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February 4, 2000

PETITION FOR RECONSIDERATION AND FOR STAY OF ACTION

DOCKET NO. 98N-0044

Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To the Commissioner of Food and Drugs:

Pursuant to FDA regulations governing "administrative reconsideration of action," 21 C.F.R. § 10.33, and governing "administrative stay of action," 21 C.F.R. § 10.35, the undersigned submits this petition both for reconsideration and for stay of the effective date of the decision of the Commissioner of Food and Drugs in Docket No. 98N-0044, described below.

A. DECISION INVOLVED

In the Federal Register of January 6, 2000 (65 Fed. Reg. 1000), FDA issued final 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." 21 C.F.R. § 101.93, "Certain types of statements for dietary supplements," at subsection (f) "Permitted structure/function statements," and at subsection (g) "Disease claims." 65 Fed. Reg. at 1000 and at 1050.

As a part of this document, in section III.A.1. of the preamble statement, under the heading "Legal Authority . . . Scope of Section 403(r)(6) of the Act . . . Relationship Between Sections 403(r)(6) and 201(g)(1)(C) of the Act," 65 Fed. Reg. at 1033-1034, FDA states, for the first time in the history of dietary supplement regulation by the agency, that "dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the act and are therefore subject to the disclaimer, notification, and other requirements in that section and in FDA's implementing regulation." 65 Fed. Reg. at 1033. In other words, all labeling claims about the effect of a dietary supplement on the structure or function of the human body ("structure/function claims") must be accompanied by the "disclaimer" language that appears in

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section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(6),[1] and, in addition, all such claims must be the subject of a "notification" filed with FDA within 30 days after the first marketing of a dietary supplement that bears the claim, in conformity with the format and other procedures prescribed in the FDA's regulations at 21 C.F.R. § 101.93.

FDA acknowledges that this is an entirely new requirement and that previously the agency "took a contrary position" pursuant to which a structure/function claim that appeared in labeling for a dietary supplement product was not required to be accompanied by the section 403(r)(6) disclaimer or to be the subject of a section 403(r)(6) notification to FDA "provided that the claim was truthful, non-misleading, and derived from nutritive value." 65 Fed. Reg. at 1033.

FDA states that "small businesses will have 18 months from publication [i.e., from January 6, 2000] to comply" with the agency's newly-pronounced labeling and notification requirements, and that "other firms will have 12 months." 65 Fed. Reg. at 1034.

B. ACTION REQUESTED

The undersigned requests the Commissioner to reconsider and to revoke this new FDA pronouncement that all structure/function claims in labeling for dietary supplement products must be accompanied by the section 403(r)(6) disclaimer and must be the subject of a section 403(r)(6) notification to FDA. The undersigned requests that FDA, instead, return to the previously-established position that a structure/function claim in labeling for a dietary supplement need not be accompanied by the disclaimer and need not be the subject of a notification to FDA if the claim is "truthful, non-misleading, and derive[s] from nutritive value."

Furthermore, the undersigned requests that FDA stay any attempt to enforce its new pronouncement until the agency has ruled upon this petition for reconsideration, and thereafter during the pendency of any action for judicial review that is filed pursuant to FDA's action on this petition for reconsideration.

C. STATEMENT OF GROUNDS

(1) FDA's Action and Its Effects

In the Federal Register of January 6, 2000, 65 Fed. Reg. at 1033-1034, FDA has asserted for the first time (without any previous proposal for comment having been published on this point by FDA in the Federal Register or elsewhere) that all structure/function claims that are included in any label or in any other labeling for a dietary supplement:

(a) must be the subject of a "section 403(r)(6) notification" to FDA (i.e., a written notice to FDA, filed pursuant to section 403(r)(6) of the FDC Act, 21 U.S.C. § 343(r)(6), and in conformity with the format and other procedural requirements set forth in FDA's regulations at 21 C.F.R. § 101.93, submitted within 30 days after the first marketing of a dietary supplement that bears the claim, telling FDA about use of the claim and assuring FDA that the responsible company is in possession of sufficient substantiation to support the claim), and

---

[1] The "disclaimer" text is as follows: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

(b) must be accompanied on the label and in all other labeling by the disclaimer language that is established for use with certain dietary supplement labeling statements by section 403(r)(6) (i.e., by the two sentences, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.")

FDA candidly admits that this is an entirely new position on the part of the agency:

> The agency acknowledges that it took a contrary position in the September 1997 final rule preamble. . . . However, the agency has now reconsidered . . . and is revoking its statements on this subject in the September 1997 preamble. . . .

65 Fed. Reg. at 1033.

Formerly, FDA had accepted that a structure/function claim did not need to be the subject of a section 403(r)(6) notification to FDA or to be accompanied in labeling by the disclaimer language provided that the structure/function claim (in addition to being "truthful" and "not misleading") "derived from nutritive value" (or, "derived from nutritional value"). See 65 Fed. Reg. at 1033 and 62 Fed. Reg. 49859-49868, especially at 49860 et seq. (September 23, 1997). However, FDA's new Federal Register document now for the first time, without any proposal for public comment on this particular matter, recants with finality the previous FDA position and adopts the highly-burdensome new position described above.

The impact of this new FDA pronouncement, if it were to be implemented, would be that every claim about the effect of a dietary supplement on the structure or function of the human body – including even such well-accepted claims as "calcium helps build strong bones" – would be illegal for use on the label or in other labeling unless the claim, both, was submitted to FDA in a section 403(r)(6) notification within 30 days after initial use, and, was accompanied on the label and in all labeling by the section 403(r)(6) disclaimer language.

FDA's new pronouncement, if implemented, would needlessly fill up label and labeling space with negative disclaimer language that would be inappropriate for a great many products and that, as discussed below, is not properly required by the applicable law. Of course, the new mass notification requirement asserted by FDA also would add to a company's paperwork burdens in developing new dietary supplement labeling claims.

Furthermore, another significant effect of FDA's new pronouncement would be to encumber dietary supplements with negative labeling burdens that do not apply when the same claims are used in labeling for conventional foods. For example, the structure/function claim "calcium helps build strong bones," when used on the label of a dietary supplement of calcium, would need to be the subject of a section 403(r)(6) notification to FDA and to be accompanied on the product label by the negative section 403(r)(6) disclaimer, while the same claim could be made on the label for a bottle of milk or on other conventional foods that contain calcium without any need to notify FDA or to include the negative disclaimer language in the labeling. This obviously would put dietary supplements at an irrational and unfair competitive disadvantage with respect to the use of structure/function claims.

(2) FDA's Rationale

FDA's rationale for its new pronouncement is as follows:

First, FDA notes that the definition of "dietary supplement" in section 201(ff) of the FDC Act, 21 U.S.C. § 321(ff), as amended by the Dietary Supplement Health and Education Act (DSHEA), includes the following sentence:

> Except for purposes of section 201(g) [of the FDC Act, 21 U.S.C. § 321(g)], a dietary supplement shall be deemed to be a food within the meaning of this Act.

65 Fed. Reg. at 1033.

The referenced section 201(g) defines the term "drug" for purposes of the FDC Act, and, in pertinent part, provides as follows:

> (1) The term "drug" means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . and (C) articles (other than food) intended to affect the structure or any function of the body. . . .

Then, FDA asserts that the above-quoted sentence from section 201(ff), when read with reference to section 201(g), means that

> dietary supplements are not foods under section 201(g) . . . and therefore cannot qualify for the "(other than food)" exception to the drug definition in section 201(g)(1)(C). As a result, dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the [FDC Act, 21 U.S.C. § 343(r)(6)] and are therefore subject to the disclaimer, notification, and other requirements in that section and in FDA's implementing regulation.

65 Fed. Reg. at 1033.

(3) FDA's New Pronouncement Is in Error, as a Matter of Law

We respectfully submit that this new pronouncement by FDA is incorrect and improper as a matter of law and therefore should be reconsidered and revoked, for the following reasons:

(a) FDA's interpretation of the key sentence at issue, from section 201(ff) of the FDC Act, is in direct conflict with judicial case law. The United States Court of Appeals for the Second Circuit, in interpreting this same sentence from the FDC Act, has stated:

> [Section 201(ff) of the FDC Act, 21 U.S.C. § 321(ff)] specifies that: "Except for the purposes of [section 201(g) of the FDC Act, 21 U.S.C. § 321(g)], a dietary supplement shall be deemed to be a food within the meaning of [the FDC Act]." . . . The clear import

> of this language is that a product satisfying the [section 201(ff)] definition of a dietary supplement shall be treated as food for the purposes of certain sections of the [FDC Act] . . . but will not automatically qualify as food within the meaning of [section 201(g)(1)(C)]. Instead, a dietary supplement's status as a food or a drug should be determined by the application of [section 201(g)(1)(C)] without reference to the terms and provisions of [section 201(ff)].

United States v. Ten Cartons . . . Ener-B Vitamin B-12, 72 F.3d. 285, 287 (2nd Cir. 1995). (Emphasis added.) Thus, although FDA wants to require reference to section 201(ff) when applying section 201(g)(1)(C), the Court of Appeals has ruled that application of section 201(g)(1)(C) is to be conducted "without reference to the terms and provisions of" section 201(ff). And, although FDA says that a dietary supplement cannot qualify as food under section 201(g)(1)(C) because of the referenced sentence in section 201(ff), the Court of Appeals states that the effect of the sentence in section 201(ff) is merely that a dietary supplement will not "automatically qualify as food." FDA's interpretation is in direct violation of the Court's interpretation – and illegal.

(b) Accordingly, if a particular dietary supplement product qualifies as a food (i.e., under section 201(f) of the FDC Act, 21 U.S.C. § 321(f), and under generally applicable judicial case law, e.g., *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983), if the product is "used primarily for taste, aroma, or nutritive value"), it follows that the product may bear labeling claims about its effect upon the "structure" or "function" of the human body without triggering "drug" status under section 201(g)(1)(C) of the FDC Act. For example, since calcium is an essential mineral nutrient, a dietary supplement of calcium is "used primarily for nutritional value," and accordingly, is "used for food" and qualifies as a "food" within the meaning of section 201(g)(1)(C) of the FDC Act. Since the product qualifies as food, a structure/function claim to the effect that it will "help build strong bones" can be made without triggering "drug" status under section 201(g)(1)(C) of the FDC Act.

(c) The requirements for notification of FDA about certain structure/function claims and for use of the labeling disclaimer for certain claims originate in section 403(r)(6) of the FDC Act, 21 U.S.C. § 343(r)(6). At the outset, however, section 403(r)(6) states explicitly that its requirements apply only "For purposes of section 403(r)(1)(B) [of the FDC Act, 21 U.S.C. § 343(r)(1)(B)]." Section 403(r)(1)(B), in turn, applies only to claims that FDA has described as "health claims," 21 C.F.R. § 101.14; and FDA's own regulations limit the scope of a "health claim" to a claim that relates a substance to "disease," "damage," or "dysfunctioning" of the body. 21 C.F.R. § 101.14(a)(1), (5). Accordingly, the obvious and logical interpretation of the applicable law is that if one wishes to make a structure/function claim in labeling for a dietary supplement product and if the structure/function claim is one that comes within the definition of a "health claim" (i.e., if the claim, "expressly or by implication," "characterizes the relationship" of the supplement to "disease," "damage," or "dysfunctioning" of the human body, 21 C.F.R. § 101.14(a)(1), (5)), in that case notification to FDA and use of the DSHEA disclaimer is required (assuming the claim is not independently authorized by a "health claim" regulation or by an "authoritative statement").

(d) However, this does not require notification of FDA and use of the disclaimer for a labeling claim that relates to providing support for the normal, healthy structure or function of the body (e.g., a claim such as "calcium helps build strong bones") because (i) such a claim does

not relate to "disease," "damage," or "dysfunctioning" of the body and therefore is not a "health claim," and therefore (ii) the requirements of section 403(r)(6), which apply only "[f]or purposes of section 403(r)(1)(B)," i.e., for purposes of claims that are "health claims," have no application.

(e) In addition, it should be emphasized that – as FDA itself concedes – FDA's newly-issued pronouncement is in direct conflict with the agency's own previously-announced position and has not been issued until more than five years after DSHEA was enacted. Therefore, this particular FDA pronouncement cannot be entitled to any special deference as a "contemporaneous construction of the statute by the agency charged with its enforcement." *NLRB v. Boeing Co.*, 412 U.S. 67, 75 (1973). Indeed, it is the former construction of the statute that would qualify for deference as a "contemporaneous construction" by the responsible agency!

(f) It should also be noted that, if common sense is applied, it is simply inconceivable that the Congress of the United States, which enacted DSHEA to reduce FDA requirements for dietary supplements, would have meant the sentence in section 201(ff) to add to the regulatory burdens for dietary supplements, requiring use of the section 403(r)(6) disclaimer for labeling claims, such as "calcium helps build strong bones," that before DSHEA was enacted were already able to be used without being accompanied by any disclaimer. Instead, the reasonable interpretation, consistent with Congress' purpose in enacting DSHEA, is that the disclaimer is required for – and only for – those structure/function claims that otherwise would be expected to be "evaluated" by FDA before use, i.e., for those "structure/function claims" that are also "health claims" and that DSHEA now allows to be used without the FDA evaluation requirements that usually apply to "health claims." FDA's interpretation would turn upside down the legislative purpose of DSHEA.

(4) FDA's New Interpretation Is Effectively a Substantive "Rule" that Cannot Properly Be Imposed Without First Publishing a Notice of Proposed Rulemaking and Complying with Other Rulemaking Procedures

FDA appears to regard its new pronouncement as a matter that is not subject to rulemaking requirements, perhaps on the theory that a preamble statement is an "interpretative rule" or otherwise not a "rule."

However, in reality, this particular pronouncement is not merely an expression of agency interpretation but instead functions as a substantive "rule," i.e., as an "agency statement of general or particular applicability and future effect designed to implement . . . law. . . ." 5 U.S.C. § 551(4).

Indeed, FDA's document explicitly recognizes that most dietary supplement products currently do not bear the section 403(r)(6) labeling disclaimer and states that FDA's new pronouncement now will require such labeling – and the agency provides staggered effective dates, first for large companies, and then for small companies, by which the new labeling now will be required to appear on products. This is, in reality, the imposition of a new labeling requirement, a substantive "rule," not just a preamble interpretation or "interpretative rule," and before any such labeling requirement could properly be imposed, as a matter of basic procedural fairness under the Administrative Procedure Act (APA), the agency must first publish a notice of proposed rulemaking and provide a fair opportunity for public comments. 5 U.S.C. § 553. No notice of any proposed action with respect to this particular matter nor any opportunity for public comment thereon was ever published by the agency. This is a violation of fundamental APA procedural requirements and requires revocation of the agency's action.

It is fundamentally unfair, in violation of the principles of the Administrative Procedure Act, for FDA to issue a pronouncement that is, in reality, a new rule requiring new labeling, without the agency's first publishing a pre-decisional proposal for comment in the Federal Register – a step that most clearly did not occur in this case.

(5) The Term "Derives from Nutritive Value" is Broad and Encompasses Many Structure/Function Claims

In petitioning FDA to reconsider its newly-announced pronouncement and to return to its formerly-established position, i.e., that a structure/function claim in labeling for a dietary supplement does not need to be the subject of a section 403(r)(6) notification to FDA, and does not need to be accompanied by a section 403(r)(6) disclaimer, if the claim is truthful, not misleading, and "derives from nutritive value," we want to be clear for the record that the term "nutritive value," as used in this context, is a broad one and is not limited to those few substances for which FDA has issued RDIs (reference daily intakes) or DRVs (daily reference values).

For example, in letters issued in 1999, FDA itself accepted that "vegetable oil sterol esters" and "plant stanol esters" have "nutritive value" and/or function "as a nutrient" and properly may be the subjects of structure/function claims that do not trigger "drug" status – although neither of these substances is the subject of an RDI or DRV. FDA letter dated April 30, 1999 from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, FDA Center for Food Safety and Applied Nutrition, to Daniel R. Dwyer re Food Master File 000625; FDA letter dated May 17, 1999 from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, FDA Center for Food Safety and Applied Nutrition, to Vivian A. Chester and Edward B. Nelson, M.D., Ph.D., re Food Master File 000626.

On many occasions in the recent past FDA has recognized that the term "nutrient" is very broad and includes many substances that are not the subject of an RDI or DRV. For example, in a Federal Register document concerning dietary supplement labeling, FDA stated that the "coverage" of the term "nutritional substances" is "broad" and includes, among other substances, a long list of examples that appears in a discussion between Senators Metzenbaum and Symms that occurred during passage of the Nutrition Labeling and Education Act (NLEA) of 1990. 62 Fed. Reg. at 49859-49860. The quoted list of agreed-upon examples of "nutritional" substances includes the following items:

> Primrose oil, black currant seed oil, coldpressed flax seed oil, "Barleygreen" and similar nutritional powdered drink mixes, Coenzyme Q10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium-EAP (colamine phosphate), glandulars, hydrogen peroxide (H2O2), nutritional antioxidants such a [sic] superoxide dismutase (SOD), and herbal tinctures.

62 Fed. Reg. 49859, 49860 (September 23, 1997).

Moreover, an FDA regulation that defines "nutritive value" for purposes of the agency's rules concerning "health claims" provides:

> Nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

21 C.F.R. § 101.14(a)(3). It is instructive to note that when FDA published this regulation in the Federal Register of January 6, 1993 (58 Fed. Reg. 2478), the agency included the following explanatory discussion:

> FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. Accordingly, the agency has worded the definition of "nutritive value" in new § 101.14(a)(3) to provide significant flexibility in determining whether a substance possesses such value. FDA used the phrase "such . . . as" in the definition to insure that the three referenced processes will be understood to be general examples of the ways in which a substance may legitimately confer nutritive value, rather than as an all-inclusive list.
>
> The agency believes that it is inappropriate to codify findings of nutritive value for specific substances. Such findings would only serve to undermine the intended flexibility of the definition because an extended listing of those substances that possess nutritive value could be interpreted as an exclusive list.

58 Fed. Reg. at 2488. (Emphasis added.) This statement by FDA indicates that substances that "can play a role in reducing the risk of chronic diseases" may thereby qualify as substances that provide "nutritive value."

The "bottom line" of all of this is that, in returning to its former position that a structure/function claim may be made in labeling for a dietary supplement product without notification to FDA and without use of the section 403(r)(6) disclaimer, provided that the claim is truthful, non-misleading, and "derives from nutritive value," FDA should also recognize that "nutritive value" is a very broad concept in this context, that it includes many food-based substances that do not have RDIs or DRVs, and, that nutritive value can include value in reducing the risk of disease.

(6) Conclusion

For the reasons described above, we respectfully request that FDA reconsider and withdraw its pronouncement that all structure/function claims in dietary supplement labeling must be accompanied by the section 403(r)(6) disclaimer and also must be the subject of a section 403(r)(6) notification to FDA.

Instead, FDA should return to the previously-established position that a structure/function claim may be included in dietary supplement labeling without being accompanied by the section 403(r)(6) disclaimer and without being the subject of a section 403(r)(6) notification, if the claim is (a) "truthful," (b) "non-misleading," and (c) "derives from nutritive value."

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