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**GROCERY MANUFACTURERS OF AMERICA**

MAKERS OF THE WORLD'S FAVORITE BRANDS OF  
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: First Amendment Issues  
67 Fed. Reg. 34942 (May 16, 2002)  
Docket No. 02N-0209

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage, and consumer brand companies. With consumer sales of more than \$460 billion, GMA member companies employ more than 2.5 million workers in all fifty states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues. Because the impact of the First Amendment on numerous Food and Drug Administration (FDA) regulations and policies under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is of major importance to the entire food industry, GMA and its member companies have a substantial interest in the application of this fundamental constitutional principle to the regulation of commercial speech under recent judicial decisions.

Executive Summary

The commercial speech doctrine enunciated in Supreme Court and lower court decisions has now been recognized by the Supreme Court as fully applicable to FDA decisions under the recent case of Thompson v. Western States Medical Center.<sup>1</sup> Accordingly, it is

<sup>1</sup> 122 S. Ct. 1497 (2002).

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incumbent upon FDA to review its regulations and policies to determine that they comply fully with the First Amendment protections afforded to commercial speech. GMA applauds FDA for promptly opening up these issues to full public consideration in accordance with the above-cited notice.

GMA submits these comments to make the following four points. First, the FDA standard for judging “misleading” food labeling under Section 403(a) of the FD&C Act must be changed from protecting the “ignorant, unthinking, and credulous” to protecting the reasonable person. Second, the severe limitations on structure/function claims for both conventional food and dietary supplements must be substantially reduced, and there must be a parity of structure/function claims between conventional food and dietary supplements. Third, FDA must revise its regulations governing nutrient descriptors (content claims) to allow greater use of synonyms, increased use of comparative claims, and use of nonmisleading terms that are not yet defined by FDA. Fourth, FDA must revise its regulations and policies with respect to disease (health) claims for food, to broaden the narrow scope of permitted disease claims under the current regulations, to recognize that such claims can in appropriate situations cover both treatment and prevention of disease, to establish a parity of claims between conventional food and dietary supplements, and to recognize that dietary supplements can appropriately be marketed in conventional food form as long as they remain clearly distinguishable.

I. Introduction.

Beginning in 1976, the United States Supreme Court has consistently determined that commercial speech is subject to qualified protection under the First Amendment.<sup>2</sup> The Supreme Court developed a four-part test to determine whether any restriction on commercial speech is compatible with First Amendment protection in the Central Hudson decision in 1980.<sup>3</sup> To survive First Amendment scrutiny, the government must justify the restriction on the ground either that (1) the speech involves unlawful activity or is false or misleading, or that (2) there is a substantial governmental interest in regulating the speech and (3) the governmental restriction directly advances that interest and (4) the restriction is no more extensive than necessary to achieve that legitimate governmental interest.

Since the Virginia Board of Pharmacy and Central Hudson decisions, the Supreme Court has established the following five fundamental rules that are of direct importance in reviewing current FDA regulations and policy:

First, the government may not restrict commercial speech on the mere assertion that it is “potentially” misleading.<sup>4</sup> The government has the burden of proving that the speech to which it objects is actually or inherently misleading.

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<sup>2</sup> Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

<sup>3</sup> Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980).

<sup>4</sup> E.g., Ibanez v. Florida Department of Business and Professional Regulation, 512 U.S. 136, 146 (1994).

Second, the value of the commercial speech that is at issue is irrelevant.<sup>5</sup> All speech is presumed to be protected by the First Amendment regardless of its intrinsic worth.

Third, commercial speech may not be restricted on the fear that the public could misuse the information. The Supreme Court has repeatedly said that this “highly paternalistic approach” conflicts with First Amendment rights.<sup>6</sup>

Fourth, the government cannot discriminate among persons who are permitted and not permitted to engage in the specific commercial speech involved.<sup>7</sup> If one entity or group is permitted to disseminate the commercial speech at issue, others must similarly be permitted to do so.

Fifth, the First Amendment requires that the regulation of commercial speech “must be a last -- not a first -- resort.”<sup>8</sup>

In the context of these five broad and fundamental constitutional principles, GMA urges FDA to address changes in four important areas of commercial speech that directly affect the food industry: (1) the standard for determining whether labeling is misleading under Section 403(a)

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<sup>5</sup> E.g., Edenfield v. Fane, 507 U.S. 761, 767 (1993).

<sup>6</sup> E.g., Virginia Board of Pharmacy, 425 U.S. at 765; 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996).

<sup>7</sup> E.g., Rubin v. Coors Brewing Co., 514 U.S. 476, 488-489 (1995).

<sup>8</sup> E.g., Thompson, 122 S. Ct. at 1507.

of the FD&C Act, (2) the regulation of structure/function claims, (3) the regulation of nutrient descriptors, and (4) the regulation of disease claims.

II. The FDA Standard for “Misleading” Labeling Under Section 403(a) of the FD&C Act Should be Changed.

In a series of cases over the past fifty years, FDA has successfully argued in court that the statutory prohibition against labeling that is “misleading in any particular” must be interpreted and applied to protect “the ignorant, the unthinking, and the credulous” consumer:

“The Act as a whole was designed primarily . . . to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze.”<sup>9</sup>

“. . . the test is not the effect of the label on a ‘reasonable consumer,’ but upon ‘the ignorant, the unthinking, and the credulous’ consumer.”<sup>10</sup>

“We have construed section 343 broadly, since the test is not the effect on the label of a reasonable consumer, but upon ‘the ignorant, the unthinking and the credulous’ consumer.”<sup>11</sup>

In effect, this is no standard at all. No food labeling could possibly pass this test if it were applied literally. Some consumers will misunderstand even the clearest and most unambiguous statement. Even the FDA-required nutrition labeling format is regarded by many consumers as confusing and misleading.

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<sup>9</sup> United States v. El-O-Pathic Pharmacy, 192 F.2d 62, 75 (9th Cir. 1951).

<sup>10</sup> United States v. An Article of Food . . . “Manischewitz . . . Diet Thins,” 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

<sup>11</sup> United States v. Strauss, 999 F.2d 692, 696 (2d Cir. 1993).

The Federal Trade Commission (FTC) has addressed this same issue under virtually the identical statutory mandate. During the five-year legislative history of the FD&C Act prior to enactment in 1938, one of the major issues involved was whether FDA or the FTC should have jurisdiction over food advertising. Congress settled this issue in 1938 by enacting two separate statutes -- the FD&C Act,<sup>12</sup> which gave FDA jurisdiction over food labeling, and the Wheeler-Lea Act<sup>13</sup> which amended the FTC Act to give the FTC jurisdiction over food advertising. New sections 12 and 15 of the FTC Act expressly prohibited any food advertising that is “misleading in a material respect.”<sup>14</sup> Thus, the statutory standards for the prohibition of misleading food labeling and misleading food advertising have been indistinguishable since they were enacted in 1938.

In 1963, the FTC recognized that the type of standard for “misleading” information imposed by FDA was unworkable:

“An advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all ‘Danish pastry’ is made in Denmark. Is it therefore an actionable deception to advertise ‘Danish pastry’ when it is made in this country? Of course not. A representation does not become ‘false or deceptive’ merely because it will be unreasonably misunderstood by an

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<sup>12</sup> 52 Stat. 1040 (1938).

<sup>13</sup> 52 Stat. 111 (1938).

<sup>14</sup> 15 U.S.C. 52 and 55.

insignificant and unrepresentative segment of the class of persons to whom the representation is addressed.”<sup>15</sup>

At that time, the FTC standard for misleading advertising included any statement that had the tendency and capacity to mislead or deceive a prospective purchaser. During the next twenty years FTC decisions began to reflect reliance on a “reasonable person” standard. In October 1983, the FTC reconsidered its standard for misleading advertising and, finding the old one to be circular, officially adopted a new approach. Under the new policy, the FTC concluded that the determination of whether an advertisement is misleading “must be considered from the perspective of the reasonable consumer.”<sup>16</sup> The FTC stated unequivocally that “The test is whether the consumer’s interpretation or reaction is reasonable.” Applying this “reasonable person” standard consistently during the past twenty years, the FTC has taken major action to protect consumers. It has, in fact, brought far more formal enforcement actions against misleading food advertising than the FDA has brought against misleading food labeling. Adoption of the reasonable consumer standard has therefore not diminished public protection.

In continuing to use the ignorant, unthinking, and credulous consumer standard, FDA is violating several of the most important First Amendment principles adopted by the Supreme Court in recent years. In spite of a virtually identical statutory standard, it bans from food labeling commercial speech that is permitted in food advertising. It is a paternalistic approach that proceeds on the assumption that anything that is potentially misleading or that

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<sup>15</sup> Heinz W. Kirchner, 63 F.T.C. 1282, 1290 (1963).

<sup>16</sup> 103 F.T.C. 174, 177 (1984).

could potentially be misused should be banned. It fails to recognize that banning speech is a last resort. Accordingly, to avoid violating the First Amendment GMA urges FDA to abandon this antiquated standard and to adopt the reasonable person standard that the FTC has successfully used for twenty or more years.

III. FDA Regulation of Structure/Function Claims.

A. Restrictions On the Scope of Structure/Function Claims Should be Reduced.

Under the definition of a “drug” in Section 201(g)(1)(C) of the FD&C Act, food labeling is explicitly permitted to include claims relating to the intended affect on the structure or any function of the body of man, without classifying the product as a drug. Recognizing this, in the Dietary Supplement Health and Education Act of 1994 Congress specifically permitted, as “statements of nutritional support,” a claim for a dietary supplement that:

“ . . . describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function. . . .”<sup>17</sup>

These 1938 and 1994 statutory provisions are indistinguishable in scope. Indeed, it is apparent that Congress regarded the 1994 statutory language as simply an explication of the 1938 statutory provision. Both the 1938 and the 1994 statutes also explicitly forbid disease claims for a food (except for those approved by FDA under the Nutrition Labeling and Education Act of 1990).

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<sup>17</sup> Section 403(r)(6)(A) of the FD&C Act.

Neither the 1938 nor the 1994 statute authorizes FDA to regard as disease claims a structure/function claim that indirectly or impliedly relates to a disease. If Congress had wished to take that approach, it could have done so. In other provisions of the FD&C Act, Congress has in fact used the phrase “expressly or by implication” and “directly or indirectly” in order to sweep broadly rather than to target narrowly.<sup>18</sup> In distinguishing between structure/function and disease claims, however, Congress chose not to do so.

In promulgating regulations that purport to distinguish between structure/function and disease claims, however, FDA swept within the disease category all structure/function claims that FDA concluded are “implied” as well as “express” disease claims.<sup>19</sup> GMA pointed out at the time not only that this violated the statute but that it was in fact quite feasible to divide what FDA has designated as the “implied” disease claims into two categories: those that are direct implied claims and those that are indirect implied claims. GMA submitted a petition (FDA Docket 98N-004, PRC 5) requesting that FDA make that distinction in order to effectuate the congressional purpose. In that petition, GMA urged FDA to include within the implied disease claim category only those claims where there is a direct causal relationship between the structure or function parameter in the claim and a specific known disease, citing specific congressional intent as well as the First Amendment. FDA has not yet responded to that petition.

This broad assertion that structure/function claims that refer only to physiological mechanisms that maintain good health -- and that do not refer to any disease condition or process

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<sup>18</sup> E.g., Sections 403(r)(1) and 403a(A) of the FD&C Act.

<sup>19</sup> 21 C.F.R. 101.93(g)(2); 65 Fed. Reg. 1000 (January 6, 2000).

-- nonetheless constitute "implied" disease claims directly violates the First Amendment principles outlined above. The result of this FDA regulation is to ban truthful and nonmisleading commercial speech. FDA presented no evidence of any kind to support its assertion that the structure/function claims that it is banning are actually understood by consumers as drug claims. Instead, FDA took the paternalistic approach that consumers should be denied this type of information because it might potentially be misunderstood or misused. Yet this information is routinely provided in food advertising, where it is not only accepted but even encouraged by the FTC because it is truthful, not misleading, and helpful to consumers in improving their own health.

GMA therefore urges FDA to reopen the structure/function regulation for reconsideration under the First Amendment principles outlined in these comments. These regulations should be revised to recognize the Supreme Court's stricture that the prohibition of truthful and accurate speech, which is not misleading in any particular, is the last resort, not the first resort, and must be fully supported by documented evidence.

B. Structure/Function Claims for Conventional Food Should be at Least on a Parity with Structure/Function Claims for Dietary Supplements.

On several occasions -- most notably in promulgating the structure/function regulations -- FDA has refused to deal equally with the scope of structure/function claims for conventional food and dietary supplements.<sup>20</sup> FDA made this distinction on the pretext that the Dietary Supplement Health and Education Act dealt only with dietary supplements. FDA

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<sup>20</sup> Id. at 1034

ignored the fact that the FD&C Act has specifically permitted structure/function claims for all food (including dietary supplements) since 1938. FDA has sought thereby to discourage commercial speech and chill the First Amendment rights of the conventional food industry.

It is incumbent on FDA to recognize that conventional food and dietary supplements have the same rights to make accurate and nonmisleading structure/function claims. The First Amendment prohibits FDA from discriminating between these two type of consumer products as long as the claims are accurate, truthful, and not misleading.

IV. FDA Regulation of Nutrient Descriptors.

A. Permitted Use of Synonyms Should be Expanded.

When Congress enacted the Nutrition Labeling and Education Act, it authorized FDA to establish definitions of nutrient descriptors for food labeling.<sup>21</sup> The statutory provisions state that food labeling may only include terms which are defined in FDA regulations. Although the statute did not specifically authorize FDA to prohibit synonyms of defined terms, FDA chose as a matter of policy to take that approach. Under current regulations, FDA has banned nutrient descriptor terms not explicitly authorized in the regulations<sup>22</sup> and permits only reasonable variations in the spelling of authorized terms.<sup>23</sup>

GMA submitted comments urging the use of an unlimited number of truthful and nonmisleading synonyms and gave specific examples. FDA rejected this approach. Neither in

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<sup>21</sup> Section 403(r)(1)(A) of the FD&C Act.

<sup>22</sup> 21 C.F.R. 101.54(a)(1).

<sup>23</sup> 21 C.F.R. 101.13(b)(4).

the preamble nor in the rulemaking record did FDA provide evidence to support an argument that other synonyms, such as those submitted by GMA, are in fact misleading to consumers.<sup>24</sup>

The FTC has specifically recognized the fallacy of the FDA approach. In its Enforcement Policy Statement on Food Advertising of June 1994,<sup>25</sup> the FTC said that it will apply the FDA nutrient descriptor definitions in its regulation of food advertising, but that it would not accept the FDA limitations on synonyms for defined descriptors. Instead, the FTC adopted a much broader approach, consistent with the requirements of the First Amendment:

“The Commission will examine advertising to ensure that claims that characterize the level of a nutrient, including those using synonyms that are not provided for in FDA’s regulations, are consistent with FDA definitions.”<sup>26</sup>

This is the approach that GMA urged FDA to adopt in its own regulations.

The current regulations are in direct conflict with fundamental First Amendment principles. They ban truthful and nonmisleading commercial speech without evidence of consumer deception. They ban the very terms that are permitted by the Federal Trade Commission in advertising. GMA urges FDA to revise its current regulations to permit all truthful and nonmisleading synonyms in compliance with the First Amendment.

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<sup>24</sup> 58 Fed. Reg. 2302, 2319-2320 (January 6, 1993).

<sup>25</sup> 59 Fed. Reg. 28388 (June 1, 1994).

<sup>26</sup> Id. at 28391.

B. Permitted Use of Comparative Claims Should be Broadened.

Under the Nutrition Labeling and Education Act, FDA has also restricted the use of comparative claims far beyond what is needed to assure truthful and nonmisleading labeling.<sup>27</sup>

The FDA regulations unequivocally ban accurate and nonmisleading comparative claims.

Recognizing this, the FTC adopted the following approach:

“ . . . a comparative advertising claim that is accurately qualified to identify the nature of a nutrient difference and to eliminate misleading implications may comply with section 5 [of the FTC Act] even if the nutrient difference does not meet FDA’s prescribed differences for purposes of labeling.”<sup>28</sup>

The FTC recognized that it is in the interest of consumers to obtain accurate and useful comparative claims even when they do not meet the FDA restrictions.

The severe FDA restrictions on comparative claims cannot withstand First Amendment scrutiny. FDA offered no evidence to support the assertion that banned comparative claims are in fact misleading or result in consumer harm. FDA has banned comparative claims that the FTC recognized can be accurate and not misleading. GMA therefore urges FDA to reopen the regulations governing comparative claims in order to review these restrictions under First Amendment principles.

C. Use of Undefined Terms Should be Authorized.

Under Section 403(r)(2)(A)(i) of the FD&C Act, as added by the Nutrition Labeling and Education Act, a term that is not defined by FDA cannot be used in food labeling.

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<sup>27</sup> 21 C.F.R. 101.13(j).

<sup>28</sup> 59 Fed. Reg. at 28391.

Thus, the simple failure of FDA to define a category of nutrients automatically bans any reference to that category, even if that category is well-recognized in the nutrition profession and is widely used by nutritionists and dietitians in recommending appropriate diets to the public.

One example is the term “complex carbohydrates.” This subcategory of the total carbohydrate category has not been recognized and defined by FDA, despite its almost universal acceptance in the nutrition community.<sup>29</sup> Text books, consumer publications, professional advice, and a whole host of publicly available nutrition information include reference to complex carbohydrates. By refusing to recognize it, FDA has completely banned use of this terminology in food labeling, even though it is used in all other forms of communication, including food advertising.

The food industry has requested FDA to establish a definition of this nutrient subcategory, but FDA has declined to do so without citing any evidence that this subcategory is in any way an inaccurate or misleading term. This refusal to recognize terminology that is widely accepted by others represents a clear violation of the First Amendment. GMA urges FDA either to reopen this matter, in order to achieve an acceptable definition, or to recognize the right of food manufacturers to refer in food labeling to definitions used by professional societies and others in the nutrition community.

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<sup>29</sup> 58 Fed. Reg. 2079, 2085, 2100-2101 (January 6, 1993); 58 Fed. Reg. 2302, 2345 (January 6, 1993).

V. Disease Claims.

A. The FDA Regulations Should be Revised to Reflect the Statutory Standard.

The Nutrition Labeling and Education Act authorized FDA to approve disease claims for food. In its proposed and final regulations,<sup>30</sup> FDA sought to narrow the scope of this statutory authority in order to accomplish two objectives. First, FDA limited claims to those that meet an extremely high standard, often compared to the standard used for approval of new drugs or to a scientific consensus standard. This high standard has drastically reduced the number of disease claims approved by FDA for food labeling. Second, FDA also eliminated all claims that accurately and truthfully describe studies that are at the beginning or in the middle of developing a scientific consensus but that have not yet achieved the level demanded by FDA for approval. This ban has eliminated all reference to emerging science from food labeling, no matter how accurately and truthfully such claims could be and no matter how much this might assist individuals in improving their personal and family health. The result has been severely to limit truthful, accurate, and nonmisleading information in food labeling on the relationship of diet to disease.

One of the purposes of the Nutrition Labeling and Education Act was to provide useful information to consumers in order to promote a public understanding of the relationship of diet to disease and health. Instead, FDA has restricted this information. For both statutory and constitutional reasons, FDA should revise its current regulations both to change the standard for

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<sup>30</sup> 56 Fed. Reg. 60537 (November 27, 1991); 58 Fed. Reg. 2478 (January 6, 1993); 21 C.F.R. 101.14.

approval of disease claims and to permit those claims that accurately and truthfully present emerging science.

The FDA prohibition against qualified disease claims is contrary to the statute. Under Section 403(r)(1)(B) of the FD&C Act, as added by the Nutrition Labeling and Education Act, Congress has explicitly authorized claims in food labeling that characterize the relationship of any nutrient to a disease. Section 403(r)(3)(B) states only that there must be “significant scientific agreement” that the claim is supported by the totality of publicly available scientific evidence. Nothing in the statute authorizes FDA to prohibit claims about emerging science, as long as the claim is accurate, truthful, and not misleading, and there is significant scientific agreement that the claim, as qualified, is supported by the totality of the publicly available scientific evidence. For example, there may be “significant scientific agreement” that two preliminary studies suggest a nutrient/disease relationship, but that further studies are needed to determine whether there is a causal relationship, far earlier than there will be “significant scientific agreement” that the nutrient/disease relationship is definitively established. Neither the FD&C Act nor the First Amendment permits FDA to deprive the public of potentially helpful preliminary scientific information on which to make their own informed health decisions.

The FTC has specifically recognized that the FDA approach is untenable. In its Enforcement Policy Statement on Food Advertising of June 1994, the FTC disavowed the FDA standard as the sole criterion for determining the acceptability of disease claims for food

labeling.<sup>31</sup> Noting that “the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products,” the FTC said that, in reviewing disease claims that have not received FDA approval, it would employ the “competent and reliable scientific evidence” standard that it enunciated in 1984.<sup>32</sup> The FTC explicitly recognized that there may be some food disease claims that are not authorized by FDA, but that would be regarded by the FTC as not misleading “if the claims are expressly qualified to convey clearly and fully the extent of the scientific support.”<sup>33</sup> Thus, once again, the FDA has banned disease prevention claims under an approach that not only violates the statute but that conflicts with the FTC approach and that contravenes the First Amendment. Particularly in the area of emerging science, where new information can readily be presented in a clear, truthful, and nonmisleading way, the FDA must reopen its regulations governing disease claims to recognize that it does not have the power to ban truthful commercial speech.

B. The Scope of Permitted Disease Claims Should be Broadened.

Section 403(r)(1)(B) of the FD&C Act, as added by the Nutrition Labeling and Education Act, explicitly authorizes claims in food labeling that characterize the relationship of any nutrient “to a disease.” Section 201(g)(1) was amended to exclude these disease claims from the definition of a drug. These provisions do not state that such claims must be limited to prevention of disease. Yet FDA has interpreted this provision to permit only disease prevention

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<sup>31</sup> 59 Fed. Reg. at 28393.

<sup>32</sup> 104 F.T.C. 839 (1984).

<sup>33</sup> 59 Fed. Reg. at 28394.

claims and to prohibit disease treatment claims.<sup>34</sup> Nothing in the statute permits this restriction on commercial speech. Nor can such a restriction withstand First Amendment scrutiny.

The FTC does not recognize this distinction. Food disease treatment claims are governed by the same rules of deception and substantiation as food disease prevention claims by the FTC. There is no reason why the FDA cannot also distinguish the truthful from the misleading and the supported from the unsubstantiated, rather than prohibiting an entire class of claims altogether.

GMA urges FDA to abandon this attempt to ban legitimate disease treatment claims for food labeling. Such a ban unquestionably violates the First Amendment principles identified in these comments.

C. Disease Claims for Conventional Food Should be at Least on a Parity with Disease Claims for Dietary Supplements.

Following the decision in Pearson v. Shalala,<sup>35</sup> FDA purported to limit the application of that case to dietary supplements and to exclude conventional food. GMA submitted comments objecting to this approach and then petitioned FDA to authorize the same disease claims for conventional food that FDA has permitted for dietary supplement under the Pearson decision. Because of the importance of this matter, GMA prepared a substantial analysis of this particular matter prior to the date of the FDA notice requesting comments on First

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<sup>34</sup> E.g., 65 Fed. Reg. 14219, 14221-14222 (March 16, 2000); letter from Director of the FDA Center for Food Safety and Applied Nutrition Joseph A. Levitt to Jonathan W. Emord (May 26, 2000).

<sup>35</sup> 164 F.3d 650 (D.C. Cir. 1999).

Amendment issues. This analysis has already been submitted as part of the record of this proceeding. Accordingly, it is unnecessary to reiterate those GMA comments here.

D. Dietary Supplements Should be Permitted In Food Form.

As part of the Dietary Supplement Health and Education Act, Congress repealed the prohibition against dietary supplements in food form that had been included in the Vitamin-Mineral Amendments of 1976 and retained only the prohibition that a dietary supplement may not be represented for use as a conventional food.<sup>36</sup> Recognizing this statutory change, FDA stated in the preamble to the final regulations implementing the labeling requirements of the Dietary Supplement Health and Education Act that a dietary supplement could be made in food form.<sup>37</sup> Subsequently, however, FDA officials have stated that dietary supplements cannot be marketed in food form, even with clear and nonmisleading labeling. Yet it is common knowledge that numerous dietary supplements are marketed in the form of beverages and bars with truthful, accurate, and nonmisleading labeling that does not represent them for use as conventional food.

These conflicting FDA statements have created substantial confusion. Not only does the attempt to restrict the marketing of dietary supplement products in food form violate the statute itself, and the congressional intent in enacting the 1994 Act, but it also conflicts with the First Amendment. If a dietary supplement can be marketed in beverage or bar form -- which FDA has condoned without objection since 1994 -- there is a First Amendment right to market it

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<sup>36</sup> Section 3(c) of the Dietary Supplement Health and Education Act, 108 Stat. 4325, 4328 (1994).

<sup>37</sup> 62 Fed. Reg. 49859, 49860 (September 23, 1997).

in any other nonmisleading form. FDA has violated the fundamental First Amendment principle that restrictions on free speech must be the last resort. Truthful, accurate, and nonmisleading labeling can without question be used to assure that the marketing of dietary supplements in food form will be fully understood by the American consumer and that there will be no confusion between dietary supplements and conventional food. Labeling must distinguish clearly between dietary supplements and conventional food, but this does not require an outright ban on marketing dietary supplements in food form.

Conclusion

For the reasons set forth above, GMA urges that the identified regulations and policies be reconsidered and revised in accordance with First Amendment principles.



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James H. Skiles  
Vice President and General Counsel