



Regulatory Compliance Guidelines

Welcome and thank you for joining the Natural Hope Herbals Affiliate program.

The Dietary Supplement Health and Education Act (DSHEA), the FDA, and FTC require manufacturers and distributors of dietary supplements and/or herbal products to follow specific regulations on what can be said about our products. Employees and marketers, including affiliates are required to follow these regulations when they discuss Natural Hope Herbals' products online, in-person, and in writings such as literature, pamphlets, blogs, articles, e-mails, testimonials, and books.

Anyone working for/with Natural Hope Herbals must adhere to these regulations to ensure that our company remains in good standing with the FDA and other regulatory agencies.

As an affiliate you are responsible for being familiar with the federal and state laws that govern how you market our products. We have created this Regulatory Compliance Guidelines document in order to assist you in your compliance. These guidelines will show you examples of what you may and may not legally say about our products. While we tried to be thorough in these guidelines, we cannot cover every product or situation. If you are ever unsure if you can say something, please feel free to ask and we will be happy to be of assistance.

We wish you and your family God's richest blessings,
The Natural Hope Herbals Team

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The Federal regulations were created to protect both companies and consumers. These regulations require that all advertising/marketing be truthful, not misleading, and substantiated. When writing or speaking to the public, we must be extremely careful not to make herbal product statements that claim to diagnose, cure, mitigate, treat, or prevent disease. When a claim makes or implies that a product can cure, mitigate, treat, or prevent disease the FDA/FTC will consider it to be an unapproved drug claim. Instead of drug/disease claims structure-function statements may be made for products used internally. Both disease/drug claims and structure function claims must be avoided for cosmetics or topical products.

The FDA does not accept tradition as an acceptable claim. You can not say that an herbal product has been traditionally used to cure, mitigate, treat, or prevent disease.

Basic Guidelines:

1. Avoid making untrue, misleading, or unsubstantiated health related claims.
2. No statements that suggest or claim an herbal product can diagnose, cure, mitigate, treat, or prevent disease. Keep in mind that not only blogs but even personal testimonials or customer reviews must be edited to maintain compliance.
3. Use structure/function claims for products used internally.
4. Structure function claims should never be worded so that they suggest a cure, mitigation, treatment, or prevention of disease.
5. Focus on health and wellness instead of disease. Use words such as: supports, maintains, promotes, health, wellness.
6. Do not use words such as: cures, heals, treats, therapeutic, disease, illness, and repairs.
7. Do not make drug/disease or structure/function claims for products considered cosmetics such as topical salves. Instead use cosmetic claims.
8. Use words like enhances, cleanses, softens, and promotes for topical cosmetic products.
9. Include a disclaimer when structure/function claims are made.
10. A website url should not include disease claims.
11. Images should not suggest or imply that a supplement will cure, mitigate, treat, or prevent disease. Example: Do not make a graphic of a women with cold symptoms connected to a Natural Hope Herbal product then show her appear to be well in another photo after taking that product.
12. Never suggest an herbal product is a substitution for a medication.



13. Include a disclaimer notifying readers about any affiliate links before any blogpost or article.

What is disease according to federal regulations?

“Disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.”

Examples: cancer, asthma, cold, flu, Crohn’s disease, diabetes.

What are drug or disease claims?

A drug claim suggests that the product is intended for use in the “diagnosis, cure, mitigation, treatment, or prevention of disease”. Drug and disease claims are forbidden.

Example of what not to say:

Ech-N-Elder can be used to treat colds and the flu.

Yeast/Candida cures systemic candidiasis.

Yeast/Candida is antifungal.

How can we determine if we are making a disease claim?

The FDA has a list of 10 criteria that are useful in determining if a statement is a disease claim or implied disease claim. These criteria can assist you in determining if your writing or statements are using appropriate language.

1. Claims an effect on a disease or class of diseases.
 - a. Examples of disease claim: “protective against the development of cancer” or “reduces the pain and stiffness associated with arthritis”.
 - b. Examples of implied disease claims: “relieves crushing chest pain (angina),” “improves joint mobility and reduces inflammation (rheumatoid arthritis),” or “relief of bronchospasm (asthma).”
2. Claims an effect on characteristic signs or symptoms of disease using scientific or lay terminology.
 - a. Example of inappropriate language: “inhibits platelet aggregation” or “reduces cholesterol”.
3. Claims an effect on a condition associated with a natural state or process.



- a. Two criteria determine if such a condition will be considered a disease: (1) if the condition is uncommon; or (2) if the condition can cause significant or permanent harm.
 - b. Examples of acceptable structure/function claims are "mild memory loss associated with aging," "noncystic acne," or "mild mood changes, cramps, and edema associated with the menstrual cycle."
 - c. Examples of disease claims are "Alzheimer's disease or senile dementias in the elderly," "cystic acne," or "severe depression associated with the menstrual cycle."
4. It is an implied disease claim because of the product name, formulation, use of pictures, or other factors.
 - a. Do not use photos that imply disease or that contain symbols, like the heart symbol, EKG tracings, or RX symbol.
 5. Claims that a product belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease.
 - a. Do not say products are analgesics, antibiotics, antidepressants, antimicrobials, antiseptics, antivirals, or vaccines.
 - b. The exception is if there is context that makes clear that the intended effect of the product is on structure/function and not disease. Ex: "Diuretic that relieves temporary water-weight gain."
 6. Claims to be a substitute for a product that is a therapy for a disease.
 7. Claims to augment a therapy or drug intended to diagnose, mitigate, treat, cure, or prevent a disease.
 8. Has a role in the body's response to a disease or to a vector of disease.
 - a. Example of inappropriate wording: "supports the body's ability to resist infection" and "supports the body's antiviral capabilities".
 - b. Appropriate wording: "supports the immune system".
 9. Claims to treat, prevent, or mitigate adverse events associated with a therapy for a disease.
 - a. Example of inappropriate wording: "to maintain the intestinal flora in people on antibiotics"
 - b. "If the adverse event is not a disease, then this type of claim is acceptable. For example, a claim that a product is useful because it counterbalances the effect of a drug in depleting a nutrient or interfering with the metabolism of a nutrient would be an acceptable structure/function claim."
 10. Otherwise suggests an effect on a disease or diseases.



What are structure function claims?

A structure-function claim suggests that dietary or herbal products are “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, provided that such statements are not disease claims. “

Structure-function claims can be made for a dietary supplement or herbal product, but NOT a cosmetic.

Examples:

Ech-N-Elder supports immune system health.

Yeast/Candida can be used to support normal balance of the microbiota and yeast in the mouth, intestines, and genitourinary tracts.

When you make a structure-function claim you must include the following 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.”

General Terms and Qualifiers

Qualifiers can help show the difference between minor conditions and actual disease.

Examples: Mild, minor, regular, typical, occasional, normal.

“Gentle and great tasting formula designed to support normal healthy bowel function without causing dependency. Tasty Bowel Reg combines herbs that are used for the relief of occasional constipation with carminative herbs that support digestion.”

What about disease symptoms?

Symptoms are considered evidence in the body that suggest disease and therefore should not be used in a way that would suggest cure, mitigation, treatment, or prevention.

Example of symptoms: cough, fever, sore throat, congestion, diarrhea, constipation.

Example of what not to say: Wild Cherry Compound eliminates cough and reduces congestion.

Example of appropriate statement: Wild Cherry Compound soothes the lungs and supports the healthy function of the respiratory system.



What are cosmetic claims?

Statements that claim a product cleanses, beautifies, promotes attractiveness, or alters appearance.

Structure-function claims should not be made for topical products. Cosmetic claims should be used for these products.

Example: Promotes healthy looking skin.

Common Conditions & Natural States or Processes

Common conditions associated with natural states or processes that do not cause significant or permanent harm will not be treated as diseases.

Hot flashes, common symptoms associated with the menstrual cycle, ordinary morning sickness associated with pregnancy, mild memory problems associated with aging, hair loss associated with aging, and non cystic acne are not treated as diseases.

Uncommon or serious conditions like senile dementia, toxemia of pregnancy, severe depression associated with the menstrual cycle, and cystic acne are treated as diseases.

Examples of appropriate language:

Ladies Formula may ease occasional monthly discomfort, stress, and irritability related to your normal menstrual cycle.

Full Term—this proprietary blend was designed to provide tonic uterine support through every phase of a healthy pregnancy.

Calm/Nerve can be used to nourish and support a healthy nervous system during times of stress.

Affiliate Disclaimer

The FTC requires a clear and conspicuous disclaimer before or near affiliate links.

These are often put at the top of blog posts. Banner ads do not need disclosures.

Examples:

“I get commissions for purchases made through links in this post.”

“I get commissions for purchases made through links in this post. This is to help support my blog and does not have any impact on my recommendations”.



Resources and Laws:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.14>

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?fr=101.93>

<https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>

<https://www.ftc.gov/tips-advice/business-center/guidance/ftcs-endorsement-guides-what-people-are-asking>

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm>

<https://www.americanherbalistsguild.com/legal-and-regulatory-faqs>

<https://www.naturalhopeherbals.com/wp-content/uploads/2023NHHWinterHerbalGuide.pdf>

Thank you for taking the time to read and comply with these guidelines. We appreciate your conscientious effort in sharing our products.

By signing this document, you agree to abide by these guidelines.

X _____
Affiliate Signature