

# Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation

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## I. INTRODUCTION

For the past three years, there was intense pressure on Congress to reduce the regulatory burdens on dietary supplements by amending the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>1</sup> Many members of the House of Representatives and Senate stated that they had received more mail, phone calls, and constituent pressure on this subject than on anything else — including health care reform, abortion, or the deficit.

In response, Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>2</sup> Senator Orrin Hatch (R-Utah) was the leading proponent of the legislation in Congress, and the act enjoyed broad bipartisan support. The measure was approved by unanimous consent both in the House of Representatives, at approximately 3:00 a.m. on October 7, 1994, and in the Senate, shortly after midnight on October 8, 1994. The President signed the act into law on October 25, 1994.

Like all legislation, the new law is a compromise. It does not include all of the restraints on the Food and Drug Administration's (FDA's) regulation of dietary supplements that the sponsors originally wanted. Indeed, it imposes some significant new requirements for such products. Nevertheless, the legislation on the whole is viewed as a very positive development for those who sell dietary supplements such as vitamins, minerals, herbs, botanicals, amino acids, and similar substances.

This article focuses on the changes that the DSHEA has made in the way dietary supplements are regulated by the FDA and the opportunities these changes present for additional marketing and for attention by the *United States Pharmacopeia (USP)*.

## II. BROAD, EXPANDED DEFINITION OF "DIETARY SUPPLEMENT"

There is a substantial dietary supplement business in the United States.<sup>3</sup> These products usually consist of tablets or capsules, which provide not only vitamins or minerals viewed as essential by mainstream nutritionists, such as vitamin A or iron, but other substances that FDA personnel often regard as being of dubious usefulness — such as rutin, other bioflavonoids, herbs, or shark cartilage.

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<sup>1</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et seq. (1988).

<sup>2</sup> Pub. L. No. 103-417, 108 Stat. 4325 (1994) (to be codified at 21 U.S.C. §§ 321(ff), (s)(6), note, 331(u), 342(f), (g), 343(q)(5)(F), (r)(6), (s), note, 342-2, 350(b)(2), (c)(1)(B), 350b, 42 U.S.C. § 287c-11).

<sup>3</sup> The FDA has long regarded dietary supplements as food intended for "special dietary uses." Section 403(j) of the FDCA, which has been part of the Act since its original passage in 1938, provides that a food shall be deemed "misbranded" (and therefore illegal) "[i]f it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses." FDCA § 403(j), 21 U.S.C. § 343(j). This section of the FDCA recognizes that a product that is intended "for special dietary uses" because of "its vitamin, mineral, and other dietary properties" is a type of food. *Id.* Note that section 403(j) authorizes, but does not require, the issuance of regulations to prescribe

Prior to the DSHEA, agency personnel maintained that it was misleading to distribute as a "dietary supplement" a substance that the agency regarded as lacking nutritional value. FDA personnel sometimes also asserted that a substance that did not provide "taste, aroma, or nutritional value" in its supplemental (pill-type) form could not be sold properly as a food product.<sup>4</sup>

The new DSHEA deals with this fundamental issue by unequivocally providing an expansive definition of "dietary supplement" that includes a

product . . . intended to supplement the diet that bears or contains . . . a vitamin; . . . a mineral; . . . an herb or other botanical; . . . an amino acid; . . . a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or . . . a concentrate, metabolite, constituent, extract, or combination [of any ingredient described above].<sup>5</sup>

The practical effect of this definition is to ensure that the new protections provided by the DSHEA for dietary supplements apply to a wide class of products, even those that FDA nutritionists regard as having no nutritional value.

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mandatory label information. *Id.* The authority of the Secretary of the Department of Health and Human Services (DHHS) to issue regulations under the FDCA has been delegated to the Commissioner of Food and Drugs, who directs the FDA. 21 C.F.R. § 5.10(a)(1) (1994). FDA regulations issued pursuant to section 403(j) of the Act state that the term "special dietary uses" includes "[u]ses for *supplementing* or fortifying the ordinary or usual *diet* with any vitamin, mineral, or other dietary property." *Id.* § 105.3(a)(1)(iii) (hence "dietary supplement") (emphasis added).

At present, there are no regulations in effect that prescribe a mandatory format for nutrition labeling of dietary supplement products. The current edition of the *Code of Federal Regulations* contains two sets of regulations that might appear to be applicable: (1) regulations specifically concerning "[n]utrition labeling of dietary supplements of vitamins and minerals," which were scheduled to become effective on July 5, 1995, and (2) the agency's basic regulations concerning "nutrition labeling of food," which already are effective, and which one might interpret as being applicable to food products that do not come within the scope of the first regulation. 21 C.F.R. §§ 101.36, 101.9. The FDA, however, published a notice in the *Federal Register* stating that because of the enactment of the DSHEA, the FDA intends to modify its regulations on nutrition labeling for dietary supplements and does not intend to enforce nutrition labeling regulations for supplements "until after December 31, 1996." 60 Fed. Reg. 7711-12 (Feb. 9, 1995).

<sup>4</sup> See *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983); *American Health Prods. Co. v. Hayes*, 574 F. Supp. 1498 (S.D.N.Y. 1983), *aff'd*, 744 F.2d 912 (2d Cir. 1984). The FDA, however, also has long accepted that "[i]ngredients or products such as rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition . . . may be marketed as individual products or mixtures thereof: *Provided*, That the possibility of nutritional, dietary, or therapeutic value is not stated or implied . . ." 21 C.F.R. § 101.9(i)(5) (1993). Tablets or capsules of such products might have no taste, aroma, or nutritional value, but the agency nevertheless acknowledged that the products could properly be sold as foods (provided that no misleading nutritional or therapeutic claims were made). This particular statement no longer appears in the FDA's revised regulations on nutrition labeling. See 21 C.F.R. § 101.9 (1994). However, when the FDA revised its nutrition labeling regulations to delete this statement, it explicitly said that it was not intending to change its policy that permitted sale, as food, of a substance that offered no nutritional value (in the FDA's judgment). See *generally* 58 Fed. Reg. 2166 (Jan. 6, 1993).

<sup>5</sup> FDCA § 201(ff)(1), 21 U.S.C. § 321(ff)(1). There are additional criteria. The product must either be intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid droplet form, or, if not intended for ingestion in such a form, not be "represented for use as a conventional food or as a sole item of a meal or the diet." *Id.* § 201(ff)(2), 21 U.S.C. § 321(ff)(2). In addition, it must be labeled as a "dietary supplement." *Id.* §§ 201(ff)(2)(C), 403(s)(2)(B), 21 U.S.C. § 321(ff)(2)(C), 343(s)(2)(B). The new definition includes some highly-technical provisions about the situation where an ingredient in a supplement also is approved by the FDA for use as a drug. In general, if "an article" has been "marketed as a dietary supplement or as a food" before it is approved by the FDA as a new drug, certified by the FDA as an antibiotic, or licensed by the FDA as a biologic, it may continue to be marketed as a dietary supplement unless the FDA publishes a prohibitory regulation (which would be subject to judicial review). *Id.* § 201(ff)(3)(A), 21 U.S.C. § 321(ff)(3)(A).

### III. EXEMPTION OF DIETARY INGREDIENTS IN DIETARY SUPPLEMENTS FROM “FOOD ADDITIVE” STATUS

From the perspective of the manufacturers and consumers of dietary supplement products, one of the most important provisions of the new law is the explicit amendment of the FDCA to prevent the term “food additive” from being applied to a dietary ingredient in, or intended for use in, a dietary supplement.<sup>6</sup>

Previously, the FDA had argued that substances added to dietary supplement products were much like substances added to any other food product. If a substance was not “generally recognized as safe” (GRAS) by experts whose opinion was based on published scientific literature, it would be subject to regulation as a “food additive.”<sup>7</sup> Under the FDCA, a substance that is a food additive may not be added to food products unless the FDA issues a food additive regulation explicitly permitting such addition.<sup>8</sup> Typically, the preparation of a food additive petition, from the conduct of needed research (including extensive animal feeding studies) to participation in the ensuing administrative proceedings, can cost a petitioner \$1,000,000 or more; and it often is five years or more after the receipt of a well-founded food additive petition before the FDA issues an approving food additive regulation.<sup>9</sup> Thus, dietary supplement ingredients that had been alleged to have “food additive” status without an approving food additive regulation were treated as illegal, curtailing the marketing of many products. The FDA had pursued regulatory actions against many once-popular dietary supplement ingredients, based on allegations of unapproved food additive status — including calcium acetate, orotate compounds such as magnesium orotate, evening primrose oil, black currant oil, borage seed oil, linseed/flaxseed oil, chlorella, lobelia, St. Johnswort, and coenzyme Q10.

The new law frees dietary supplement ingredients from the continuing risk that the FDA might assert that its scientists did not believe a particular dietary ingredient was GRAS for use in dietary supplements, and therefore, that the ingredient was an unapproved food additive and illegal.

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On the other hand, if, before “an article” is “marketed as a dietary supplement or as a food,” either (1) the FDA has approved the article as a new drug, certified the article as an antibiotic, or licensed the article as a biologic, or (2) the FDA has authorized the article for investigation as a new drug, antibiotic, or biologic, and “substantial clinical investigations have been instituted,” and “the existence of such investigations has been made public,” the article may not be marketed as a dietary supplement unless the FDA first issues an approving regulation. *Id.* § 201(ff)(3)(B), 21 U.S.C. § 321(ff)(3)(B).

<sup>6</sup> *Id.* § 201(s)(6), 21 U.S.C. § 321(s)(6).

<sup>7</sup> *Id.* § 201(s), 21 U.S.C. § 321(s). Prior to the enactment of the DSHEA, the FDA used the food additive allegation for dietary ingredients in dietary supplement products. *See, e.g.*, FDA, COMPLIANCE POLICY GUIDE NO. 7117.04, BOTANICAL PRODUCTS FOR USE AS FOOD (July 1, 1986). Even before enactment of the DSHEA, however, some courts had expressed the view that the FDA was overreaching in its attempts to regulate dietary ingredients in dietary supplement products as “food additives.” *See, e.g.*, *United States v. Two Plastic Drums . . . Black Currant Oil*, 984 F.2d 814, 819 (7th Cir. 1993) (ruling that black currant oil in a gelatin capsule was not subject to regulation as a “food additive,” and that the FDA’s allegations of food additive status constituted an “Alice-in-Wonderland approach . . . to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances”); *United States v. 29 Cartons . . . Oakmont Investment Co.*, 987 F.2d 33, 39 (1st Cir. 1993) (“The proposition that placing a single-ingredient food product into an inert capsule as a convenient method of ingestion converts that food into a food additive perverts the statutory text, undermines legislative intent, and defenestrates common sense. We cannot accept such anfractuous reasoning.”).

<sup>8</sup> 21 U.S.C. § 342(a)(2)(C), 348(a).

<sup>9</sup> *FDA Safeguards Against Improper Disclosure of Financially Sensitive Information: The Product Approval Centers*, FINAL REPORT 162 (Nov. 14, 1991); 33 FOOD CHEM. NEWS, Nov. 4, 1991, at 67.

#### IV. NEW SAFETY STANDARDS

As a *quid pro quo*, the new law replaces the voided food additive provisions with some new safety standards.

In general, the DSHEA provides that a dietary supplement will be deemed to be adulterated if it "presents a *significant or unreasonable risk of illness or injury*" ("under . . . conditions of use recommended or suggested in labeling, or . . . if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use").<sup>10</sup> The new law is clear, however, that the FDA shall bear the burden of proof in court if it asserts that a dietary supplement is adulterated under this standard.<sup>11</sup>

There are additional requirements with respect to a "new" dietary ingredient, i.e., an ingredient that "was not marketed in the United States before October 15, 1994."<sup>12</sup> A dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless, either, the supplement "contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered," or, there is a "history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling . . . will reasonably be expected to be safe."<sup>13</sup> In the latter case, "at least 75 days before being introduced or delivered for introduction into interstate commerce," the manufacturer or distributor of the dietary ingredient or supplement must provide the FDA "with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe."<sup>14</sup>

In addition, the new legislation provides that the Secretary of the Department of Health and Human Services (DHHS) may declare a dietary supplement "to pose an imminent hazard to public health or safety."<sup>15</sup> In this case it immediately becomes illegal to market the product, although the Secretary must thereafter promptly hold a formal hearing to assemble data "to affirm or withdraw the declaration."<sup>16</sup> (The new law provides that the authority to declare a dietary supplement to be an imminent hazard must be exercised by the Secretary him/herself, and may not be delegated to the FDA.)

In summary, under the new law, the FDA-asserted "food additive" requirement for agency preclearance of dietary ingredients not believed to be GRAS has been deleted, but the FDA and the Secretary of DHHS have been granted substantial new policing authority to stop the distribution of a dietary supplement if government personnel believe they can show that the product is not safe.

#### V. NEW RIGHTS FOR SELLERS TO CONVEY INFORMATION ABOUT USEFULNESS OF DIETARY SUPPLEMENTS

Some of the most potentially important changes brought about by the new legislation relate to the use of published literature by sellers of dietary supplements to

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<sup>10</sup> FDCA § 402(f)(1)(A), 21 U.S.C. § 342(f)(1)(A).

<sup>11</sup> *Id.* § 402(f)(1), 21 U.S.C. § 342(f)(1).

<sup>12</sup> *Id.* § 413(c), 21 U.S.C. § 350b(c).

<sup>13</sup> *Id.* § 413(a), 21 U.S.C. § 350b(a).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* § 402(f)(1)(C), 21 U.S.C. § 342(f)(1)(C).

<sup>16</sup> *Id.*

inform potential customers about dietary ingredients.

Prior to the enactment of the new legislation, the FDA asserted that a book, article, or other publication used in connection with the sale of a dietary supplement could be regulated as "labeling." If the publication included information claiming that an ingredient present in the product might be useful in the cure, mitigation, treatment, or prevention of any disease, the product itself would be subject to regulation as a drug. For example, the FDA asserted that a seller of a dietary supplement product could not promote the product to customers by showing the customers copies of books or articles that extolled disease-prevention benefits of nutrients provided by the supplement.<sup>17</sup>

The new law greatly restricts the FDA's ability to object to the use of books and other publications in connection with the sale of dietary supplement products. The legislation provides that 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," "shall not be defined as labeling" and may be "used in connection with the sale of a dietary supplement to consumers" if the publication is "reprinted in its entirety" and meets certain specific criteria.<sup>18</sup> Among the criteria that must be met are: (1) the publication must not be "false or misleading," (2) it must not "promote a particular manufacturer or brand of a dietary supplement," (3) it must be "displayed or presented . . . so as to present a balanced view of the available scientific information," (4) if "displayed in an establishment," it must be "physically separate from the dietary supplements," and (5) it must not "have appended to it any information by sticker or any other method."<sup>19</sup>

So long as these criteria are met, the new law appears to authorize a salesperson to guide the attention of a potential customer to published nutritional or other scientific literature that describes the health benefits of a dietary supplement's ingredients.

There is an additional, explicit provision in the new legislation that the law shall not act to "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."<sup>20</sup> This is the first affirmative provision in the FDCA to protect the right of sellers of dietary supplements also to sell publications that describe the health-related benefits of nutrients and indirectly contribute to sales of such nutrients.

## VI. STATEMENTS OF NUTRITIONAL SUPPORT

FDA regulations published pursuant to the Nutrition Labeling and Education Act (NLEA) provide that no health claim may appear on the label or in other labeling (including brochures) of any food products, including dietary supplements, unless the FDA first approves the use of the claim in a final regulation.<sup>21</sup>

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<sup>17</sup> For a judicial ruling upholding FDA assertions of this type, see *United States v. Articles of Drug . . . Honey*, 344 F.2d 288 (6th Cir. 1965) (ruling that a jar of honey became subject to regulation as a drug when a book that made drug claims for honey was used in "immediate connection with the sale of the product" by the retailer). Cf. *United States v. "Sterling Vinegar and Honey" . . . Balanced Foods*, 338 F.2d 157 (2d Cir. 1964) (ruling that a book that made drug-type claims for a vinegar-honey combination did not create drug status for a vinegar-honey product, although the book was available for sale in the same store as the product, when there was "no evidence of any joint promotion" of the book and the product).

<sup>18</sup> FDCA § 403B(a), 21 U.S.C. § 343-2(a).

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* § 403B(b), 21 U.S.C. § 343-2(b).

<sup>21</sup> 21 C.F.R. § 101.14(e)(1).

The DSHEA crafts a new exception to this regulation that allows dietary supplements to make four types of “statements of nutritional support” on labels or in other labeling without obtaining FDA approval. These exceptions include:

- a “statement [that] claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States”;
- a statement that “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans”;
- a statement that “characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function”; and
- a statement that “describes general well-being from consumption of a nutrient or dietary ingredient.”<sup>22</sup>

The legislation provides that such a statement may be made in labeling for a dietary supplement if:

- the manufacturer “has substantiation that such statement is truthful and not misleading”;
- the labeling contains, prominently displayed, the following additional text, “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”; and
- the manufacturer notifies the FDA “no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.”<sup>23</sup>

## VII. PROVISIONS OF PARTICULAR SIGNIFICANCE TO THE USP

There are certain provisions in the new legislation that are of special significance to the *USP*.

### A. “Specifications” for Dietary Supplement Products

It should be noted that the DSHEA provides that a dietary supplement shall be deemed to be “misbranded” (illegal) if it:

- (i) is covered by the specifications of an *official compendium*;
- (ii) is represented as conforming to the specifications of [the] *official compendium*; and
- (iii) fails to so conform; . . .

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<sup>22</sup> FDCA § 403(r)(6), 21 U.S.C. § 343(r)(6).

<sup>23</sup> *Id.* It would appear that labeling claims that come within the four types of “statements of nutritional support” described in new section 403(r)(6) will *not* always come within the FDA’s definition of a “health claim.” See 21 C.F.R. § 101.14(a)(1)-(6). For example, a label claim that “calcium helps build strong bones” is a claim that “describes the role” of calcium “to affect the structure or function in humans.” Yet, such a claim does not come within the FDA’s definition of a “health claim.” See *id.* § 101.14(a)(6). In such circumstances, it would appear that neither the approval of a health claim regulation nor compliance with the DSHEA’s requirements for the new “statements of nutritional support” exception from health claim requirements would be applicable or needed.

or if it

- (i) is *not* covered by the specifications of an *official compendium*; and
- (ii)(I) fails to have the identity and strength that the supplement is represented to have; or
- (II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.<sup>24</sup>

These new provisions appear to invite the United States Pharmacopeial Convention to consider expanding its *USP* specifications for dietary supplement products, or for dietary ingredients intended for use in dietary supplement products.

The *USP* has long been a significant resource in setting specifications for certain dietary supplement products. Indeed, a monograph for cod liver oil was included in the *USP* as early as the 1800s. The current edition (*USP 23*) includes not only monographs for numerous individual nutrients (ranging from beta carotene capsules to vitamin E capsules, as well as the venerable cod liver oil), but it also provides an extended separate section on “nutritional supplements” (including twelve additional monographs for combination products such as “minerals capsules,” “minerals tablets,” and “oil-soluble vitamins capsules”).<sup>25</sup>

The new legislation’s endorsement of labeling references to official compendial standards is reasonable and helpful, given all of the information on supplements already provided by the *USP*. In the future, the *USP* may want to consider expanding the list of nutritional items for which it has issued monographs. The *USP* might even want to consider adopting specifications for products, such as evening primrose oil or various herbs, which the FDA previously has not welcomed as dietary supplements, but which are now legal and appropriate for such use.

### B. *Good Manufacturing Practices for Dietary Supplement Products*

A second provision of the new legislation that appears to invite *USP* attention is the section on good manufacturing practices (GMPs). The legislation authorizes the FDA to issue “current good manufacturing practice regulations” to describe mandatory conditions under which dietary supplements must be “prepared, packed, or held,” including “regulations requiring, when necessary, expiration date labeling.”<sup>26</sup> The legislation provides that such regulations “shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology.”<sup>27</sup> Once such regulations are issued, a dietary supplement that is manufactured in violation of the requirements would be deemed adulterated and subject to regulatory action.

Although this section of the legislation does not explicitly refer to GMPs endorsed by an official compendium, nevertheless, the *USP* GMPs for supplements<sup>28</sup> provide a useful, independent reference, which might either remove the need for FDA

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<sup>24</sup> FDCA § 403(s)(2)(D), (E), 21 U.S.C. § 343(s)(2)(D), (E) (emphasis added).

<sup>25</sup> UNITED STATES PHARMACOPOEIA 185-86, 416, 1631-32, 2129-92 (23d ed. 1995) [hereinafter *USP 23*].

<sup>26</sup> FDCA § 402(g), 21 U.S.C. § 342(g).

<sup>27</sup> *Id.*

<sup>28</sup> *USP 23*, *supra* note 25, at 2186-92.

action or enable the FDA to address the matter by adopting some or all of the official compendium's GMPs.

There is a fundamental problem, however, that the FDA may need to take into consideration before it could adopt the *USP* GMPs. The opening section of the *USP* 23 chapter on "Manufacturing Practices for Nutritional Supplements" states that many of the principles are "derived from the current good manufacturing practices *for drugs*."<sup>29</sup> This could present a problem for FDA adoption because, as noted earlier, the DSHEA provides that FDA GMPs for dietary supplements "shall be modeled after good manufacturing practice regulations *for food*."<sup>30</sup>

If the *USP* wants to facilitate the FDA's adoption of its work, the *USP* may want to reconsider, and possibly to amend, its GMPs for supplements to make them more "food"-like. The *USP* GMPs currently include some significant requirements that are not imposed by the FDA GMP regulations for foods (e.g., "Tamper-Resistant Packaging").<sup>31</sup>

### VIII. CONCLUSION

The new legislation will cause substantial changes in the way that the FDA regulates dietary supplements. The major changes established by the legislation include:

- creation of a broad, new definition of "dietary supplement" products;
- moderation of the regulatory burdens for use of dietary ingredients in dietary supplements, changing both the safety standard for use of an ingredient and the regulatory procedure from one of FDA preclearance to one of FDA policing; and
- permitting additional promotional use of information about the nutritional benefits of dietary supplements, both through the use of "statements of nutritional support" on labels or in other labeling, and by enabling sellers to refer customers to books, articles, and other publications that provide health-related information.

These changes provide many potential opportunities for additional marketing and for *USP* involvement.

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<sup>29</sup> *Id.* at 2186 (emphasis added).

<sup>30</sup> FDCA § 402(g), 21 U.S.C. § 342(g) (emphasis added).

<sup>31</sup> 21 C.F.R. pt. 110.