

## FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements

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### I. INTRODUCTION

Recently, there has been public debate about whether the Food and Drug Administration (FDA) has sufficient authority to regulate dietary supplements under the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>1</sup> and the Dietary Supplement Health and Education Act of 1994 (DSHEA),<sup>2</sup> and about whether the laws need to be changed to give FDA greater authority.<sup>3</sup> The authors of this article believe that FDA's existing authority is ample and sufficient, that FDA should not be given greater powers, and that the provisions of DSHEA need not be amended.

### II. WHY WAS DSHEA ENACTED?

At the outset, one should consider why Congress approved DSHEA, less than 10 years ago, by unanimous consent.<sup>4</sup> DSHEA was enacted because FDA was viewed as distorting the law that existed before DSHEA to try improperly to deprive the public of safe and popular dietary supplement products.<sup>5</sup> FDA's authority needed to be better defined and controlled. Consider the following: In its official report about the need for DSHEA to curtail excessive regulation of dietary supplements by FDA, the Senate Committee on Labor and Human Resources stated explicitly that "in fact, FDA has been distorting the law in its actions to try to prevent the marketing of safe dietary supple-

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Hyman, Phelps & McNamara, P.C. assists industry with respect to the regulation of foods, drugs, medical devices, cosmetics, and related products. The firm's clients include companies that manufacture and distribute dietary supplements and may agree with the views expressed in this article. The firm's clients, however, also include companies that manufacture and distribute drugs and may not agree with the views expressed in this article.

<sup>1</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

<sup>2</sup> Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note (1994)).

<sup>3</sup> For example, recent correspondence between the Food and Drug Administration (FDA) and the chairman of the U.S. House of Representatives' Committee on Government Reform in which, *inter alia*, the chairman cites a *New York Times* article in which a senior FDA official is said to have stated that FDA's "hands were tied by DSHEA," and FDA replied that the official did not make such a statement. Letter from Dan Burton, Chairman, Committee on Government Reform, U.S. House of Representatives, to Bernard Schwetz, Acting Commissioner, FDA (Jan. 22, 2002) (on file with authors); *see also* Reply Letter from Melinda K. Plaisier, Acting Commissioner for Legislation, FDA, to Dan Burton, Chairman, Committee on Government Reform, U.S. House of Representatives (Feb. 1, 2002) (on file with authors). *See also* David A. Kessler, *Editorial: Cancer and Herbs*, 342 NEW ENG. J. MED. 1742, 1743 (June 8, 2000) (Dr. Kessler is a former FDA Commissioner); Stephen H. McNamara, *Reply Letter to the Editor*, 343 NEW ENG. J. MED. 1270 (Oct. 26, 2000).

<sup>4</sup> 140 CONG. REC. S11, 173-79 (daily ed. Oct. 6, 1994); 140 CONG. REC. S14, 798-800 (daily ed. Oct. 7, 1994).

<sup>5</sup> *See infra* notes 6-15 and accompanying text.

ment substances.”<sup>6</sup> The Senate Committee also concluded, “FDA has attempted to twist the statute [i.e., the provisions of the FDCA, as it then existed] in what the Committee sees as a result-oriented effort to impede the manufacture and sale of dietary supplements.”<sup>7</sup>

Among the examples of FDA excesses described by the Senate Committee was FDA’s campaign to prevent the marketing of safe dietary supplements of black currant oil (from the same fruit used to make jam).<sup>8</sup> FDA argued that the addition of black currant oil to a gelatin capsule caused the black currant oil to become a “food additive” within the meaning of the FDCA, and that as a “food additive,” the substance could not be marketed as a dietary supplement without first obtaining FDA issuance of an approving “food additive” regulation.<sup>9</sup> In this regard, the Senate Committee noted the prohibitive costs and delays for dietary supplement manufacturers that were inherent in FDA’s attempt to require such “food additive” approval: “The cost to a manufacturer to prepare a food additive petition can run to \$2 million. FDA approval of a food additive petition typically takes from 2 to 6 years.”<sup>10</sup>

As Congress also noted, the federal courts had rejected repeatedly FDA’s allegations of “unapproved food additive” status and consequent illegality for dietary supplements of black currant oil, although FDA was still persisting to attack the product. For example, the U.S. Court of Appeals for the Seventh Circuit, in a unanimous three-judge opinion, stated as follows:

The only justification for this Alice-in-Wonderland approach [i.e., FDA’s “food additive” allegation] is to allow the FDA to make an end-run around the statutory scheme. . . . We hold that [black currant oil] encapsulated with glycerin and gelatin is not a food additive. . . . FDA has not shown that [black currant oil] is adulterated or unsafe in any way. . . .<sup>11</sup>

The U.S. Court of Appeals for the First Circuit, also in a unanimous three-judge opinion, ruled similarly to the Seventh Circuit:

FDA’s reading of the [FDC] Act is nonsensical. . . . 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 anfractuious reasoning.<sup>12</sup>

Another example noted by Congress of FDA excess was provided by the agency’s similar campaign to try to eradicate dietary supplements of evening primrose oil. Although evening primrose oil was (and remains today) widely available around the world as a safe and popular dietary supplement, FDA asserted that this substance, too, was an “unapproved food additive.”<sup>13</sup> As an illustration of the agency’s massive campaign, evidence was presented before the House of Representatives and the Senate in 1993

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<sup>6</sup> S. REP. NO. 103-410, at 16 (Oct. 8, 1994).

<sup>7</sup> *Id.* at 22.

<sup>8</sup> *United States v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part, Viponte Ltd. Black Currant Oil Batch No. BOOSF 039*, 984 F.2d 814 (7th Cir. 1993).

<sup>9</sup> *Id.*

<sup>10</sup> S. REP. NO. 103-410, *supra* note 6, at 21.

<sup>11</sup> *Black Currant Oil*, 984 F.2d at 819, 820.

<sup>12</sup> *United States v. Oakmont Investment Co.*, 987 F.2d 33, 37, 39 (1st Cir. 1993).

<sup>13</sup> *United States v. 45/194kg. Drums of Pure Vegetable Oil*, 961 F.2d 808 (9th Cir. 1992).

that the FDA Commissioner had awarded the Commissioner's Special Citation to 61 FDA personnel, who at that time comprised the "Evening Primrose Oil Litigation Team."<sup>14</sup>

Nevertheless, although two U.S. district courts and two three-judge U.S. courts of appeals had all unanimously rejected FDA's regulatory program, Congress concluded that unless it stepped in and passed DSHEA, the facts showed that FDA would continue to try to prohibit marketing of safe and proper dietary supplements by using its own interpretation of the then-existing law:

Although a fair reading of the current statute [i.e., the "food additive" provisions of the FDCA], as most recently interpreted by two United States courts of appeal, should make. . . amendment [of the FDCA by DSHEA] unnecessary, the committee has heard testimony that the FDA has rejected these [judicial] holdings. The committee is therefore concerned that the FDA will persist in such litigation, and thereby continue to subject small manufacturers to the choice of abandoning production and sale of lawful products, or accepting the significant financial burden of defending themselves against baseless lawsuits [brought by the FDA].<sup>15</sup>

So, when FDA last believed that it had comprehensive authority to preclear the use of dietary ingredients in dietary supplement products (under its "food additive" theory), both the federal courts and Congress concluded that the agency repeatedly had abused its authority to try to prevent the marketing of safe and proper dietary supplement products.<sup>16</sup>

It is important to remember this history, both because it helps to explain why, under current law, FDA is not entrusted with blanket pre-approval authority over the marketing of all dietary supplement products, and because it illustrates the risk of excessively-restrictive regulation that might be presented if FDA were to be given such comprehensive preclearance authority in the future.

### III. FDA'S EXISTING AUTHORITY OVER DIETARY SUPPLEMENTS UNDER DSHEA IS SUBSTANTIAL AND SUFFICIENT

Contrary to allegations raised by those who want to direct more powers to FDA to regulate dietary supplements, the agency has substantial and sufficient authority under DSHEA to provide ample protection for the public health, consistent with the type of authority that ought to be entrusted to such an agency in a free society.

#### A. *Requirements for Dietary Supplements*

##### 1. *Prohibition of Dietary Supplements That Present "Significant or Unreasonable Risk"*

DSHEA provides that a dietary supplement shall be deemed to be "adulterated"

<sup>14</sup> *Dietary Supplements, Before the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*, 103d Cong., 1st Sess. 208 (Oct. 18, 1993). See also S. REP. NO. 103-19, at 128 (Oct. 21, 1993).

<sup>15</sup> S. REP. NO. 103-410, *supra* note 6, at 21.

<sup>16</sup> Accordingly, one of the provisions of DSHEA amended the definition of "food additive" in the FDCA to provide explicitly that the term does not include dietary ingredients in dietary supplements. 21 U.S.C. § 321(s)(6) (FDCA § 201(s)(6)).

(and therefore illegal) if it presents, or if it contains a dietary ingredient that 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>17</sup> This provision does not require FDA to prove that a product will harm anyone; instead, a dietary supplement is deemed to be “adulterated” (illegal) if it simply presents a “significant or unreasonable risk” of illness or injury.

## 2. *Prohibition of Any “Poisonous or Deleterious Substances” in Dietary Supplements*

DSHEA retains and incorporates the section of the FDCA that provides that a food (this includes a dietary supplement<sup>18</sup>) shall be deemed to be “adulterated” (and accordingly illegal) if it “bears or contains any poisonous or deleterious substance which may render it injurious to health . . . under the conditions of use recommended or suggested in the labeling of such dietary supplement.”<sup>19</sup> This provision does not require FDA to prove that a substance will be injurious, only that it may render a product injurious.

## 3. *Prohibition of Dietary Supplements That Are “Unfit for Food”*

Another section of the FDCA, which was not modified by DSHEA and remains in full effect, provides that a food (again, this includes a dietary supplement<sup>20</sup>) shall be deemed to be “adulterated” (and accordingly illegal) if it is “unfit for food.”<sup>21</sup> This extremely expansive provision gives FDA plenary authority to take action to stop the marketing of any dietary supplement that the agency believes is not a fit item for human consumption.

## 4. *Prohibition of “Drug” Claims for Dietary Supplements*

DSHEA does not allow a dietary supplement to bear labeling claims that represent that the product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; claims that suggest such an intended use subject a dietary supplement to regulation as a drug.<sup>22</sup> Such a product becomes illegal if it fails to comply with all drug requirements, including the requirement for FDA approval of a “new drug” prior to marketing.<sup>23</sup>

## 5. *Requirement for Truthful and Informative Labeling*

The FDCA, as amended by DSHEA, and as implemented by FDA’s regulations, requires extensive informative labeling for dietary supplements, including an informative name for each product, the net quantity of contents, detailed information about the nutrients provided by the product, including the name and quantity of the dietary ingredients presented in a standard format (the “Supplement Facts” labeling), informa-

<sup>17</sup> *Id.* § 342(f)(1)(A) (FDCA § 402(f)(1)(A)).

<sup>18</sup> *Id.* § 321(ff) (FDCA § 201(ff)).

<sup>19</sup> *Id.* § 342(a)(1), (f)(1)(D) (FDCA § 402(a)(1), (f)(1)(D)).

<sup>20</sup> *Id.* § 321(ff) (FDCA § 201(ff)).

<sup>21</sup> *Id.* § 342(a)(3) (FDCA § 402(a)(3)).

<sup>22</sup> *Id.* §§ 321(g)(1)(B), 343(r)(6)(C) (FDCA §§ 201(g)(1)(B), 403(r)(6)(C)); 21 C.F.R. § 101.93(f) and (g).

<sup>23</sup> 21 U.S.C. §§ 321(p), 355 (FDCA §§ 201(p), 505).

tion about any other ingredients, and the name and place of business of the responsible company.<sup>24</sup> Failure to comply with any of these requirements causes a dietary supplement to be deemed “misbranded” (and accordingly illegal).

The FDCA also provides that a dietary supplement is “misbranded” (and accordingly illegal) if any of its labeling is “false or misleading in any particular.”<sup>25</sup>

## B. *Sanctions for Violations*

There are substantial and severe sanctions for violations of the above-described requirements. A dietary supplement that is “adulterated,” “misbranded,” or in violation of applicable drug requirements, is subject to seizure, condemnation, and destruction in the U.S. district courts.<sup>26</sup> A person who is responsible for the shipment of such a product in interstate commerce is subject both to an injunction action and to criminal prosecution.<sup>27</sup> Moreover, such a violative product is subject to FDA’s regulations concerning requests for recall,<sup>28</sup> and the importation from foreign countries into the United States of any product that simply “appears” to be violative in any manner described above is also prohibited.<sup>29</sup>

## C. *Examples of FDA Enforcement*

Since DSHEA has become law, FDA has undertaken a number of regulatory actions for violations of one or more of the requirements described above. These actions demonstrate that, when the agency wants to do so, it has ample powers under the current law to control dietary supplement products that present undue risk to the public health. For example:

### (1) *United States v. Syntrax Innovations, Inc.*<sup>30</sup>

In this civil seizure action, filed in the U.S. District Court for the Eastern District of Missouri, FDA obtained a ruling of seizure, condemnation, and destruction against the product “Triax,” which had been marketed and sold as a dietary supplement to assist in weight reduction but contained the active thyroid hormone tiratricol, which FDA regarded as unsafe for dietary supplement use. As urged by FDA, the court ruled that the product should be seized and condemned because it was really an illegal drug.

### (2) *United States v. Undetermined Quantities of Cases . . . Labeled in Part . . . Sign of Quality . . . Opti-Cran . . . Vitamin C Formula Plus SeaPlex . . . Ginseng . . . Garlic . . . Uva Ursi . . . Ginkgo Biloba . . . St. John’s Wort . . . Turmeric*<sup>31</sup>

This case implemented a mass seizure and condemnation of many different dietary supplement products that were not alleged to be unsafe in any respect but, nevertheless, were deemed to be illegal drugs

<sup>24</sup> 21 C.F.R. §§ 101.3, 101.4, 101.5, 101.36, 101.105.

<sup>25</sup> 21 U.S.C. § 343(a)(1) (FDCA § 403(a)(1)).

<sup>26</sup> *Id.* § 334 (FDCA § 304).

<sup>27</sup> *Id.* §§ 331, 332, 333 (FDCA §§ 301, 302, 303).

<sup>28</sup> Recalls, 21 C.F.R. pt. 7, subpt. C.

<sup>29</sup> 21 U.S.C. § 381(a) (FDCA § 801).

<sup>30</sup> 149 F. Supp. 2d 880 (E.D. Mo., Feb. 14, 2001).

<sup>31</sup> No. 00-C-0262-S (W.D. Wisc., May 1, 2000).

because the products' labels and labeling, . . . promotional literature, including information contained in their catalogs and web sites, and the circumstances surrounding the products' distribution, establish that the . . . products are intended to be used in the cure, mitigation, treatment and prevention of diseases. . . .<sup>32</sup>

(3) *United States v. World Without Cancer, Inc.*<sup>33</sup>

This case secured injunctions to stop the improper promotion of laetrile products for the treatment of cancer. Injunctions against multiple defendants were obtained in less than a month.

(4) *United States v. Ten Cartons . . . ENER-B Nasal Gel*<sup>34</sup>

This was a successful FDA-initiated seizure and condemnation, affirmed by the U.S. Court of Appeals for the Second Circuit, of a purported dietary supplement that FDA successfully maintained was really a drug, although it provided vitamin B<sub>12</sub> to the body because it was absorbed into the body through the nasal mucosa instead of being swallowed.

(5) FDA Import Alert No 54-10<sup>35</sup> stopped the importation of dietary supplements containing aristolochic acid, a contaminant FDA believes to be carcinogenic.

(6) On January 21, 1999, FDA issued a public warning and announced a recall of dietary supplement products that contained gamma butyrolactone because of "reports of serious health problems."<sup>36</sup>

(7) On October 31, 2001, FDA announced a civil seizure of a quantity of ephedrine hydrochloride products that had been distributed as dietary supplements but were alleged really to be illegal drugs.<sup>37</sup>

#### IV. NEW DIETARY INGREDIENTS

DSHEA also includes additional safety-related requirements with respect to the introduction into commerce in the United States of *new* dietary ingredients. A "new dietary ingredient" is defined as "a dietary ingredient that was not marketed in the United States before October 15, 1994."<sup>38</sup> DSHEA provides that, in addition to all of the other safety-related requirements described above in this article, a dietary supplement

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<sup>32</sup> *Id.* Complaint at 7 (on file with authors).

<sup>33</sup> (S.D. Fla. Aug. 25, 2000) (unpublished opinion) (on file with authors).

<sup>34</sup> 888 F. Supp. 381 (E.D.N.Y. 1995), *aff'd*, 72 F.3d 285 (2d Cir. 1995).

<sup>35</sup> FDA, Import Alert No. 54-10, Detention Without Physical Examination of Bulk or Finished Dietary Supplements and Other Products That May Contain Aristolochic Acid (July 6, 2000) (revision Apr. 6, 2001), *available at* (last visited Mar. 20, 2002) [www.fda.gov/ora/fiars/ora\\_import\\_ia5410.html](http://www.fda.gov/ora/fiars/ora_import_ia5410.html).

<sup>36</sup> FDA Talk Paper No. T99-5, FDA Warns About Products Containing Gamma Butyrolactone or GBL and Asks Companies to Issue a Recall (Jan. 21, 1999), *available at* (last visited Mar. 20, 2002) [www.fda.gov/bbs/topics/ANSWERS/ANS00937.html](http://www.fda.gov/bbs/topics/ANSWERS/ANS00937.html).

<sup>37</sup> FDA Talk Paper No. T01-53, U.S. Marshals Seize Unapproved Drug in FDA Case, (Oct. 31, 2001), *available at* (last visited Mar. 20, 2002) [www.fda.gov/bbs/topics/ANSWERS/2001/ANS01114.html](http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01114.html).

<sup>38</sup> 21 U.S.C. § 350b(c) (FDCA § 413(c)).

that contains a “new dietary ingredient” shall be deemed to be “adulterated” (and subject to all of the enforcement sanctions described above) unless, *either*: 1) 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,”<sup>39</sup> *or*, 2) 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 of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides 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>40</sup>

In essence, if a dietary ingredient that is to be used in a dietary supplement was not marketed in the United States before October 15, 1994, and if the ingredient has not otherwise been present in the food supply as an article used for food in a form that has not been chemically altered, the dietary ingredient may not be marketed in a dietary supplement product unless one first submits evidence of safety to FDA and waits at least 75 days for a response from the agency about whether the ingredient may be marketed.

FDA has published regulations to govern the submission to the agency of “new dietary ingredients notifications,”<sup>41</sup> and the agency has processed numerous notifications of this type and has notified a number of companies not to market particular “new dietary ingredients” in the United States.<sup>42</sup>

It also should be noted that this requirement for FDA notification before marketing a new dietary ingredient for use in dietary supplements is more stringent than the requirements that apply to the marketing of new ingredients in other food products (i.e., for conventional foods, unlike dietary supplements, so long as a manufacturer determines for itself that a new food ingredient is “generally recognized as safe” (GRAS), the manufacturer is free to market that ingredient for food use without any notice to, or preclearance by FDA).<sup>43</sup>

## V. AUTHORITY IMMEDIATELY TO STOP MARKETING OF ANY DIETARY SUPPLEMENT THAT PRESENTS AN “IMMINENT HAZARD”

In addition to all of the other provisions described above, DSHEA authorizes the Secretary of the Department of Health and Human Services immediately to stop shipment of any dietary supplement product by declaring it “to pose an imminent hazard to public health or safety.”<sup>44</sup> If the Secretary declares a dietary supplement or dietary

<sup>39</sup> *Id.* § 350b(a) (FDCA § 413(a)).

<sup>40</sup> *Id.*

<sup>41</sup> 21 C.F.R. § 190.6.

<sup>42</sup> FDA actions are on public display in FDA Docket No. 95S-0316, FDA Dockets Management Branch, 5630 Fishers Lane, Rm. 1061, Rockville, MD.

<sup>43</sup> 62 Fed. Reg. 18,938, 18,941 (Apr. 17, 1997) (“a manufacturer may market a substance that the manufacturer determines is [generally recognized as safe] GRAS without informing the agency [FDA]”).

<sup>44</sup> 21 U.S.C. § 342(f)(1)(C) (FDCA § 402(f)(1)(c)).

ingredient "to pose an imminent hazard," the government must promptly thereafter conduct an administrative proceeding to review the merits of the "imminent hazard" conclusion. During the proceeding, however, the product cannot be sold to the public.

This "imminent hazard" authority over dietary supplements is a power that the government does not have over other food products. The FDCA does not provide any similar "imminent hazard" authority to the Secretary with respect to conventional foods or ingredients in conventional foods (i.e., under DSHEA the government has more power to immediately stop the marketing of a dietary supplement than it has for any conventional food).

## VI. GOOD MANUFACTURING PRACTICES

DSHEA also authorizes FDA to issue regulations to "prescribe good manufacturing practices for dietary supplements," and the law provides that a dietary supplement shall be deemed to be "adulterated" (and subject to all of the sanctions described above) if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations . . . issued by [FDA]."<sup>45</sup>

More than two years after the passage of DSHEA, FDA published an "advance notice of proposed rulemaking" concerning good manufacturing practice (GMP) regulations for the dietary supplement industry.<sup>46</sup> At the time this article was written, however, more than seven years after DSHEA was passed, and more than five years after publishing the "advance notice," FDA still had not published proposed regulations for public comment. It is hoped that the agency will publish proposed regulations, based on comments received in response to the "advance notice." When FDA eventually issues final regulations, they will have the status of law and will be subject to enforcement in the courts.<sup>47</sup>

## VII. TWO PARTICULAR ISSUES

There are two particular types of possible additional regulation that are sometimes mentioned by those who push for greater FDA control of dietary supplements: mandatory manufacturer/product registration and mandatory reporting of adverse experiences.

### A. *Mandatory Registration of Manufacturers or Products*

It is true that under current law there is no provision for mandatory registration with FDA of manufacturers of dietary supplements or of the products themselves. With respect to such registration, however, there is no reason to focus on dietary supplements apart from other types of food. The law recognizes that dietary supplements are a type of food,<sup>48</sup> and there are no requirements in the FDCA for registration with FDA of food manufacturers or food products generally. Accordingly, dietary supplements are not subject to some unusual exemptive treatment in this regard.

If Congress wants to consider imposing requirements for mandatory registration with FDA of food manufacturers and food products, and establishing an additional national government bureaucracy to manage such a registration program, such consideration should focus on foods generally. There is no reason to focus solely or particu-

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<sup>45</sup> *Id.* § 342(g) (FDCA § 402(g)).

<sup>46</sup> 62 Fed. Reg. 5700-09 (Feb. 6, 1997).

<sup>47</sup> 21 U.S.C. § 342(g)(1) (FDCA § 402(g)(1)).

<sup>48</sup> *Id.* § 321(ff) (FDCA § 201(ff)).



larly on dietary supplements, or to treat dietary supplements differently than other foods in this respect. Indeed, if risk to human health would be the reason for requiring registration, many other categories of food would appear to present greater risks than dietary supplements (e.g., unpasteurized beverages, which have killed and caused serious injury because of *E. coli*; fresh fruits and vegetables, which can harbor several serious disease-causing organisms; bean sprouts, which can harbor deadly *Listeria monocytogenes*; and oysters or other shellfish, which kill several persons each year in the United States because of harmful microbial organisms).

### B. *Mandatory Reporting of Adverse Product Experiences*

Similarly, with regard to the reporting of adverse product experiences, there is no reason to distinguish dietary supplements from other food products. There is no requirement in the FDCA for reporting adverse experiences to FDA with respect to foods generally, and dietary supplements are not subject to some special exemption in this respect.

Furthermore, currently there also is no general requirement for the reporting of adverse experiences to FDA, even with respect to nonprescription (over-the-counter) drug products. There would appear to be little reason why a mandatory adverse experience reporting system and a government bureaucracy to manage the system should be established for dietary supplements such as tablets of vitamin C, when such requirements do not apply to aspirin or other nonprescription drugs.

## VIII. FDA HAS MISAPPLIED ITS EXISTING RESOURCES AND AUTHORITY

FDA appears to have allocated or applied its current resources and authority under DSHEA in a way that may have suggested to the public, inaccurately, that the agency lacks sufficient authority over the marketplace. Sometimes the agency has not enforced the authority that it possesses; sometimes the agency has asserted that certain requirements exist but then has not followed up to enforce; and sometimes the agency has expended substantial resources unsuccessfully on inappropriate targets. All of these actions can contribute to an inaccurate public misperception that the agency lacks sufficient authority.

For example, this article already has noted how FDA, for years, has delayed implementing the substantial authority that DSHEA gives the agency to issue regulations to establish mandatory GMP requirements.

As another example, although the agency issued a *Federal Register* announcement that current law requires that all dietary supplement products contain 100% of the labeled amount of each added dietary ingredient for the entire shelf life of the supplement,<sup>49</sup> the agency has not made any sustained effort to follow up, investigate, and take regulatory actions against dietary supplement products that have been reported in the media not to contain the full amount of the ingredients declared on their labels. FDA has ample authority to act against supplements that do not provide the full amounts of the nutrients they are labeled as providing; yet the agency has done almost nothing to use this authority.

And, as another example, FDA proposed to restrict drastically the strength and uses of ephedra-containing dietary supplement products in a "proposed rule" published in the *Federal Register*.<sup>50</sup> After expending considerable resources on this pro-

<sup>49</sup> 62 Fed. Reg. 49,838-39 (Sept. 23, 1997).

<sup>50</sup> *Id.* at 30,678-724 (June 4, 1997).

posal and after the affected industry spent considerable resources to respond, the agency was compelled to withdraw major portions of its proposal when an audit by the U.S. Government General Accounting Office found the agency's reliance upon invalidated adverse experience reports to have been scientifically flawed.<sup>51</sup>

## IX. CONCLUSION

In sum, it appears that the situation with respect to FDA's regulation of dietary supplements is not that FDA lacks sufficient authority to regulate effectively, rather, it is that FDA has not used appropriately the ample authority it possesses.

FDA's existing powers described in this article clearly are substantial and are more than sufficient for the agency to regulate dietary supplements successfully for the protection of the public health. There is no need to amend DSHEA to increase FDA's authority over such products.

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<sup>51</sup> GOVERNMENT ACCOUNTING OFFICE, DIETARY SUPPLEMENTS: UNCERTAINTIES IN ANALYSES UNDERLYING FDA'S PROPOSED RULE ON EPHEDRINE ALKALOIDS (Aug. 4, 1999), *available at* (last visited Mar. 20, 2002) [www.ephedrafacts.com/gaoreport.pdf](http://www.ephedrafacts.com/gaoreport.pdf); FDA Notice, Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part, , 65 Fed. Reg. 17,474-77 (Apr. 3, 2000).