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Department of Health and Human Services  
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Rockville, Maryland 20852.

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**PETITION FOR RECONSIDERATION AND STAY OF ACTION**

**DOCKET NO. 98N-0044**

The undersigned, the Council for Responsible Nutrition ("CRN") and the Consumer Healthcare Products Association ("CHPA"), submit this petition for reconsideration and stay of a decision of the Commissioner of Food and Drugs announced in the preamble to the Final Rule in Docket No. 98N-0044. CRN and CHPA represent numerous manufacturers and distributors of dietary supplements who would be affected by the decision, and the CRN and CHPA have submitted comments in this proceeding.<sup>1</sup> The Commissioner's decision was not based on any element of the original proposal in this docket.

**A. Decision involved**

On January 6, 2000, the Food and Drug Administration published at 65 Fed. Reg. 999 a Final Rule on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. In the preamble to the Final Rule, FDA took the position that dietary supplements are precluded from being "food" for purposes of Section 201(g)(1)(C)

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<sup>1</sup> CHPA is a 119-year-old trade association of manufacturers and distributors of over-the-counter drugs and dietary supplements. CRN is a trade association representing approximately 100 companies in the dietary supplement industry.

98N-0044

PRC 2

of the Federal Food, Drug, and Cosmetic Act (“the Act”), so that any structure/function claim made for a dietary supplement must comply with Section 403(r)(6) of the Act to avoid having the product classified as a drug. 65 Fed. Reg. at 1033. This position is contrary to the plain language of the Act and legal precedent and constitutes a reversal of the position FDA has consistently taken on this issue since the passage of the Dietary Supplement Health and Education Act (“DSHEA”).

### **B. Action requested**

Petitioners hereby request that upon reconsideration, the Commissioner reverse the position taken by FDA that dietary supplements are precluded from being "food" for purposes of Section 201(g)(1)(C) of the Act, and reinstate FDA’s prior position that dietary supplements having nutritive value could constitute “food,” independent of their status as dietary supplements, for purposes of Section 201(g)(1)(C) of the Act and that therefore structure/function claims for dietary supplements having nutritive value could be made without reference to Section 403(r)(6) of the Act. Petitioners further request that the implementation of this decision announced in the preamble to the final rule in Docket No. 98N-0044 be stayed pending the Commissioner’s consideration of this Petition and during any applicable period for appeal.

### **C. Statement of grounds**

DSHEA added Section 201(ff) to the Act, which defined “dietary supplement.” The last sentence of Section 201(ff) states, “Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of the Act.” Section 201(g) contains the general definition of “drug”. Under DSHEA, a dietary supplement can be regulated as a drug if its label

or labeling contains a claim suggesting that the product is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .,” Section 201(g); *see also* Section 403(r)(6)(C), or where FDA has evidence that the product is intended for use as a drug. The clause in the dietary supplement definition of Section 201(ff) that, “Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of the Act,” refers to the fact that, unless through its labeling or otherwise, a dietary supplement is found to be a drug and is therefore subject to regulation as a drug, a dietary supplement is deemed to be a food and shall be regulated accordingly.

Since the enactment of DSHEA in 1994, FDA has consistently taken the position that dietary supplements having nutritive value were also “food” under the Act, without reference to the last sentence of Section 201(ff), and that structure/function claims could be made for such supplements under Section 201(g)(1)(C) of the Act without following the notification and disclaimer requirements of Section 403(r)(6). For example, in the preamble to the final rule on Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49859 (1997), FDA made the following statements:

The agency agrees that the disclaimer provided for in section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the exception from the drug definition that is provided for in section 201(g)(1) of the act for products that comply with section 403(r)(6). Section 201(g)(1)(C) of the act recognizes that common sense foods, that is, products with nutritional value, affect the structure or function of the body because of their nutritional value. Thus, the types of claims described in section 403(r)(6)(A) of the act can be made to describe the nutritive value of a product without fear of action against the product as a drug (e.g., “calcium builds strong bones and teeth”) so long as the claims are not false or misleading.

...

Dietary supplements have to comply with section 403(r)(6) of the act to be subject to the exception (unless, of course, as stated above, they are subject to the other exception for “food” as that term has been interpreted by the courts, *see Nutrilab Inc. v. Schweiker*, 713 F.2d. 335, 338 (7th Cr. 1983)).

62 Fed. Reg. at 49863, 49864. In that same preamble, FDA collectively refers to dietary supplements and “other foods”: “All other food products, that is, those that are not identified as dietary supplements, will be subject to regulation as conventional foods.” 62 Fed. Reg. at 49862.

In 1995, F. Edward Scarbrough, Ph.D., then Director of FDA’s Office of Food Labeling, also publicly stated FDA’s position that structure/function claims could be made for all products having nutritive value, including dietary supplements, without invoking the provisions of Section 403(r)(6) of the Act:

The agency believes that claims about the effect of the food on the structure or function of the body as a result of its use as a food, primarily its nutritive value, are not health claims, nor are they subject to the notification and disclaimer provisions of the DSHEA. Therefore, a “structure/function” claim such as “calcium builds strong bones and teeth” may be used on the labels of food - conventional foods or dietary supplements, without bearing the disclaimer required by the DSHEA and without being subject to regulation as a drug.

Handouts from “Labeling -- Current Issues and Policy Decisions,” address given at the 39<sup>th</sup> Annual Educational Conference, Food and Drug Law Institute, December 12, 1995 at 9. Dr. Scarbrough further explained that in drafting DSHEA, Congress realized that some, but not all, dietary supplements would contain ingredients that did not have nutritive functions, and for which a disclaimer would therefore be necessary:

It appears, with DSHEA, that Congress established a type of structure/function claim for dietary ingredients in dietary supplements, with the full realization (by its use, throughout the DSHEA, of the phrase “nutrient or dietary ingredient”) that not all dietary ingredients have nutritive value. Congress appears to have also considered the possibility that there may not be general scientific agreement that the structure or function effect of a nutrient or dietary ingredient in a dietary supplement is achieved through its value as a food, and manufacturers may alert consumers to this fact by use of the disclaimer.

Id. at 9-10. By definition, a disclaimer would not be necessary for claims relating to nutritive value and Congress did not intend that disclaimers should be used with such claims.

Courts have also held that the definitions under the Act are generally not mutually exclusive and that a product can fall into more than one classification category. For example, in *Nutrilab Inc. v. Schweiker*, 713 F.2d. 335, 336 (7th Cir. 1983), cited by FDA in the preamble to the Final Rule on Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. at 49864, the Seventh Circuit held that a product may be both a food and a drug under the Act:

It is well established that the definitions of food and drug are normally not mutually exclusive; an article that happens to be a food but is intended for use in the treatment of disease fits squarely within the drug definition in part B of Section 321(g)(1) and may be regulated as such.

*See also National Nutritional Foods Ass'n v. Matthews*, 557 F.2d 325, 334 (2d Cir. 1977) (“Although an article may be recognized as a food, this does not preclude it from being regulated as a drug.”).

As explained above, FDA has now, without notice, and without an explanation of the need for its action, reversed both its traditional position that definitions are not mutually exclusive, and its position publicly held since at least 1995 that a product may be both a dietary supplement and separately a food. At page 1033 of the preamble to the final structure/function regulation, FDA stated that dietary supplements are precluded from being "food" for purposes of Section 201(g)(1)(C) of the Act, so any structure/function claim must comply with Section 403(r)(6) to avoid classification as a drug. FDA expressly states that all new products must make 403(r)(6) submissions for RDI-nutrient claims, and all existing products that do not fall

under a "small business" exemption must be relabeled and be the subject of Section 403(r)(6) submissions made within 11 months of the implementation of the final rule.

FDA's legal analysis is flawed in that it fails to take into account that definitions under the Act are generally not mutually exclusive, so an item can be both an "article" under the definition of food in Section 201(f) and a "product" under the dietary supplement definition in Section 201(ff). *See, e.g., Nutrilab Inc. v. Schweiker*, 713 F.2d. at 336 and *National Nutritional Foods*, 557 F.2d at 334. As explained above, Section 201(ff) expressly provides that dietary supplements are "deemed to be" foods, i.e., are to be treated as food even if not such before the passage of the definition, except for purposes of Section 201(g) of the Act, i.e., unless, through labeling claims or otherwise, these products are also subject to regulation as drugs. FDA's position in the preamble to the final structure/function regulation that dietary supplements are precluded from being "food" for purposes of Section 201(g)(1)(C) of the Act is thus contrary to the plain language of the Act, the interpretation of the courts and FDA's own long-held position.

FDA's precipitous action also seriously skews the economic relationship between nutrient claims made for foods in the form of dietary supplements and those made for food in other forms: it will be perceived that a claim that calcium tablets help build strong bones is less certain or deserving of acceptance than the same claim made for calcium fortified foods. That, indeed, would appear to violate 21 C.F.R. § 101.9(k) (as would the opposite claim made for a dietary supplement, 21 C.F.R. § 101.36(j)). It is also misleading to require, as the decision would, a label statement on dietary supplements, but not on other foods, that FDA has not evaluated a claim that calcium helps build strong bones.

Similar problems are presented in the case of antioxidant claims for vitamins such as C and E, which claims FDA has acknowledged are based on "nutritive value." 59 Fed. Reg. 395,

408 (1994). FDA's position thus raises serious issues of public health policy where the use of dietary supplements is an important means of assuring adequate intake of many nutrients, and the required use of the statutory disclaimer would improperly cast doubt on the usefulness of these important products.

The undersigned therefore seek reconsideration of FDA's position on this issue and a reinstatement of the agency's prior position that dietary supplements consumed for their nutritive value can be both dietary supplement and independently food for purposes of Section 201(g)(1)(C) of the Act and that therefore structure/function claims for dietary supplements having nutritive value can be made without reference to Section 403(r)(6) of the Act.

Petitioners further request that the implementation of this decision contained in the preamble to the Final Rule in Docket No. 98N-0044 be stayed pending the Commissioner's consideration of this Petition and during any applicable period for appeal. FDA has announced that all new nutritive value-based claims for dietary supplements after February 7, 2000, must comply with Section 403(r)(6), and any existing such claims that do not currently so comply must be brought into compliance within either an additional 11 or 17 months (depending on whether the company involved is a "small business"). Because the decision was not based on any element of the original proposal (63 Fed. Reg. 23624 (1998)), its immediate implementation without the opportunity for comment and FDA consideration of the comments, that is, without the initiation of rulemaking, would be a violation of the Administrative Procedure Act. *See Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098 (4th Cir. 1985); *Animal Health Inst. v. FDA*, CCH FOOD, DRUG, COSMETIC LAW REP. (1977-78 Transfer Binder) ¶ 38,154 (D.D.C. Feb. 8, 1978).

Moreover, this action was taken without any reasoned explanation of the need for a reversal of the long-standing public position of the Agency, a position that dates almost from the passage of DSHEA. The Supreme Court has held that when an agency reverses an earlier ruling, that agency is required to provide a reasoned analysis for the change:

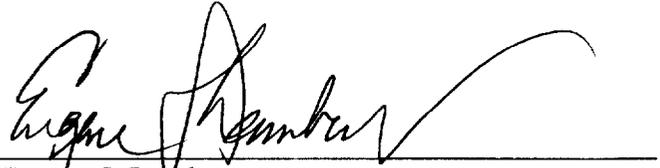
Revocation constitutes a reversal of the agency's former views as to the proper course. A "settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to." Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when the agency does not act in the first instance.

*Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983) (citations omitted). If FDA, rather than granting reconsideration as requested, initiates rulemaking on this issue in accordance with the *Chocolate Manufacturers* and *AHI* decisions, the agency must additionally comply with its obligation to provide a reasoned explanation for the reversal of its long-held position, a burden "beyond that which may be required when the agency does not act in the first instance."

The short span for compliance for "pipeline" products, i.e., those awaiting commercial introduction and not covered by the additional 11 and 17 month periods, is also manifestly unfair given that FDA's public position, virtually from the passage of DSHEA, and on which industry has continued to rely, has been consistent with both court and agency precedents that definitions under the Act are not mutually exclusive. These products, as well as those products that are currently being marketed, should be included in a stay of FDA's new position pending reconsideration and any required further proceedings.

For the foregoing reasons, we urge FDA to reconsider the decision announced at 65 Fed. Reg. 1033, and stay the effective date and any enforcement of that decision pending the requested reconsideration and any (we hope unnecessary) court review.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Eugene I. Lambert", written over a horizontal line.

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