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Thanks to 'clarification' by federal regulators, consumers of dietary supplements will now have better information when they seek to "improve their absentmindedness" or "maintain their healthy intestinal flora." These are just two examples of the permissible claims contained within the Food and Drug Administration's (FDA) proposed rule, with the lofty title, "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body."[1] The rule seeks to clarify the distinction made with the passage of the Dietary Supplement Health and Education Act of 1994 for which types of health claims are impermissible as drug claims, and which claims may be made as related to the body's structure or function, the so-called, "structure/function claims." According to William Shultz, the FDA's Deputy Commissioner for Policy: "Consumers want access to dietary supplements, but also need reliable information about the products they are consuming. By clarifying for manufacturers what types of claims can and cannot be made on a dietary supplement label, this new proposal helps consumers make more informed and wiser choices." While clarification is sorely needed in this arena, some of the FDA's examples are bound to keep manufacturers and consumers alike at least as confused as before, if not more so.

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1. 63 Fed. Reg. 23624, 23625 (1998) (to be codified at 21 C.F.R. § 101) (proposed April 29, 1998). All subsequent quotations within the text also come from the proposed rules. Please see the Appendix to this commentary, which contains an edited version of the proposed rules, for further support. Further and more definitive information may be found in the FDA's final rules regulating structure/function claims on dietary supplements issued on January 6, 2000. *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1000 (2000) (to be codified at 21 C.F.R. § 101).

CAN THIS BE ANY CLEARER?

In the FDA's attempt to remove all references to "recognizable signs or symptoms" of disease in dietary supplement labeling, an example of a prohibited claim would be, "reduces joint pain," while allowable would be, "improves absentmindedness." Some mental gymnastics are needed to realize this probably doesn't mean the product makes one forget more. Another silly example of an allowable claim in this category is, "inhibits platelet aggregation." Is the average consumer really expected to understand what this means and what the product could possibly be for?

Another of the FDA's criteria for determining disease claims is whether the product claims to have a role in the body's response to a disease or a vector of disease. Under the proposed rule, the FDA would not permit claims that a product "supports the body's antiviral capabilities" or "supports the body's ability to resist infection" because such claims involve the body's ability to prevent or respond to infectious diseases. However, a more general reference, such as "supports the immune system" would be permitted. But isn't one of the main purposes of the immune system to respond to infectious diseases?

But the winner for the most absurd example of a prohibited versus allowable claim is this. Prohibited: "alleviates constipation;" allowable: "helps maintain healthy intestinal flora." What the heck is intestinal flora? Images of air freshener come to mind. While some manufacturers may use such inside lingo, will this truly "help consumers make more informed and wiser choices"?

A DISTINCTION WITHOUT A DIFFERENCE

The FDA specifically requested comment on the distinction between maintaining normal function, the basis for an allowable structure/function claim, and preventing or treating abnormal function, which is potentially a disease claim. As the FDA admits: "This can be a difficult distinction conceptually, especially if the only reason for maintaining normal function is to prevent a specific disease or diseases associated with abnormal function." Further, the FDA notes that "there can be disagreement about the circumstances in which a reference to maintaining normal function implies disease treatment or prevention." To put it mildly.

By way of example, under the proposed rule, "lowers cholesterol" would be prohibited, while "helps maintain healthy cholesterol level" would be permitted. Now, the FDA notes that cholesterol raises particularly difficult issues and specifically requests comment in this area. But the problem here relates to the broader issue which is really at the root of the confusion and silly examples the FDA is proposing: for what purpose a consumer is likely to turn to these products in the first place. While some products may actually be intended for, and used for the *prevention* of

certain health problems or diseases, other products are unlikely to be used until a consumer is faced with an actual health problem. In the latter situation, all this language about "maintaining" a healthy state becomes irrelevant. If someone has been found to have high cholesterol levels and turns to a dietary supplement, then reading "maintains healthy cholesterol level" on the label will probably not make any substantive difference to that consumer over the claim "lowers cholesterol levels" because the latter is what the consumer seeks. It's quite unlikely that a person with healthy cholesterol levels would take a product to help maintain those levels. Further, chances are that any confusion will be cheerfully cleared up by a helpful salesperson in the store. The FDA can say that dietary supplements should not be used to treat health problems, but we must face the reality that they are being used for this very purpose in some instances. This is why trying to fashion a one-size fits all solution for an industry with very different types of products does not work. For example, vitamin supplements can and do serve a very different purpose than herbal remedies. Perhaps the FDA would be better off going back to the drawing board and making different rules for products with different purposes. There is simply no getting around the reality of consumers turning to dietary supplements for treatment-related purposes. The FDA's attempt to bury its head in the sand and pretend this is not happening because manufacturers are not allowed to label and market its products as such is both irresponsible and futile. If the FDA is sincere in its desire to write a rule which "helps consumers make more informed and wiser choices" than facing this reality would be an important step in this direction.

APPENDIX

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23624, 23625 (1998) (to be codified at 21 C.F.R. § 101) (proposed April 29, 1998).

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SUMMARY: The Food and Drug Administration (FDA) is proposing regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The proposed regulations also establish criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. This action is intended to provide direction to the dietary supplement industry and to respond to guidance on this issue provided by the Commission on Dietary Supplement Labels (the Commission).

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PART 101--FOOD LABELING

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§101.14 Health claims: general requirements.

(a) * * *

(6) *Disease or health-related condition* means any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to this section or §101.70).

3. Section 101.93, as currently in effect, is amended by revising the section heading and by adding paragraphs (f) and (g) to read as follows:

§101.93 Certain types of statements for dietary supplements.

(f) *Permitted structure/function statements.* (1) Dietary supplement labels or labeling may, subject to the requirements of this section, bear statements that describe the role of a nutrient or dietary ingredient 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, but may not bear statements that are disease claims under paragraph (g) of this section.

(g) *Disease claims.* (1) Definition of disease. For purposes of 21 U.S.C. 343(r)(6), a "disease,, is any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease.

(2) *Disease claims.* FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under section 403(r)(6) of the act if it meets one or more of the criteria listed in this paragraph (g)(2). In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims,

explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect, using scientific or lay terminology, on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different specific diseases;

(iii) Has an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body;

(iv) Has an effect on disease through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient that has been regulated by FDA as a drug and is well known to consumers for its use in preventing or treating a disease;

(C) Citation of the title of a publication or reference, if the title refers to a disease use;

(D) Use of the term "disease" or "diseased"; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease and manifested by a characteristic set of signs or symptoms; or

(x) Otherwise suggests an effect on a disease or diseases.