DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

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Dietary Supplement Health and Education Act of 1994

The House of Representatives adopted on October 7 a revised version of S. 784, and the Senate concurred in that amendment on October 9, sending new dietary supplement legislation to the President, who is expected to sign it into law. This is the first major dietary supplement legislation since the adoption of section 411 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") in 1976; the Dietary Supplement Health and Education Act of 1994 ("the Dietary Supplement Act" or "the Act") is more encompassing, and for the first time defines dietary supplements, and deals broadly with their regulation.

This memorandum summarizes the key provisions of the Act. Where the Act amends the FD&C Act, reference is given to the new statutory provision; other changes are cited to sections of the Act.

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Scope

The Dietary Supplement Act defines dietary supplements, creates a safety system for dietary supplements and their dietary ingredients, regulates claims and labeling of dietary
supplements, provides for good manufacturing practices for dietary supplements, and establishes new government agencies to influence government regulation of dietary supplements.

The Act does not repeal the FD&C Act or the Nutrition Labeling and Education Act ("NLEA") amendments to the FD&C Act with respect to dietary supplements. The Dietary Supplement Act does, however, limit or alter how the FD&C Act and NLEA apply to dietary supplements.

"Dietary Supplement"

For a product to be a "dietary supplement," it must meet a compositional requirement and a form requirement, and is subject to potential limitations due to the existence of FDA-approved drugs.

First, it must contain one or more "dietary ingredients," i.e.,--

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- any other ingredient used "to supplement the diet by increasing the total dietary intake"
- a metabolite, constituent, extract, concentrate or combination of any of the forgoing.

Second, it must either be in traditional supplement dosage form, i.e., a tablet, capsule, softgel, powder or liquid, or if not in such form (e.g., in flake or bar form), it must be labeled as a dietary supplement and it must not be represented as a meal replacement or a total diet or for use as a conventional food. The current limitation in section 411 of the FD&C Act that a supplement cannot "simulate" a conventional food is repealed; now the only limitation is that it cannot be "represented" as a conventional food.

The limitation with respect to drug products focuses on the timing of market introduction. If an "article" (which means a "product") was marketed as a dietary supplement and later approved as a new drug, antibiotic, or biological drug, the two uses coexist in the market unless FDA, by rulemaking, determines that the dietary supplement is unsafe (under the tests described later in this memo) as it is recommended to be used. Conversely, if the article was approved as a new drug, antibiotic or biological drug, or publicly acknowledged "substantial clinical investigations" were started under an authorized IND, then subsequent dietary supplement marketing of that article, i.e., something having the same route of administration and strength, requires an approving FDA regulation.

In an action reminiscent of section 509 of the FD&C Act, the definition concludes that a dietary supplement "shall be deemed a food" "except for purposes of section 201(g)," which is the drug definition. Thus, if a dietary supplement comes within one of the drug definitions, it is a drug as well as a food. As a result, it is not clear how to deal with the circularity of the food exclusion from section 201(g)(1)(C): is a dietary supplement a "food" for purposes of the exclusion, or does the "except" language in the new dietary supplement definition, section 201(gg), limit that normal reading?
Dietary Supplement Safety

The Dietary Supplement Act creates a new self-contained mechanism for determining the safety of dietary supplements and their "dietary ingredients," i.e., those ingredients that form the compositional basis for being a dietary supplement. In order to do this, the Act --

1. excludes dietary ingredients from the scope of the definition of "food additive," section 201(s)(6), thus eliminating the use of the "food additive" concept to regulate dietary supplements; this also eliminates the "GRAS" concept. Because the recently proposed packaging and labeling requirements for iron supplements were based on food additive concepts, the legal basis will have to be reevaluated by FDA. Section 11 of the Act declares the advance notice of proposed rulemaking (ANPR) on the safety regulation of dietary supplements be null and void, and requires a Federal Register notice of withdrawal; in light of the exclusion of dietary ingredients from the definition of food additive, most of the ANPR is moot.

2. applies three tests of adulteration: "a significant or unreasonable risk of illness or injury," "an imminent hazard to public health or safety," or a "poisonous or deleterious substance which may render it injurious to health," in each case based on labeled recommended uses, or customary conditions if none are recommended. Before a court case can be brought under the first test, an opportunity to present oral or written views must be granted, similar to the opportunity under section 305 of the FD&C Act. The Act specifies that the FDA bears the burden of proof of each element of adulteration, and that the court "shall" decide any issue on a de novo basis; this latter provision is designed to preclude the use of rulemaking to determine adulteration.

3. creates a new category of "new dietary ingredient" defined to mean a dietary ingredient not marketed by anyone prior to October 15, 1994, section 413(c). A new dietary ingredient may be used immediately if it is "an article used for food in a form in which the food has not been chemically altered." Section 413(a)(1). The deliberately limited legislative history of the Act specifies that "chemically altered" does not include physical processes of dehydration, lyophilization, milling, or creating a tincture or solution or suspension.

4. creates a new premarket notification procedure if the test of section 413(a)(1) is not met. At least 75 days before marketing, the marketer of the new dietary ingredient must supply FDA with information - a history of use or other evidence of safety - "which is the basis [for the marketer] conclud[ing] ... [it is] reasonably ... expected to be safe." Although section 413 states that a new dietary ingredient is adulterated under new section 402(f) "unless it meets [this] requirement[",]", in fact section 402(f)(1)(B) states only that a new dietary ingredient is adulterated if "there is inadequate information to provide a reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury," which is quite different than the broader "reasonably ... expected to be safe." Equally curiously, a new section 301(u) is added by the Act making it a prohibited act to ship in interstate commerce "a dietary supplement that is unsafe under section 413," although section 413 does not use the term "unsafe" to characterize noncompliance.

5. permits, but does not require, the filing of a petition to establish by regulation the safe conditions of use for any dietary ingredient. Section 413(b). The language and statutory timing - 180 days for an FDA decision - are similar to the food additive provision of the FD&C Act, but the standard is the "will
reasonably be expected to be safe" used in the rest of section 413.

**Claims and Labeling**

The Act deals with an exclusion from the definition of "labeling," an exclusion from NLEA "health claims," and compliance with ingredient labeling as well as NLEA nutrition labeling and nutrient content labeling.

1. **Exclusion from labeling.** Existing case law establishes that, unless printed matter is used in an integrated fashion to promote a specific product, it is not "labeling" even if displayed in the same establishment as a product to which the material refers. The Dietary Supplement Act creates a new exemption from labeling, under strict conditions, for material that would not meet the current case law because it is used to promote the sale of a product. Under new section 403B "an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication" (the only permitted summarization of specific scientific material) is not labeling " when used in connection with the sale of a dietary supplement to consumers" IF the material is not false or misleading; does not promote a specific brand or manufacturer; is displayed or presented in a "balanced" fashion; if displayed, is separate from products; and has no "appended ... information," e.g., a "courtesy of ..." or "reprinted by ..." sticker. Recognizing the anomaly of requiring the retailer to establish that a scientific article is not false or misleading, section 403B(c) establishes that FDA has the burden of demonstrating that material is false or misleading in any court proceeding.

2. **Exclusion from health claims.** Since the passage of the NLEA, there has been controversy over the reach of the health claims provision, which bars any implied claim about the relationship between a nutrient and a "health-related condition" without FDA approval of the claim. Much of the controversy has revolved around so-called structure or function claims for nutrients, which can be as simple as calcium builds strong bones, or as elaborate as a description of how antioxidants transform free radicals into stable molecules, with attendant protection of cell walls. A new section 403(r)(6) provides a safe harbor from the health claims definition for statements that describe the role "of a nutrient or dietary ingredient" to affect structure or function, characterizes the "documented mechanism" by which it does so, or describes "general well-being" resulting from their consumption. To use the safe harbor, the maker must have "substantiation" (probably referring to the FTC standard of a "reasonable basis") that the claim is truthful and not misleading, must notify FDA within 30 days of first marketing a supplement with such statement, and must include in the statement --

"prominently displayed and in boldface type, the following: '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.'"

Section 403(r)(6)(C). In addition, claims meeting the test of section 403(r)(6) are excluded from the drug definition under section 201(g)(1)(C) under a revision to the exclusion from the drug definition contained in section 10(a) of the Act. Section 403(r)(6) is likely to be important only to those dietary
supplement ingredients that are not traditional nutrients, and for which claims might be viewed as health or drug claims, which is not the case for traditional nutrients. This disclaimer approach applies only to dietary supplements, and not to traditional foods making similar claims; the second sentence would be inconsistent with FDA-approved health claims for calcium and folic acid containing supplements, or any other health claim approved for dietary supplements in the future. The Act does not alter or expand the health claims available for dietary supplements, or change the regulatory procedure or criteria for the adoption of health claims.

3. **Labeling requirements.** In two separate provisions, the Act requires dietary supplements to list the name and quantity of each dietary ingredient. This is covered directly by a new section 403(s)(2)(A) and indirectly by revised section 403(q)(5)(F). A technical correction may be needed to assure that the same quantitative information is required under both provisions. Under the latter provision, NLEA labeling must be a single listing of dietary ingredients, starting with those with Daily Values, followed by all others identified as having no DV. The listing can also include the source ingredient of the dietary ingredient, and the traditional ingredient declaration need not repeat those ingredients (although a technical correction is needed so that the first cross reference in section 403(q)(5)(F) is to "subsection (i)" rather than to "subclause (i)").

Dietary supplements are required to be labeled with that term (which can be modified to identify the nature of the supplement, e.g., "calcium dietary supplement"). Section 411 is amended to permit names and other descriptions to include all dietary ingredients, even if not vitamins or minerals, and to eliminate the restriction in advertising and labeling of giving prominence to non-vitamin/mineral ingredients. If a dietary supplement claims to conform to an official compendium, it must do so; if no compendial standards apply, the supplement must nonetheless have the strength it is represented to have and meet any quality (including disintegration) specifications it is represented to have. While dietary ingredients for which there is a Daily Value remain subject to the existing high/good/more NLEA regulation, dietary ingredients for which there is no Daily Value are excluded from NLEA requirements. Finally, under a sentence added at the end of section 403, a dietary supplement will not be misbranded just because it has directions for use or warnings.

While compliance with the new labeling requirements can begin immediately, full compliance is required for product labeled after December 31, 1996. Because the statutory requirements under new section 403(s) and revised section 403(q)(5)(F) are different than the FDA regulations adopted in January 1994, those regulations will have to be substantially modified.

**Good Manufacturing Practices**

The Act adds a new section 402(g)(1) that renders a dietary supplement adulterated if it is not in compliance with "current good manufacturing practice regulations" that may require expiration date labeling. Under section 403(g)(2), these regulations must be issued after notice and opportunity for comment, must be modeled after existing food cGMPs, and may not impose standards "for which there is no current and generally available analytical methodology."
New Government Agencies

The Dietary Supplement Act creates two new government entities.

1. **Commission on Dietary Supplements.** This is an independent agency within the executive branch composed of seven members appointed by the President, at least three of whom must have a scientific background, and one of those must have experience in medical botany or traditional herbal medicine; members and staff are to "be without bias on the issue of dietary supplements." In the two year period after enactment, the Commission is to provide written recommendations for regulatory or legislative changes to FDA and Congress based on a study of --

   "... the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims... [in order to determine] how best to provide truthful, scientifically valid, and not misleading information to consumers ... [to permit] informed and appropriate health care choices...."

   Section 11(c). FDA is obligated under section 11(e)(3) to publish any recommendations for regulation changes, as proposed rulemaking, and to complete the rulemaking within two years after receiving the Commission report. Failure to complete action nullifies the January 1994 rules (some of which must be changed to meet new labeling requirements).

2. **NIH Office of Dietary Supplements.** This Office is to conduct research, coordinate intramural research and extramural funding of research, on dietary supplements and disease prevention, compile a data base of scientific research on dietary supplements, and serve as "principal advisor" to HHS, NIH, CDC and FDA on dietary supplement regulation, safety and health claims, all on $5 million a year.

Some Marketing Implications

**Scope of Dietary Supplement.** The new definition of dietary supplement is intended to be all-encompassing: traditional nutrients, herbal and botanical products, metabolites and extracts of all these ingredients, and the catch-all of any ingredient used to increase dietary intake. Thus so long as a product is marketed as a dietary supplement in labeling and positioning, it is one; not even the form is any longer a limitation as it was under prior section 411. Thus, subject to the drug wrinkle, and the "new dietary ingredient" issue, anything can be a dietary supplement.

A two step analysis must be made to determine whether any particular dietary ingredient is included or excluded from the new definition for drug approval reasons. First, it is important to determine the date of first marketing of the ingredient as a dietary supplement, and compare that with the date of the earliest drug approval. (The key is drug approval; pre-1938 prescription drugs that have no NDAs do not affect the analysis.) Second, it is important to determine whether the drug and the dietary supplement are the
same "article," i.e., have the same route of administration and dosage strength. Only if the drug was first marketed and the dietary ingredient is the same "article" does the exclusion apply. In all other circumstances, the existence of a drug product containing the same ingredient does not limit dietary supplement marketing. Of course, FDA by rulemaking can override the exclusion; if 1 mg folic acid were to be found to be important to supplement the diet, application could be made to FDA to permit 1 mg supplements despite the 1 mg drug approvals.

**Dietary Ingredients.** The revised safety provisions of the Act will eliminate much of the difficulty encountered in the past in reviewing the acceptability of new ingredients. First, the application of the entire food additive structure of the FD&C Act is made inapplicable to dietary ingredients. Second, all dietary ingredients in use as of October 15, 1994, are essentially "grandfathered"; only if substantial risks of actual harm arise are they likely to be questioned by FDA. Third, "new dietary ingredients" fall into two classes, those that are essentially food components that have not been chemically altered, and other new ingredients. Manufacturers are free to use the former kind of ingredient without any submission to FDA. It is only the latter ones for which a submission to FDA is required to demonstrate the basis for the manufacturer's conclusion that the ingredient, as proposed to be used, "will reasonably be expected to be safe." The Act provides no basis for FDA to reject a submission, or require additional information. If FDA disagrees with the submission, however, it may block the use of the ingredient only if it can establish that information is lacking to assure that it "does not present a significant or unreasonable risk of illness or injury," a much higher standard than the one that must be met in the submission to FDA.

**Structure or Function Claims.** Despite the addition of new section 403(r)(6), the disclaimer in that section is unlikely to apply to most structure or function claims for traditional nutrients; nor will the requirement of post-marketing submissions to FDA. The reason for this conclusion is two-fold. First, there is no independent penalty for failure to use the disclaimer or make the submission to FDA. There is no prohibited act and no misbranding provision triggered by the failure to comply with section 403(r)(6); failure to comply only means that the claim must be tested under the health claims provision of the FD&C Act, section 403(r)(1)(B), and FDA's implementing regulation, 21 C.F.R. 101.14(a) (1), (6). Second, under those provisions, if the claim is not a health claim, then the prohibition of section 403(r)(1)(B) does not apply. Similarly, if the claim is for a "food" (based on the statutory definition and court decisions), then the exclusion from section 201(g)(1)(C) of the drug definition applies without the need for the revised exclusion added by the Dietary Supplement Act.

On the other hand, new section 403(r)(6) is likely to be important in at least three situations. First is if the desired claims could reasonably be found to be implied health claims, i.e., although describing a structure or function effect, that effect was so well recognized as to be a surrogate for a disease claim. An example would be claims for reducing serum cholesterol, widely accepted by consumers as an implied heart disease prevention claim. Similarly, claims concerning immune function would likely fall into this category. These claims can be made under the protection of the disclaimer and notification procedures in section 403(r)(6) so long as no explicit disease treatment or prevention claim is made.

Second, functional claims for dietary ingredients that do not qualify as "nutrients" will for the first time be able to be made without creating problems under the health claims or drug definition, so long as the section 403(r)(6) procedures are followed. Thus the role of phytochemicals, herbal ingredients, and other non-DV dietary ingredients can be described without triggering health claims risks, and without the threat of a section 201(g)(1)(C) "drug" claim, because claims complying with section 403(r)(6) are expressly
excluded from that drug definition by the Dietary Supplement Act.

Third, this provision is applicable to both the label and labeling, and permits the development of nonpackage labeling that provides broader information than can fit on the label, again without health claims risks or drug risks (so long as explicit disease-related claims are not made).

Compliance with section 403(r)(6) requires that the manufacturer have substantiation for the claim, but this substantiation need not be submitted to FDA, and technically, FDA has no authority to demand to see or copy the substantiation. The notice to FDA is a post-marketing notice, and only that a covered claim is being made for the first time; it is not clear that marketing of subsequent brands or formulations with the same claim requires additional notices.

**Supplement Labeling.** The new labeling provisions essentially override the nutrition labeling provisions adopted by FDA in January 1994 at least insofar as FDA prohibited the inclusion of non-DV dietary ingredients in the Nutrition Facts list, and precluded the inclusion of the nutrient source in the Nutrition Facts list. If NLEA-compliant labels have been adopted, they can be used at least through December 31, 1996. Because new section 403(s) also requires quantitative ingredient information, the simplest approach to labeling will be to combine the section 201(s) and section 403(q)(5)(F) requirements into a single Nutrition Facts/ingredient panel, with a following listing of "non-dietary ingredient" ingredients.

**Scientific Papers.** The new exclusion from labeling should assist in providing scientific papers to consumers. The new exclusion from "labeling" in section 403B talks about the use of these kinds of materials in conjunction with the sale of dietary supplements. Thus those in both retail and direct selling can use these materials in direct connection with sales without violating the labeling laws so long as the limitations of this new section are met. First, complete articles, chapters and other publications must be used; no summaries of articles prepared by the seller will be acceptable. However, scientific articles on particular topics, even if authored by company personnel, qualify as "a publication" so long as they meet the tests of not being misleading and not promoting a particular brand of supplement. Second, as presented to the consumer by the distributor, there must be a reasonable "balance" in the materials for each dietary ingredient covered. Finally, there can be no seller or source identification imprinted on attached to or used with the literature.

If a company develops or uses other materials that are not direct scientific publications, then all of the current strictures about labeling apply. Such materials cannot make claims that could not be made on the label of the product. They can take advantage of the "safe harbor" under section 403(r)(6) to make structure or function, and possibly some implied health claims, so long as the disclaimer is used, and the materials are submitted to FDA after first use.

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1 The "product" cannot be "tobacco."