



Supplement Advisory Group

Women's Health Claims

Compliance, Risk, & Marketing Best Practices



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Legal Disclaimer



- This presentation consists of general information. It is intended for general education only.
- Due to the importance of individual facts of every situation, the generalization in this presentation may not necessarily be applicable to all situations. Changes in the law could make parts of this presentation obsolete in the future.
- This information is provided with the understanding that if specific advice is required, the services of a competent attorney should be sought.

Great FDA Resource!

Small Entity Compliance Guide on Structure/Function Claims

How Do I Determine if a Claim is a Structure/Function Claim or a Disease Claim?

There are 10 criteria in the rule that are useful in determining if a statement is a disease claim.

Great FDA Resource!

Criterion 1: Claims an effect on a disease or class of diseases

"reduces the pain and stiffness associated with arthritis"

Criterion 2: Claims an effect on characteristic signs or symptoms of disease using scientific or lay terminology

"inhibits platelet aggregation" or "reduces cholesterol" are such characteristic signs or symptoms associated with stroke and cardiovascular disease and interventions to treat those diseases that any claim about them would be an implied disease claim.

Great FDA Resource!

Criterion 3: Claims an effect on a condition associated with a natural state or process

What is meant by "a natural state or process?"

Some natural states or processes such as aging, menopause, and the menstrual cycle are not themselves diseases, but can be associated with abnormal conditions that are diseases.

Women's Health Claims

Criterion 3: What is a Disease?

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.

Women's Health Claims

Criterion 3: What is Allowed?

Examples of acceptable structure/function claims are "noncystic acne," or "mild mood changes, cramps, and edema associated with the menstrual cycle."

Menopause Related Claims

Attribute statements to menopause

Night sweats = crossing the compliance line

Menopause-related night sweats = more compliant



“PCOS” = Disease Claim

FDA Warning Letter: Herbal Vitality, Inc.

PCOS Formula

- Product name: The product name implies the product is intended to cure, mitigate, treat, or prevent polycystic ovary syndrome (PCOS).

Women's Health Claims

- Mood
- Hormone balance
- Difficulty sleeping
- Dry skin
- Hair loss
- Period pain
- Fertility

Risks Associated with “Bloating”

FDA Warning Letter: Jackson Health & Wellness Clinic

- “[H]as had terrible migraines for the past 10 years... After a couple of months drinking Dr. Miller's Tea, he no longer has the migraines.”
- “[A]nd no longer have the bloating and acid reflux I was having.”

Risks Associated with “Bloating”

Zenwise LLC Class Action

“Clinically proven” is a common litigation trigger.

From litigation: → “ACTS FAST,” and is “Clinically Proven [to] Work in Hours.”

Risks Associated with “Bloating”

Zenwise LLC Class Action

“Research has not supported that DE111 is effective in combatting gas and bloating. Nor has research on the general use of Bacillus subtilis supplements supported its use in eliminating or even reducing gas and bloating.”

“Notably, research on DE111 typically has been conducted in 3-6 week periods.”

Thank You



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