



# General Product Advice

## 2016

# PRODUCT CLAIMS

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# General Product Advice

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# BASIC FDA COMPLIANCY GUIDELINES

This document is intended to help ensure labels are compliant to current Food and Drug Administration compliancy policies by giving basic guidelines for claims and product directions

Please note that this is not an all-inclusive list of policies and that certain categories of products or claims may have specific compliancy policies covered in other documents

**The FDA has primary responsibility for claim on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale.**

**The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials**

**Both Agencies coordinate on dietary supplement claim policy issues**

Both the FDA and FTC expect (and legally require) that all claims regarding dietary supplements must meet both of these basic requirements:

Truthful and not misleading; and adequately substantiated at the time the claim is made

## **Definition of a claim:**

A claim is anything the FDA considers to advise customers on the intended use or effects of a product. These do not have to be expressly stated and may also include images or product names in addition to taglines.

All compliancy policies enforced by Nutra Group USA LLC, are based off of current understandings of FDA rules and regulations, as well as being drawn from observations of their enforcement of these policies. As such, our policies, like our formulations, are subject to change based off of new information or understandings. We guarantee that our policies reflect the current FDA's standards for dietary supplements as closely as we understand them.

## **Policies regarding claims**

- ∂ Claims should usually be worded to support or aid processes rather than cause changes in the body.
  - Good anchor words for claims: helps, supports, mild, occasional, promotes, aids, assists
    - Adding "Supports" or "May help" may not always be enough to make a supplement claim out of a drug claim
      - ex: "May Help Improve Immune Function", "Supports Repair of Liver" and "Aids Disease Prevention" are all still over the line.
- ∂ Products may not claim to improve body functionality or lower the risk of disease or other unhealthy or unnatural states
  - FDA Red Flag adjectives: Chronic, acute, pain, cure, prevent, alleviate, treat, restore, manage, etc.
- ∂ No product may claim to substitute or augment a treatment, warn against going to healthcare professionals or medicinal treatments, indicate its ingredients are used in certain drugs, or in any way advise a consumer against seeking advice, treatment, or diagnosis. These statements constitute health fraud and are punishable by law.
  - Products may not advertise themselves for use alongside therapies or treatments, such or for specific types of patients, such as cancer patients.
- ∂ Claims may not guarantee specific effects, such as promising certain amount of weight loss, results within a set time frame
  - Certain adjectives for certain processes end up creating these sorts of claims while the same adjective might be okay for another process.

- For example, one could say that a detox or cleanse is fast as such a process shouldn't take more than a couple of days or weeks. However, "fast weight loss" implies a more immediate and noticeable result than one typically sees regarding this process.
  - Avoid words such as "Instant" or "Immediate" or phrases such as "works in minutes/days"
- ∂ All claims made on a product should be appropriate and truthful for the respective product.
  - Claims must have appropriate amount of acceptance from a scientific body to be considered generally accepted. General acceptance from advertisers of products is not considered sufficient evidence
    - Due to the fact that claims aren't pre-approved, evidence that a claim has been used before doesn't guarantee that it is compliant
      - **Just because something appears on Amazon doesn't mean that it is okay to use simply that it has not been subject to FDA enforcement**
  - Claims should not be puffery or subjective to point of having no reasonable basis for support
  - The phrase "May help" before a claim does not allow for inappropriate claims.
- ∂ Claims are evaluated holistically. Other items on a label may interact with a claim, as might presentation of information.
- ∂ Products may not identify themselves as pharmaceutical, identify themselves as belonging to the same category as a medicinal product (e.g. claiming to be a pill or lozenge), or otherwise imply being or acting as a substitute for a drug or therapy.
  - Antimicrobial, antiviral, and antifungal claims are considered drug claims.
  - Products should not claim to have historical use as medicine or have proven medicinal or therapeutic (as it relates to diseases) values.
- ∂ No product may claim to be a food or act as meal replacement. This includes identifying itself as a snack or other food item.
- ∂ Products cannot be advertised as being "All Natural", use the term "100%" to describe the contents or effects of the product in any way (company policies on the product, such as "100% satisfaction guarantee" or "100% money back guarantee" are fine, but claims such as "Pure" "100% [ingredient]" or "100% effectiveness" are prohibited)
  - The use of "Natural" as an adjective is subject to context when describing a product
- ∂ No product can be labeled as "Vegan", or "Non-Allergenic". Only a few select products may be called Gluten free.
  - Products may not claim "contains no [allergens]" or other statements at odds with our cross-contamination warning. That warning is mandatory due to potential danger for those with severe allergies that may experience effects from the smallest trace of allergens
  - Not all of our products are vegetarian. Capsules made with gelatin may use bovine as a source for the container.
    - Similarly, special coatings for certain products, such as enteric coating or vanilla flavor, may only be declared on products actually including these.
  - Certain products Nutra Group USA LLC carries are made with Vegan ingredients. These particular products may be identified in this manner but cannot claim to be Vegan products.
  - Certain products Nutra Group USA LLC carries are non-GMO. These particular products may be identified as such.
- ∂ All products (except for Gummies) are exclusively for persons above the age of 18. **NO OTHER PRODUCT HAS BEEN SAFELY CLEARED FOR USE BY CHILDREN UNDER THE AGE OF 18**

## CONTACT INFORMATION & LOGOS

- ∂ All labels must contain required amounts of contact info. This includes the name of the distributor (company or individual), place of business, and indication of the connection with the supplement (required on any supplement where the name on label is not the manufacturer).
  - For the address, the following is required: City, State and Zip of business, as well as one of the following: a street address, a PO Box, or a phone number.
    - Websites, emails, and social media pages are not valid forms of contact information
  - Phrases that reveal connection to supplement include, but are not limited to:
    - Distributed by
    - Manufactured for
    - Developed for
    - Formulated for
    - Produced for
- ∂ GMP seals must specify that the product is sourced from a GMP certified facility. Failure to specify this implies that certification of the products production and packaging was done under the customer's distribution info on the label, and would require proof of such
  - The FDA's current Good Manufacturing Practices (cGMP's) are guidelines to be followed. The FDA does not certify facilities as GMP, rather this is accomplished by a third party inspection to assure the cGMPs are being met. As such, GMP certification seals cannot mention the FDA.
  - Nutra Group USA LLC can supply compliant GMP certification seals for use on products.
  - Any label that mentions GMP certification must specify that the contact info listed on the label is "Manufactured for"
- ∂ The FDA's official logo is **not** cleared for use on **any** private sector material, including labels or websites. Use of this is considered falsely claiming FDA endorsement and is enforced as such.
  - Labels may make mention that a product has been manufactured and packaged in an FDA registered and inspected facility.
    - The FDA does not "approve" products or facilities.
  - Use of the acronym, FDA, in large bold letters can be considered misleading to consumers, even if the official logo is not used.
- ∂ Certain seals are commonly misused. The following sorts of seals cannot appear on any of our labels: 100% All-Natural, All-Natural, Organic, Gluten Free, Vegan, Pure, etc.
- ∂ Use of icons for different social media outlets is subject to the individual policies regarding their respective logos and icons.
  - In general, use of the icon alone is not allowed, and mentions must be made to indicate specific pages or accounts owned, licensed, held, or maintained on said social media site.
    - Indication might be made by either direct reference to said link or by indicating one can be found or reached on said site(s). [See specific sites for more information]
- ∂ <sup>TM</sup> refers to claiming a trademark on the material next to it. ® refers to a registered trademark that has been registered with a national trademark office. Trademarks not owned by the creator of a label must give credit to their owners. All registered trademarks must be listed and credited properly.
  - Nutra Group USA LLC must have documentation of a trademark's registration in order to use the ® symbol. Regular trademarks do not require this documentation.

## LINKS AND REFERENCES

- ∂ Please note that the names of links and references can constitute drug or disease claims and are subject to the same rules as any other part of the label in terms of what they can imply.
  - Names of referenced articles (e.g. “The Effects of Graviola on Cancer Cells”), snippets of text from Amazon barcodes, and other material can constitute disease claims.
- ∂ Material in links printed on the label are considered part of the labeling itself according to the FDA, and as such, claims in those sites can misbrand the label, even if there are no issues with the printed label.
  - Nutra Group USA LLC does not check the content of links or references on labels and maintains responsibility only for the printed content on the label. Please be sure that the material you are providing links to on your label complies with FDA guidelines.
- ∂ Please be sure that you do not endorse comments, tweets, customer reviews, etc. that make references to drug or disease properties. Even if you do not feature the customer supplied comment, a simple “Like” can be considered endorsement of a testimonial according to FDA regulations.

Nutra Group USA LLC, Inc.® compliancy policies only apply to the labels we print and/or apply to bottles. However, we wish to advise you that the FDA considers all associated literature to be a part of the product's labeling. Therefore, that one's websites, social media, pamphlets, newsletters, store pages, etc. have the potential to misbrand their products if they make prohibited claims about the products regardless of what is on the actual label.

## FDA DISCLAIMER

**“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.”**

The Food and Drug Administration disclaimer on a label is used to identify that a product has not undergone a pre-market evaluation that drug products must undergo. As such, it also means that none of the claims on a label must be preapproved by the FDA before a product can go to market (assuming they are structure/function or nutrition content claims and not health claims, which are claims indicating usage of a product is linked with reduced risk of disease or health-related condition).

In addition, it advises consumers that the product shouldn't be used as substitute for medical care, regardless of how they've been advised by outside sources.

What this disclaimer **does not** do, however, is allow any claim to be made on the label without regard for the compliancy regulations of the FDA.

Claims that suggest a product should be used for treatment or prevention or have effects it does not possess are still impermissible even with this statement on the label.

In addition, this disclaimer does not waive responsibility to use other necessary disclaimers for a specific claim, if required.

# PROPRIETARY BLENDS

- ∂ Only ingredients in the formula without daily values may be included in a proprietary blend.
  - Only ingredients with the same unit of measure may be grouped together in a proprietary blend.
- ∂ Blend must be identified as such with either the term “Proprietary Blend” or appropriately descriptive name. This term may be bolded for emphasis.
  - Total weight of blend should be on the same line as “Proprietary Blend” or the name of the blend
- ∂ List of ingredients should begin with “Consisting of:”
- ∂ Ingredients in the proprietary blend must be put in descending order by weight.
- ∂ Blend may either be in separate lines (indented or without hairlines between them) or in paragraph form.
  - If using hairlines, do not put a hairline between “Proprietary Blend” or the name of the blend and “Consisting of:” or “Consisting of:” and the first ingredient, as hairlines are meant to separate different ingredients
- ∂ Plant parts, Latin names, and other required information about the product must be included in the blend.
  - Slight revisions may be used for ease of reading. Ex:
    - Acai Powder (fruit) → Acai Fruit Powder
    - Uva Ursi (powder) → Uva Ursi Powder
    - Green Tea (95% Extract) (leaf) → Green Tea Leaf 95% Extract / Green Tea 95% Leaf Extract
    - Cinnamon Bark Extract (providing 4% essential oils) → Cinnamon Bark 4% Extract
    - Guarana (33% extract providing 100mg naturally-occurring caffeine) → Guarana 33% Extract.

## DOCTOR RECOMMENDED CLAIMS

- ∂ These sorts of claims include “Doctor recommended,” “Dentist recommended,” “#1 Doctor-Recommended Brand”
- ∂ The fact that the product is recommended by one or even a handful of doctors is not enough to qualify for this statement
  - If you are a licensed practitioner, or represent a licensed practitioner, you may indicate the product to be “Recommended by Dr. \_\_\_\_\_”
- ∂ Regulators expect a national survey of doctors concerning their experience in their ordinary practice.
  - Survey should be random, statistically representative.
    - Highly recommend using company that specializes in surveys to design and conduct the survey, as the language of the survey and the way that the survey is conducted will be very important to regulators
- ∂ Please note that usage of the word Doctor, Physician, Medical Specialist, and so on, as well as imagery of persons wearing lab coats, stethoscopes, surgical masks or other recognizable apparel that could mark them as doctors is not allowed without similar approval or specification of that individual (MUST BE APPROVED BY SAID INDIVIDUAL)
  - i.e. a product from Dr. Example's Natural Vitamins could have a picture of a doctor on the front while a product from John Smith's Natural Vitamins could not. Of course this assumes that Dr. Example has given permission to the company to use his name on the products.
    - Dr. Example does not have to be the doctor in the picture used. Similarly John Smith in a lab coat wearing a stethoscope would not be allowed, even if he has given permission to use his image on the label.
- ∂ Usage of Rx on a label with Doctor will cause it to imply prescription use, and is thus prohibited.
- ∂ Medical imagery is not allowed on labels. This includes: Red crosses (or red backgrounds with white crosses), syringes, ambulances, thermostats, EKG tracings, bandages, blood pressure gauges, the Rod of Asclepius, and so on
  - Please note there is a difference between a Caduceus and the Rod of Asclepius. The Caduceus (two snakes coiling up a staff, usually with an orb at the top and wings on either side) is not officially a medical symbol and may currently be used [see below] while the Rod (a single snake, as seen in the Star of Life use by emergency medical services) is a recognized symbol and is off-limits for use on any supplement label.
    - Please note that while the hard rule of expressly medical imagery does not apply to the caduceus, the FDA operates a large portion of their enforcement based off customer perception, and the fact that the caduceus is often associated with medicine means that this allowance may be subject to change
- ∂ Even with a doctor's approval, phrases, claims, or imagery that imply a product to be a medicinal product, part of a treatment, or otherwise be used for diseases is not allowed.
  - A medical professional may choose to recommend patients use a supplement, but for the purpose of labeling, all stock formulas purchased from Nutra Group USA LLC are intended for use as dietary supplements and as such must adhere to the FDA's policies on supplements.

## SUBLINGUAL CLAIMS

- ∂ The FDA states that only products intended for digestion are dietary supplements, and that a sublingual product does not fit this description
- ∂ Through warning letters, they have established that “intended for digestion” means that the product must (a) be swallowed, (b) be in an approved form of delivery (capsule, tablet, etc.), and (c) be introduced to the body in the gastrointestinal tract/stomach
- ∂ Like topical creams, products absorbed into the body within the mouth are considered to be an improper introduction method for a supplement
- ∂ Due to the ingredients and the way the products are labeled and intended for use, this improper method classifies them as misbranded (exact wording is “not eligible to be marketed as a dietary supplement”), rather than reclassification and evaluation based off of new classification (usually resulting in being misbranded as a drug or cosmetic), as is the normal case for misbranding. However, any structure/function claims on such a product does reclassify it as a drug, and will be misbranded as such.
- ∂ The description “Chewable” is used to allow for an oral ingestion method that makes the most use of the product's properties but is intended to be swallowed rather than allowed to dissolve in the mouth

## ALCOHOL RELATED CLAIMS

- ∂ No indications that a product can or should be taken with alcohol are allowed, including indications that a product should be taken in a situation involving alcohol.
  - This includes references to events or situations that are known for alcohol consumption, or imagery related to alcohol or the effects of alcohol consumption.
  - A product may not be advertised as lowering blood alcohol content
- ∂ Hangover cures or prevention products have recently begun to come under FDA enforcement. In light of the many warning letters from this year, please note that indications of this intended use are not allowed
- ∂ A product may not be advertised for use at treating alcohol withdrawal, alcoholism, or repairing or preventing damage done by alcohol consumption, especially prolonged consumption.

## CARDIOVASCULAR RELATED CLAIMS

- ∂ Blood Pressure, Blood Sugar, and Cholesterol levels are defined at being diseased at anything above or below a normal range. In keeping with this understanding there are several rules on these products in particular
  - We cannot claim to raise, lower, or control (i.e. “keeps X levels in normal range) these levels
  - Normal range must be mentioned (due to customer perception of these levels). Therefore, any product that mentions or implies an effect on these levels must include a mandatory disclaimer. Variations of this include: “Supports X levels already in the normal range” or “Helps support healthy X levels within the normal range”
    - Please note that the word “healthy” does not act as substitute for “in the normal range”
    - In addition, the word “Support” must be used instead of “Promote” (especially in cases where the variation of the phrase does not include “already” or “within” or includes “healthy”)
    - This statement must appear on the the same panel claims about these levels are made on or must be prominently displayed (larger font than surrounding text and located at the top) on an adjacent panel with a symbol directly referencing this statement to the claim (i.e. an asterisk or dagger)
  - Mentions of disease states relating to these levels (e.g. hypertension, low blood sugar, diabetes) anywhere outside the caution statement will misbrand the product.
    - In addition, LDL, the “bad” cholesterol, is also considered a mention of a disease state by the FDA.
- ∂ Certain pictures cannot be used due to their common associations according to the FDA, in addition to the standard rules that prevent showing diseased organs. These include:
  - Heart symbols – Assumed to be commonly associated with disease treatment by the average consumer
  - EKG tracings – FDA states that the common consumer would not be able to distinguish a healthy tracing from an unhealthy one.
  - Cholesterol – all recognizable images are of LDL build up or HDL's interactions with LDL
- ∂ Pictures of arteries or blood cells do not necessarily constitute a disease claim so long as they appear healthy.
- ∂ Blood flow, arterial quality, heart rate, blood cell count, and other measures of a cardiovascular systems health may not be improved upon or made recognizably healthier in ways that imply treatment or existing disease states (e.g. increased circulation, artery strength/flexibility, etc.)
  - Support claims for many of these are acceptable, though any of these with quantifiable measures may need to establish previously healthy levels (e.g. cell count, heart rate, etc.)
- ∂ Cannot claim to detoxify or purify the blood
- ∂ Cardiovascular health, circulatory system health, and blood health in general may all be supported or maintained.

## HAIR RELATED CLAIMS

- ∂ FDA prohibits supplements from being used for the purposes of growing hair, preventing hair loss, treating baldness, and restoring or regrowing hair. Products that are advertised for these purposes are considered to be drugs.
  - Products labeled as supplements with such drug claims on them are considered to be misbranded drugs.
- ∂ The term “Hair Growth” is not an automatic claim, but only when it is clear the term isn't referring to causing this growth. A product may assist this natural process, as it can provide nutrients that are used in the production of hair. This means a product may advertise itself as “supporting hair growth”, implying that the body is already currently growing hair normally.
  - A product may not be advertised as “Promotes hair growth” or “hair growth supplement” as these types of claims imply a product to be used for creating new hair growth, rather than supplying nourishment for the process.
- ∂ A product may provide the necessary nutrients for strong or beautiful hair, but it cannot repair damage (to either hair or follicles), produce hair faster (implying additional growth), or be used to treat conditions such as dandruff.
- ∂ As with any other supplement, the use of the word “healthier” in reference to a specific body part or process implies a diseased state to begin with, and is considered to be a claim of treatment.
- ∂ Products cannot promise guaranteed results or results within set time frames
- ∂ Results promised cannot be puffery or subjective. For example, promises such as “hair feels more radiant/younger/more beautiful”. However visible or quantifiable results, such as saying that it “looks more radiant/beautiful” or “stronger hair”, are acceptable.
- ∂ Products do not target specific areas of the body in regard to hair.
- ∂ Products cannot inhibit hair growth
- ∂ Products cannot mention DHT specific hormones related to hair-loss
- ∂ Products cannot alter natural attributes of hair, such as color, straightness, or curliness
- ∂ The terms “fullness”, “thickness”, and “volume” must refer to quality of hair, not amount.
- ∂ Images should not suggest prohibited claims. Examples include but are not limited to: before and after images, bald or balding scalps, clearly damaged hair, follicle damage, or loose strands intended to represent lost hair.

# IMMUNE SYSTEM/DEFENSE AGAINST DISEASE RELATED CLAIMS

- ∂ No dietary supplement may claim to be for use in treating, preventing, diagnosing, curing, or in any way having effects on a disease. This includes playing a role in a body's response to a disease. Immune system support is therefore tricky
- ∂ A product may not be advertised for use with a therapy or cure
- ∂ Claims must focus on the body's system itself. It may not mention supporting the function of this system or the organs and other vectors that comprise it.
  - Wording is very important. For example, "Supports Immune System" is okay while "Promotes Immune Health" is not.
  - Some items that comprise the immune system are so intimately linked with their function that they cannot claim be supported without also claiming to be supporting the function. These include but are not limited to white blood cells (and all subcategories), antibodies, mucus, lymph nodes, and so on.
    - Certain items, such as the spleen, liver and bone marrow, can have their health supported, but care must be taken to show that the effects of the products are providing proper nourishment to these items, not direct maintenance
- ∂ All claims regarding the immune system can only be support or nourishment. Promoting, boosting, repairing, assisting, maintaining, strengthening, reinforcing, building, growing, enhancing, kick-starting, energizing, focusing, substituting for, cleansing, defense, augmenting, expanding, adding to, and other similar modification claims are prohibited
- ∂ Mentions of immunity, immune response (or response to disease, damage, antigens, or pathogens), immunodeficiency, inflammation, allergies, radiation, or specific diseases constitute disease claims
- ∂ Antioxidant products by definition may defend against free radicals and oxidation. However, products may not be advertised to counteract oxidation damage, either defending against or repairing this damage
- ∂ Probiotics may replenish healthy or beneficial bacteria. This bacteria may not be advertised as improving health of the user
  - As antibiotic usage can be considered a treatment and we cannot establish recommended time between ceasing use of antibiotic and beginning probiotic use without a physician, Nutra Group USA LLC policy is to avoid advertising product for use of replenishing bacteria lost due to previous antibiotic use
- ∂ Claims can be implied through context of label as a whole. This includes, but is not limited to using images, layman's terms, or combinations of claims that together imply product use for prohibited scenarios
  - For example, a product advertised as travel support, with implications of global traveling, and containing claims about keeping healthy and the immune system would be seen as claiming an alternative to vaccination prior to global travel.
  - Similarly, a product could use claims about skin and immune system support along with imagery of the sun or tanning beds and imply claims of skin cancer due to common consumer association of these items together
- ∂ Immune products may not advertise themselves as antimicrobial, antiviral, or antifungal.

## LAXATIVE AND DIURETIC RELATED CLAIMS

- ∂ Using the word “laxative” or otherwise suggesting the effects of a laxative product is considered a disease claim by the FDA unless the remainder of the label makes it clear that they are not intended for treatment of chronic constipation
  - This means that the product must contain either the disclaimer of “For occasional use only,” “For relief of occasional constipation,” or “This product not intended to treat chronic constipation” when claiming to be a laxative or have laxative effects
    - Unless constipation relief is directly mentioned, disclaimer doesn't need to be displayed prominently (i.e. on same panel, or large font clearly distinguished from other text), and may appear in the caution statement
    - Certain cleansing products, i.e. those that are cleared as safe for continuous use and marketed as such, cannot make claims about regularity or laxative properties, as this implies treatment of chronic constipation
- ∂ A product may help to maintain regularity, but it may not completely maintain it on its own.
- ∂ Any product containing specific laxative ingredients must declare them in the caution statement (ex. Senna leaf, cape aloe, cascara sangrada, etc.). These warnings cannot be removed from the caution statement
- ∂ Any potential toxins removed by laxative cleanses may not be described as being “toxic materials” or “harmful” as these constitute disease claims.
  - In addition, other recognized harmful materials, such as heavy metals, cannot be the subject of detoxification claims.
- ∂ Laxative products cannot claim to protect, strengthen, or restore the intestinal tract
- ∂ Laxative products cannot claim to affect the immune system
  - Detoxification processes cannot mention the liver. This includes mentioning the liver's natural detoxification process or supporting said process
- ∂ Effects of laxative products must not be puffery or subject in nature.
  - This includes results of the user feeling younger, more beautiful, rejuvenated, more energetic, or so on.
- ∂ Laxative products cannot claim to support weight loss, or increase metabolism or energy
- ∂ “Diuretic” is defined by the FDA as a drug. Use of this term when describing a product constitutes a drug claim
  - This includes mentioning products as having diuretic effects or describing a product as a natural diuretic or diuretic substitute
- ∂ Certain effects of diuretics, such as relieving temporary water weight gain, are permitted, but claims about relief for urinary tract or kidneys, causing water flow, alleviating discomfort, and so on are considered disease claims.
- ∂ Names for products with diuretic-like properties may suggest release of water retention (e.g. “Water Away”) but may not make reference to urine, urinary flow, congestion, prostate, or relief in any manner. Similarly, images of areas affected by urinary flow disorders, such as kidneys, are also prohibited.
- ∂ The diuretic-like effects of these products may not make reference to effects fluid retention or release has on the heart-related conditions.

## MIND AND MOOD RELATED CLAIMS

- ∂ Products cannot be for use for ADD/ADHD
  - Cannot claim to “keep” one concentrated or focused or maintain or sustain concentration.
  - Cannot make claims about attention
  - Cannot use names specifically relating to products for these conditions or treatments of these conditions (e.g. using suffixes like “-alin” or “-certa”)
- ∂ Memory support is allowed, but products may not be for use for conditions such as Alzheimer’s.
  - Products cannot enhance, restore, improve, or protect memory
- ∂ Products cannot increase intelligence, IQ, learning capability, etc.
- ∂ Products cannot treat neurological conditions, prevent decay, repair nerves, protect the brain.
- ∂ Mood swings, depression, stress-related conditions, bipolar disorder, anxiety disorders, panic attacks, and mania are considered diseases and cannot be treated
  - “Anxiety” in reference to nervousness rather than anxiety disorders is okay to mention under certain conditions:
    - One may not claim the formulas directly reduce anxiety. Instead the product should focus on calming or relaxing properties
    - In the caution statement, a phrase should be indicated that the product is not intended to treat clinical depression or anxiety disorders.
  - PMS symptoms can be combated, provided they are mild and not indicative of more serious conditions. Products cannot prevent PMS itself
- ∂ Cannot make claims about maintain, causing, or combating specific moods
  - Ex. A product cannot claim to cause happiness or prevent irritability
  - Stress is not a mood, and claims may be made about it. However, it may not be “treated” or “prevented”.
    - A product may help one relax, or have relaxing properties, but it should not make claims that it causes one to relax (i.e. identifying itself as a sedative rather than relaxing)
    - In addition, it is recommended that it be identified as “mild” or “everyday”, though this is not always needed.
    - Making claims about serious forms of stress or identifying a product to be used no matter the severity is forbidden
      - Claims may not link stress to health related conditions
- ∂ Some self-esteem and creativity claims are permitted, but care must be taken to ensure they are not puffery or subjective in nature
  - Ex. A product that supports positive mood could claim to support positive self-esteem as one of its claims (not the sole one, in order to avoid being seen as a treatment for depression), but it could not claim to promote self-image or improve said self-esteem
  - Ex. A product supporting brain or nervous system health could make a similar supportive claim about creativity, but it couldn't cause, promote, or improve creativity or fight artist/writer's blocks
- ∂ The terms stable and healthy are context dependent on their use.
- ∂ Products cannot be used for addiction purposes
  - This includes indicating something is to be used as a substitute or to slowly wean one off of a drug or substance
    - This includes caffeine. A product may be a healthy energy alternative, but it shouldn't indicate caffeine addiction through claims or name

## PAIN RELATED CLAIMS

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  - PMS symptoms can be combated, provided they are mild and not indicative of more serious conditions. Products cannot prevent PMS itself
- ∂ Cannot make claims about maintain, causing, or combating specific moods
  - Ex. A product cannot claim to cause happiness or prevent irritability
  - Stress is not a mood, and claims may be made about it. However, it may not be “treated” or “prevented”.
    - A product may help one relax, or have relaxing properties, but it should not make claims that it causes one to relax (i.e. identifying itself as a sedative rather than relaxing)
    - In addition, it is recommended that it be identified as “mild” or “everyday”, though this is not always needed.
    - Making claims about serious forms of stress or identifying a product to be used no matter the severity is forbidden
      - Claims may not link stress to health related conditions
- ∂ Some self-esteem and creativity claims are permitted, but care must be taken to ensure they are not puffery or subjective in nature
  - Ex. A product that supports positive mood could claim to support positive self-esteem as one of its claims (not the sole one, in order to avoid being seen as a treatment for depression), but it could not claim to promote self-image or improve said self-esteem
  - Ex. A product supporting brain or nervous system health could make a similar supportive claim about creativity, but it couldn't cause, promote, or improve creativity or fight artist/writer's blocks
- ∂ The terms stable and healthy are context dependent on their use.
- ∂ Products cannot be used for addiction purposes
  - This includes indicating something is to be used as a substitute or to slowly wean one off of a drug or substance
    - This includes caffeine. A product may be a healthy energy alternative, but it shouldn't indicate caffeine addiction through claims or name

## PROSTATE RELATED CLAIMS

- ∂ As with all products, we cannot claim to treat diseases, aid treatments, diagnose conditions, or prevent problems before they occur.
  - This means a product cannot claim the following:
    - It should be used for cancer patients
    - It helps reveal warning signs
    - reduces the chances of cancer or increases the survival rate
    - helps heal damage
    - reduce aches or pains of the prostate
    - Act as a substitute for a urologist or other medical expert
    - Is to be used for Prostatitis (see below)
- ∂ Prostate enlargement is considered a disease condition. Products may not claim to reduce swelling, inflammation, or treat prostatitis.
  - Both painful and nonpainful enlargement are considered disease conditions. Neither is okay for a label claim.
- ∂ Urinary flow abnormalities are considered indicative of disease states. In addition altering urinary flow is considered a drug claim.
  - This means a product cannot claim the following
    - Reduce frequency of urination
    - Promote less nighttime urination
    - Increase flow
    - Reduce or eliminate pain associated with urination
    - Alter properties of urine
- ∂ Prostate formulas do not necessarily effect libido. In addition, if a product is marketed as a prostate formula, one must identify the herb or ingredient in question that effects libido rather than implying the products effects on the prostate are responsible for effects on libido
- ∂ Prostate formulas may not make mentions of erections or sexual response.

# REPRODUCTIVE AND HORMONE RELATED CLAIMS

- ∂ Products in this category can affect libido and performance, but cannot “restore” either except when functions are decreased with aging.
  - Desire and arousal are categories of libido that are okay to promote. Sex drive however is considered to relate to potency (see below). The differences enforced by the FDA seems to indicate that it is okay to affect the mood, but not the biologic urge of the user
- ∂ Reproductive products cannot make claims of “potency”, as they are then considered to be used for treatment of impotency or erectile dysfunction.
  - Similarly, products cannot make claims about affecting erections or ejaculate
  - Size of body parts cannot be changed by product.
- ∂ Products cannot claim alteration of hormone properties.
  - Body's hormone production cannot be stopped or started by a product.
  - Hormone imbalance cannot be corrected by a product
    - This includes boosting or lowering testosterone or estrogen levels
      - Due to the various associations with drugs specifically meant to affect it and conditions, testosterone should not be mentioned on a label.
  - Products cannot be advertised as substitutes for therapies or to treat conditions regarding hormones.
- ∂ “Anabolic” is not a banned term. However, claims about affecting testosterone production and associations of the product with anabolic steroids are not allowed. For this reason, we advise against using this term if possible and only for appropriate products.
- ∂ Common conditions associated with natural states, such as PMS, pregnancy, aging, and menopause, are not considered disease claims, so long as these conditions are considered common and do not cause significant or permanent harm.
- ∂ Ingredients can't be advertised as being used historically to treat sexual dysfunction or other prohibited claims
- ∂ Claims cannot be puffery or subjective in nature, often related to pleasure or satisfaction of effects. Ex: Feeling more stimulation after using product
- ∂ Mentions of fertility implies treatment of infertility according to the FDA.
  - This includes any mentions of pregnancy with these products, in addition to already prohibited claims about sperm
  - Reproductive health may be supported, but function may not. This applies to individual organs associated with reproduction

## SLEEP RELATED CLAIMS

- ∂ All sleep related claims for dietary supplements need include clarification that they are for occasional sleeplessness only, or by default they are considered treatment for insomnia by the FDA
  - While the caution statements of these products do include this clarification, directly stated claims will require the disclaimer of “For Relief of Occasional Sleeplessness Only” to either be displayed on the same panel, or to be prominently displayed (bolded or larger font, separate from other text) on an adjacent panel with references to the claim (e.g. asterisks or daggers).
  - Indirect claims, such as product names or pictures suggesting sleep related usage (such as “Soothing Sleep” or a picture of a person sleeping), also require prominent disclaimers, though direct reference to them is not needed
- ∂ Insomnia, in all its forms (difficulty at properly starting, maintaining, or ending sleep, as well as extreme tiredness upon waking), is considered a disease claim. Therefore, in addition to avoiding this term, a product cannot claim to
  - Cause/start sleep
    - With the exception of occasional sleeplessness. Even then, it should not be worded to include “difficulty falling asleep” in the claim
  - Increase sleep quality/restfulness
  - Maintain sleep or keep one asleep
  - Prevent waking early or later than desired
  - Directly alter schedule of sleep
- ∂ In addition, symptoms of insomnia, including sleepiness during the day, irritability, problems with concentration or memory, etc. can imply treatment of disease when combined with sleep products.
- ∂ Products cannot be advertised as substitute for sleep (stimulant products may only assist with drowsiness or fatigue, and should be aimed at mental alertness or wakefulness, not physical tiredness resulting from lack of sleep)
  - This includes acting as relief for conditions where lack of sleep is assumed, such as claiming to be used to counteract jet lag.
    - Product may be used to help overcome the occasional sleeplessness such conditions might create, but not the condition itself (For example, product may have name that includes the term jet lag, but would have to claim relief the occasional sleeplessness of jet lag so as not to be seen as alleviating sleep deprivation)
- ∂ Nighttime sleep-aids are defined as being drugs. Dietary supplements may be identified for use in regards to sleep, but this specific name is off-limits
- ∂ Products may not list descriptions of ingredients as having control over or affecting/being used by a part of the body or substance that controls sleep

## WEIGHT RELATED CLAIMS

- ∂ All products advertising themselves as supporting weight loss must include in the suggested use section that they are intended to be used in conjunction with a sensible diet and exercise program
  - In addition, no product may include indications that they are substitutes for diet or exercise
    - No product may claim to have results not able to be accomplished by diet or exercise
  - Products cannot claim to prevent regaining weight after use
- ∂ Results cannot be promised or guaranteed, either in amount of weight lost or time for results to show effect. This includes implications of promised results, such as:
  - indicating the product will result in large weight loss
  - indicating “rapid” or “fast” results
- ∂ Only products with sufficient substantiation may advertise themselves as blocking absorption of calories, fats, starches, and so on.
  - These products cannot guarantee blocking absorption of these items regardless of the amount consumed or in other ways that are beyond the scope of what they have been proven to accomplish (such as continuously blocking these items or blocking absorption of other items)
- ∂ Products must be advertised as helping the user lose weight, not as direct weight loss, due to implications “weight loss products” have with consumers. Fat burning products (see below) may have more direct claims, but must still promote or support weight loss rather than cause it if listed under this category. In addition, products cannot be used for “weight control”, but may claim to assist such a process
- ∂ Only products with fat burning properties may be advertised as such (such as thermogenic formulas). These products may claim to directly burn fat (in addition to support fat burning), provided the claims are not extravagant about their effects. They must still abide by other rules of weight loss products
  - In addition, unless sufficient evidence exists, fat burning products cannot claim to target specific areas of fat
- ∂ Obesity is a disease claim. Products cannot make claims relating to obesity. These include but are not limited to
  - use of the product to reach, achieve, or maintain a healthy weight range
  - use for healthy weight management
  - mentions of health linked to weight (i.e. not distinguished as a separate claim)
  - indications of disease symptoms linked to obesity
- ∂ Metabolism may be supported but with few exceptions cannot be altered. This includes “promoting healthy metabolism”
- ∂ Nutra Group USA LLC policy prohibits mentions of appetite and variations of this word (e.g. cravings, hunger, etc.) as well as appetite control (curbs, suppress, etc.) in a claim.