expos.
2. Labeling (brochures, sales sheets) for cosmetic products cannot make direct or implied claims that the product or its ingredients are intended to treat, prevent, cure, or mitigate a disease or abnormal health condition (<http://www.cfsan.fda.gov/~dms/cos-lbl.html>). Specifically, structure/function claims which are permitted for supplements (which must be ingested), are not permitted for topicals or other cosmetics.
3. The FDA defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance." Note that while cosmetics may alter the appearance of the body, they may Not alter the structure of the body. For example: “Reduces the appearance of fine lines on the face,” but Not “Reduces cellulite and fat cells to slim down your thighs.
4. Over-the-counter (OTC) drugs are regulated by the FDA via condition-specific monographs in defined categories. The permitted “active ingredients” and the permissible claims are defined within each monograph. A list of categories can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_04/21cfrv5\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfrv5_04.html).
5. Note that while “cosmeceuticals” is a marketing term, it is not a recognized FDA product category—with a few exceptions, a product is either a cosmetic OR a drug. There are a few legitimate “cosmetic drugs,” such as dandruff shampoos and sunscreens, but these must comply with the applicable OTC monograph.

### ACCEPTABLE COSMETIC CLAIMS (examples)

Helps maintain healthy, smooth skin; Gives your complexion a youthful glow [Note that some cosmetic claims are viewed as “sales puffery.”]; Moisturizes your skin; Lends a soothing, relaxing feeling [e.g., for bath products]

### UNACCEPTABLE DRUG CLAIMS (examples)

Relieves muscle strain; May help treat psoriasis / eczema / dermatitis; Helps with depression; Helps with insomnia; Works transdermally to \_\_\_\_\_ [Note that cosmetics may have “cosmetic,” surface effects only, not internal benefits or actions.]

### **HOMEOPATHIC DRUGS, OTC VERSIONS**

Homeopathic drugs (OTC but not Rx), labeled as such, and in compliance with FDA regulations and guidance documents are permitted at Expos. These are particular types of drugs,

consisting of ingredients found in the U.S. Homeopathic Pharmacopoeia, and formulated and manufactured according to specific regulations set forth in the Code of Federal Regulations and in the FDA's website. An OTC homeopathic drug must have at least one OTC indication. See Conditions Under Which Homeopathic Drugs May be Marketed (Compliance Policy Guide 7132.15) (1988).