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PLEXUS® PRODUCT CLAIMS – U.S.

Quick Reference Guide

January 2022

As you know, the U.S. Food and Drug Administration [FDA] and Federal Trade Commission [FTC] set forth regulations to protect consumers. Some of these regulations were specifically developed to ensure that companies only make factual, proper, and safe claims about their products.

The FDA is responsible for regulation and supervision of Plexus Worldwide® products, including our dietary supplements, foods, and cosmetics. One of their primary duties is to enforce regulations pertaining to the benefits we can lawfully claim our products provide to consumers.

The Regulatory Affairs Department has created this quick-reference guide to help you navigate applicable product claims regulation in the United States to ensure compliance. Be advised, this reference guide applies to U.S. products and may not be applicable to other markets where Plexus products are sold.

THE DOS

- ***Use key words such as "support", "help", "healthy", "maintain", "wellness", "well-being", etc.***
- ***Refer to general body parts and or systems.*** (e.g. "supports healthy glucose metabolism" and "for occasional GI discomfort")

THE DON'TS

- ***Don't make health-related claims about Plexus products that are misleading, not true, or can't be substantiated by science.***
- ***Don't claim or suggest that our products can diagnose, treat, cure, or prevent any disease.*** Refer to "Red Flag Words" for specific examples. If you are not sure if a condition is considered a disease by FDA, contact Regulatory Affairs.
- ***Don't use words such as "disease", "illness", "cure", "treat", "repair", "chronic", etc.***
- ***Don't use testimonials in product advertising about how a Plexus product helped someone fight a disease.*** Personal experiences can be incredibly compelling, but they are regulated speech when used by the company. No matter how remarkable someone's personal experience may be, it could be a violation of U.S. regulations.
- ***Don't claim that Plexus products can treat a disease, even if you don't actually name the disease.*** U.S. regulators look at the intent of advertising statements when determining if a disease claim is being implied. Below are some examples of unacceptable disease claims, implied disease claims, and the claims you can make.

Unacceptable Claim	Implied Disease Claim	Acceptable Structure-Function Claim
Improves joint mobility and reduces joint inflammation and pain	Rheumatoid and/or osteoarthritis	Supports overall joint health and mobility*
Prevents bone brittleness in post-menopausal women	Osteoporosis	Support healthy bones*
Balances blood sugar	Diabetes	Helps maintain healthy blood glucose levels already in the normal range*

*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

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- ***Don't claim that Plexus® products treat a symptom of a disease or a class of disease, even when using everyday terms (instead of medical terminology).*** Some examples are:

Unacceptable Claim	Why is it an Implied Disease Claim?	Acceptable Structure-Function Claim
Reduces joint pain	Joint pain is widely recognized as being a characteristic of arthritis	Supports overall joint health and mobility OR helps reduce minor aches & discomfort from exercise*
Prevents memory loss	Refers to the prevention of Alzheimer's disease or dementia.	Supports cognitive function OR reduces mild memory problems associated with aging*
Balances blood sugar levels	Blood sugar imbalance is widely known to be associated with diabetes. "Balances" in this context would be understood to mean "improves".	Helps maintain healthy blood sugar levels already in the normal range*
Gets rid of "harmful" microbes	Suggests product has an antibiotic effect and can treat infection	Helps remove/cleanse unwanted microbes and substances*

- ***Don't compare Plexus products to prescription or OTC-drugs, or imply that the product will treat, cure, or prevent the same disease as a specific class of drugs.*** Some examples are:

Unacceptable	Why is it Unacceptable?
Anti-Obesity Drugs	Obesity is considered a disease.
Anti-Inflammatory	Unqualified inflammation claims are closely associated with gastrointestinal disease, such as Crohn's or Ulcerative Colitis. Anti-inflammatory is also a class of drugs.
Antibiotics	Commonly recognized as a class of prescription drugs.
Natural Prozac	Suggests the supplement could be a replacement for a drug used to treat depression.
Herbal Viagra	Claims the product will treat erectile dysfunction.

- ***Don't claim that Plexus products support or supplement a doctor's prescribed treatment or therapy.*** Some examples are:

Unacceptable Drug Therapy Claims	Why is it Unacceptable?	Acceptable Structure-Function Claim
Helps stimulate the immune system when undergoing chemotherapy	Implies the product is intended to assist in the treatment of cancer	Supports the immune system*
Helps maintain healthy flora while taking antibiotics	Dietary supplements cannot claim to mitigate adverse effects associated with a therapy for disease.	Helps maintain healthy intestinal flora*

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WHY IS THIS IMPORTANT?

Plexus® products and efficacy claims are founded on science. This science can be explained, and the amazingly effective products can (and must be) promoted in a compliant manner. For example, our dietary supplement products must be promoted with properly worded structure-function claims, rather than unacceptable disease/drug claims. Because the difference between acceptable and unacceptable claims can be tricky, we've provided some examples in "testimonial" format below.

TESTIMONIALS (EXAMPLES)

SAY THIS ✓	NOT THAT ✘
"By drinking Active, I had the energy to start exercising regularly, which helped me lose weight!"*	"I used Active and I lost 25 lbs."
"My sister uses Triplex to help rebalance her gut and promote the growth of beneficial microbes."*	"My sister uses Triplex to deal with inflammation and to prevent yeast infections."
"I give Balance to my father as part of a healthy lifestyle to help him maintain healthy glucose metabolism."*	"I give Balance to my Father who has Diabetes to help treat his blood sugar imbalance."
"My friend uses Joyome Mult-Action Collagen to reduce her wrinkles. Her skin has never looked better!"*	"My friend uses Joyome Mult-Action Collagen to fill in her acne scars and it has cured her skin!"
"I use Body Cream all over – anywhere that I want to soothe and moisturize. It works great!"	"I applied Body Cream to a spot on my arm that looks like skin cancer and the spot went away."
"Edge has really helped my alertness, and just overall mental focus."*	"Edge has really helped my adult ADHD."
"Getting older has made it difficult to enjoy certain activities. I take Ease to help with the occasional discomfort I get from overexertion. I am able to perform like I used to and feel so much better!"*	"I take Ease capsules for knee pain. "I have Arthritis and find it hard to do my daily tasks. I use Ease daily and my pain has gone away!"
"I drink Active because it helps support Nitric Oxide production and endurance."*	"I drink Active to help my Asthma when I exercise."
"VitalBiome has been really helpful in helping me stay relaxed."*	"I actually stopped taking my anti-anxiety medications after discovering the power of VitalBiome. Thanks Plexus!"
"We all get bloated, backed up, and gassy from time to time, but Bio Cleanse really delivered relief."*	"My chronic constipation was no match for Bio Cleanse."

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