The Secrets of Making Proper Structure/Function Claims

Are there really "secrets" to making proper structure/function claim?

You had better believe it!!

1. Three Secrets to Making Proper Structure/Function Claims

a. Secret 1 – NOT Going From Point A to Point Z in One Giant Step

A ***MASSIVE*** mistake that most marketers make with respect to their claims is attempting to "go from Point A to Point Z" in one giant step.

For example, they will make the claim – "Ingredients X, Y, and Z help treat/cure/prevent/reduce the risk of – cancer.

Point A — Point Z

One Giant Step

Ingredients X, Y, and Z — cure/treats/prevents a disease

That is No Bueno!!

The secret is to go from Point A, to Point B, to Point C, to Point D, and eventually to point Z.

Baby Steps!

A – B – C – D – E – F – G – H – I – J – K – L – M – N – O – P – Q – R – S – T – U – Z

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Here's what the looks like.

Step A – Our product has the following antioxidants . . .

Step B – Explain what antioxidants are.

Step C – Explain what antioxidants do.

Step D – Explain what free radicals are.

Step E – Explain what free radicals do (cause cellular degeneration)

Step F – Explain what cellular degeneration is.

Step G – Explain what cellular degeneration can lead to (cancer and other degenerative diseases).

Step H – Explain the significance of fewer free radicals circulating through your body (less cellular degeneration).

Step I – Having led the reader/viewer 99% of the way down the path, let him or her "kick it on in" and draw the ultimate conclusion – The product helps (treat/cure/prevent/reduce the risk of) cancer.

b. Secret 2 – Explain the Science at the Molecular or Cellular Level

Do you remember DSHEA's definition of a "structure/function" claim?

It is – A claim that:

> (1) describes the role of a nutrient or dietary ingredient intended to affect ***normal structure or function*** in humans;
>
> (2) characterizes the means by which a nutrient or dietary ingredient acts to ***maintain*** such ***normal structure or function***; or
>
> (3) describes general well-being.

When you talk about ***how*** a dietary ingredient affects, or ***characterizes the means it acts to maintain***, a structure or function – you will invariably discuss such affect or action at the molecular or cellular levels.

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Do you remember the example above in Secret 1?

All of the discussion was about the affect or action of dietary ingredients at the molecular (antioxidants and free radicals) or cellular (what free radicals do to cells) levels.

Thus, the second secret to making proper structure/function claims is to keep your claims focused on: (1) the affect or action; (2) of one or more dietary ingredients; (3) on molecules or cells.

Making proper structure function claims is NOT about the affect or action of dietary ingredients on diseases or abnormal states of health.

Allow your claims to take the reader from A to B to C to D to . . . Y . . . and then let the reader make the jump from Y to Z – Antioxidants prevent cancer.

c. Secret 3 – "Setting the Stage" and Grouping Your Content

I call this – A Play in Three Acts.

Act 1 – Setting the Stage

Act 2 – Starring the Product

Act 3 – The Bridge Between Acts 1 and 2

Let's talk about arthritis.

I assume that you would agree with me that arthritis is a disease.

Having the great legal mind you do, I know you realize that you cannot make a claim for a joint health product that it cures, prevents, treats, or mitigates arthritis or the symptoms of arthritis.

Act 1 – sets the stage. In this section of your materials, you talk about:

(1) What arthritis is.
(2) What causes arthritis.
(3) The affects and consequences of arthritis.
(4) The prognosis for arthritis suffers.
(5) Anything else related to arthritis, arthritis, arthritis.

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Act 2 – discusses your product and its ingredients. In this section of your materials, you talk about:

(1) What ingredients are in your product.
(2) What the ingredients do at the cellular or molecular relative to maintaining optimal joint health.
(3) How the ingredients do what they do at the cellular or molecular levels to maintain optimal joint health.

Act 3 – is the "bridge" between Acts 1 and 2. In this section of your materials, you allow the reader to come to the inescapable conclusion that your product helps cure/treat/mitigate/prevent/protect against the ravages of arthritis.

Disease/abnormal states of health — **The Claims Spectrum** — Optimal states of health

Drug Claims
Do Not Pass "Go"
Go Directly to Jail

Dietary Supplement Claims
Show Me the Money!!

In the "bridge," the point you are making is that by maintaining your body, by maintaining a particular "structure" of your body, or by maintaining a particular "function" of your body in an optimal statement of health, you are avoiding a diseased or abnormal state of health. You also point out that an "optimal state of health" is mutually exclusive with that of a "diseased or abnormal state of health."

In addition, by properly constructing your "bridge," you reinforce that fact that your claims are not about curing/treating/mitigating/preventing a disease. Again, you make clear that diseases and abnormal states of health are the absolute diametric opposite of an optimal state of health. Accordingly, a proper structure/function claim is as far away from a drug claim as a claim can be.

In closing, if you only take one thing away from this tortuously long discussion, remember that you've got to get away from talking about preventing, treating or curing abnormal health conditions and diseases, and move to (and live in) ***. . . promoting and . . . maintaining good health and proper function and structure of the body***.

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2. The Labeling Exemption

Did you know that under certain circumstances, you can use articles, books, and other material to promote the sale of your product . . . ***even if the article, book, or materials contain drug or disease claims??!!***

It is absolutely true.

DSHEA added a new section to the FDC Act, which provides:

> Sec. 403B. (a) IN GENERAL.- A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to customers when it -
>
> > (1) is not false or misleading;
> > (2) does not promote a particular manufacturer or brand of a dietary supplement;
> > (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
> > (4) if displayed in an establishment, is physically separate from the dietary supplements; and
> > (5) does not have appended to it any information by sticker or any other method.
>
> (b) APPLICATION. - Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.
>
> (c) BURDEN OF PROOF. - In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

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Section 403B exempts from being considered labeling certain balanced, third-party publications that are physically separate from product labeling and ***do not promote a particular brand or product***. (☜ That's a "biggie," so do not over look it.) This provision does not authorize dietary supplement manufacturers to ignore the restrictions in section 403(r)(6) of the act on what structure/ function claims may be made by a manufacturer about its product on the product label and in materials that are indisputably part of the product's labeling.

There are some limitations to this Section, and as you can imagine, the FDA has been extremely conservative in its interpretation of Section 403B. It writes:

> Although section 403B of the act exempts certain publications from the labeling provisions of the act, section 403B(a)(2) states that the exemption applies only when, among other requirements, the publication is "used in connection with the sale of a dietary supplement to customers when it * * * does not promote a particular manufacturer or brand of a dietary supplement." If the reference or the title of the reference was disseminated by a particular manufacturer of the dietary supplement discussed in the reference, the agency would conclude that it was being used to promote that manufacturer's brand of the dietary supplement. Therefore, the exemption in section 403B of the act would not apply.
>
> Furthermore, to qualify for the exemption in section 403B of the act, a publication must be "an article, a chapter in a book, or an official abstract * * * reprinted in its entirety" and must be "displayed or presented, or * * * displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information of a dietary supplement." A citation to an article alone could not meet these requirements.

I hasten to point out that DSHEA's labeling exemption is NOT an absolute "Get Out of Jail Free Card." Even though a publication that meets the five criteria of the labeling exemption is not labeling under the FDA Act . . . ***it IS still labeling under the FTC Act.*** That is to say, just because you are "home free" on the FDA side of the equation, nothing changes on the FTC side.

Therefore, ALL of the FTC's requirements (e.g., substantiation, non-deception, and fairness) continue to apply with full force and effect.

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