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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

PETITION FOR RECONSIDERATION AND STAY OF ACTION

STRUCTURE/FUNCTION CLAIMS

Docket No. 98N-0044

The Grocery Manufacturers of America, Inc. (GMA) submits this petition requesting that the Commissioner of Food and Drugs reconsider, and stay the effective date of, the decision in the final regulation in Docket No. 98N-0044, to treat all implied disease claims as equivalent to explicit disease claims and thus to exclude them from the scope of structure/function claims that are permitted under Section 403(r)(6) of the Dietary Supplement Health and Education Act of 1994 (DSHEA). GMA's membership consists of food, beverage, and consumer brand companies who would be adversely affected by FDA's decision, which is tantamount to a ban on structure/function claims for conventional food and dietary supplements.

GMA submits this petition for reconsideration and a stay on two grounds: (1) FDA's exclusion of all implied disease claims from the category of structure/function

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provision and (2) FDA did not adequately consider GMA's comments[1] on the illegality of FDA's proposed policy and offering an alternative proposal which would exclude from Section 403(r)(6) only those structure/function claims that directly (rather than indirectly) imply the prevention or treatment of disease. Because FDA's exclusion of all implied disease claims exceeds the scope of authority granted to the agency by Congress under Section 403(r)(6), this provision of the structure/function claim final regulation is unlawful under the FD&C Act and should be withdrawn by the Commissioner.

A. Decision involved

On January 6, 2000, FDA published final regulations setting forth the criteria the agency will apply in determining whether a statement in dietary supplement labeling is a disease claim requiring FDA approval pursuant to the new drug or health claim provisions of the FD&C Act or is a structure/function claim that is permitted for dietary supplements and conventional food under DSHEA.[2] While the final regulation incorporates the definition of "disease" established by FDA in 1993 (21 C.F.R. § 101.14) and thus reflects GMA's comments objecting to the expansive definition of "disease" proposed by FDA, the final regulation also retains the proposed regulation's unlawful expansive treatment of implied disease claims.[3] Section 101.93(g)(2) of the final

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[1] GMA filed comments in this docket on September 23, 1998 and August 4, 1999.

[2] 65 Fed. Reg. 1000 (to be codified at 21 C.F.R. § 101.93(f) and (g)) (January 6, 2000).

[3] 63 Fed. Reg. 23632 (April 29, 1998).

regulation provides that "A statement claims to diagnose, mitigate, treat, cure, or prevent disease," and thus is not a permitted structure/function claim under Section 403(r)(6), "if it claims, explicitly or implicitly, that the product" meets one of nine specific criteria (e.g., "Has an effect on a specific disease or class of diseases") or a catch-all criterion ("Otherwise suggests an effect on a disease or diseases").[4] The final regulation thus sweeps within the definition of disease claim not only express disease claims as intended by Congress but also both direct and indirect implied claims relating to disease. As discussed in detail in GMA's earlier comments, excluding all implied disease claims from Section 403(r)(6) exceeds FDA's authority under that provision and would ban structure/function claims for dietary supplements and conventional food in violation of Congress' intention in enacting DSHEA.

B. Action requested

GMA requests that, upon reconsideration, the Commissioner withdraw the implied claims component of Section 101.93(g)(2) or, in the alternative, affirm that only those implied claims are excluded from Section 403(r)(6) in which there is a direct casual relationship between the structure or function parameter in the claim and a specific known disease. GMA further requests that the Commissioner stay the effective date of the final regulation pending reconsideration and during any applicable period for judicial review.

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[4] 65 Fed. Reg. at 1050.

C. Statement of grounds

As GMA stated in its earlier comments to FDA, excluding all implied disease claims from Section 403(r)(6) is beyond FDA's authority under DSHEA. In enacting Section 403(r)(6), Congress created a subcategory of disease claims for which prior FDA approval would not be required: structure/function claims that indirectly imply a disease connection but that do not directly imply the prevention or treatment of disease. This subcategory operates as a safe harbor from the drug definition set forth in Section 201(g)(1)(B), the scope of which is limited to products marketed with express disease claims. In the absence of an explicit provision in Section 403(r)(6) excluding all implied disease claims from the scope of that provision, the language must be read to permit structure/function claims that do no more than indirectly imply utility in the prevention or treatment of disease.

Congress specifically authorized FDA to regulate food health claims under Section 403(r)(1)(B), which encompasses any claim "which expressly or by implication characterizes the relationship" of any nutrient "to a disease or health-related condition." Section 403(r)(6) explicitly excludes structure/function claims from the scope of this provision, stating that, "For purposes of paragraph (r)(1)(B), a statement . . . may be made" under Section 403(r)(6). Section 403(r)(6) thus also operates as a safe harbor from the health claim definition of Section 403(r)(1)(B). This analysis is further supported by the policy objectives of DSHEA, and by the relevant legislative history of the interlocking statutory provisions.

GMA's views and supporting information, submitted in two separate sets of comments, were either not considered at all by FDA, or not considered adequately. GMA's comments describe in detail a principle for differentiating implied disease claims which may be subjected to FDA approval from those that must be permitted under Section 403(r)(6) of DSHEA. Some statements from the preamble accompanying the final structure/function regulation appear to embody the GMA approach, but the final regulation itself retains the provision treating all implied disease claims as outside the scope of Section 403(r)(6). GMA requests the Commissioner to resolve this incongruity.

1. FDA's Assertion That No Implied Disease Claim Can Be A Lawful Structure/Function Claim Violates DSHEA

As GMA stated in its prior submissions, Congress did not give FDA authority to exclude all implied disease claims from the safe harbor established by Section 403(r)(6) of DSHEA. Under Section 201(g)(1)(B), the statutory provision upon which FDA's interpretation of "disease" claim is founded, FDA can regulate as a "drug" an article that is being marketed with explicit disease claims. No court has held that a product is a drug under this provision in the absence of evidence that the manufacturer or vendor made explicit claims that the article would diagnose, cure, mitigate, treat, or prevent disease.[5]

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[5] Every case cited by FDA (65 Fed. Reg. at 1037) in support of its authority to "regulate implied drug claims" involved express drug claims, articles whose drug status was not in dispute, or enforcement proceedings based on Section 502(a), the prohibition against false or misleading labeling.

In contrast to Section 403(r)(6), the safe harbor for health claims is drawn narrowly, providing no protection for health claims made "by implication" without specific FDA approval. Section 403(r)(1)(B) by its very terms gives FDA greater latitude to treat all implied claims like express claims for purposes of health claim regulation. Congress granted FDA no parallel authority to exclude implied disease claims from the protection offered by Section 403(r)(6) of DSHEA, which refers only to "statements" and "claims." Moreover, Section 403(r)(6) explicitly insulates structure/function claims from the reach of the health claim definition, including the implied disease claim language, explicitly authorizing all structure/function claims "for purposes of" the Section 403(r)(1)(B) health claim definition.

Congress' intention to deny FDA authority to exclude all implied disease claims from the structure/function provision of DSHEA is also demonstrated by other provisions of the FD&C Act. Section 201(n) of the Act provides that in determining whether labeling is false or misleading, FDA has authority to consider "representations made or suggested by statement, word, design, device, or any combination thereof."[6] In identifying not only representations "made" but also those "suggested" with respect to an article, Congress again recognized that there is a difference between express and implied claims. Reference to both categories in Section 201(n) and Section 403(r)(1)(B) demonstrates that Congress does not view express and implied claims as equivalent and

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6 FD&C Act § 201(n), 21 U.S.C. § 321(n).

knows how to craft language conferring authority on FDA over both when that is its intent.

As GMA has repeatedly pointed out in comments in this docket, DSHEA was intended to limit FDA authority to restrict dietary supplement manufacturers from disseminating truthful and nonmisleading speech about the health benefits of their products. The Findings in Section 2 of DSHEA discuss the importance of dietary supplements and public education about the link between health promotion and disease prevention, and contains several references to the relationship between dietary supplements and disease prevention.[7] Congress expressly recognized in Section 2 of DSHEA that structure/function claims can indirectly imply a use in the prevention of disease, and intended to permit dietary supplement manufacturers to make claims relating to disease prevention so long as manufacturers did not directly claim or imply disease prevention or treatment. The implied claims provision of the final structure/function regulation is thus inconsistent with Congress' manifest objective in enacting DSHEA and cannot be read into the statute by FDA.

FDA provides an inadequate response to this view in the preamble accompanying the final regulation. The agency glosses over this critical issue, asserting authority based on past practice and its own past regulations.[8] FDA also cites a number

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[7] Dietary Supplement Health and Education Act, Sec. 2, 108 Stat. 4325, 4326 (1994).

[8] 65 Fed. Reg. at 1037.

of past federal cases for the proposition that FDA has authority to "regulate implied drug claims."[9] DSHEA requires FDA to make a genuine evaluation of the limits of its jurisdiction under the new 1994 statute, not under its past practices, and does not authorize subjecting an entire category of structure/function claims to a complete ban.[10]

FDA's past practice of treating all implied claims as tantamount to express claims in some labeling contents cannot, as a matter of law, justify the agency's position that it can determine that a product is excluded from the structure/function definition, and thus a drug, based solely on indirect implied claims. It is one thing for the agency to issue regulations pursuant to its authority to prohibit labeling that is false or misleading "in any particular" – a phrase which evidences Congress' intent to give FDA broad authority – where the regulations do not purport to define the status of a product as a food or drug under the FD&C Act. It is another matter for the agency effectively to amend a statute by reading into it authority not conferred by Congress to categorize a product as a drug based on a claim which only indirectly may imply an effect on disease. FDA does not have authority to expand its own jurisdiction – a fact confirmed most recently in Brown & Williamson Tobacco Corporation v. FDA, 153 F.3d 155 (4th Cir. 1998), cert. granted, 119 S. Ct. 1495 (1999).

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9 65 Fed. Reg. at 1037.

10 Such a ban would appear to violate the First Amendment as interpreted and applied in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) and Washington Legal Foundation v. Friedman, 36 F. Supp. 2d 16 (D.D.C. 1999).

2. The GMA Proposal Is Consistent With FDA Policy

The preamble accompanying the final structure/function regulation contains some statements which suggest that FDA basically agrees with GMA's position that Section 403(r)(6) protects structure/function claims that indirectly, but not directly, imply a use in treating disease. The preamble accompanying the final structure/function regulation states that a claim that a dietary supplement is an "antispasmodic" is not necessarily a disease claim because antispasmodics are not "closely associated" with treating or preventing gastrointestinal disease.[11] The preamble also states that a "minor pain" claim is a permissible structure/function claim because minor pain can be caused by nondisease conditions. The agency took the same position with respect to upset stomach, occasional heartburn/indigestion, gas, motion sickness, and occasional sleeplessness because these conditions are indirectly, but not directly, linked with a disease.[12] FDA also explicitly recognized that a claim about a sign or symptom suffered primarily by people who do not have a disease or by people who have other diseases can be a structure/function claim under Section 403(r)(6).[13] In contrast, FDA stated that a claim that a dietary supplement is an "anti-inflammatory" is a disease claim because drugs in this class are "strongly associated" with treating gastrointestinal disorders.[14]

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11 65 Fed. Reg. at 1026.

12 65 Fed. Reg. at 1030, 1031.

13 65 Fed. Reg. at 1016.

14 65 Fed. Reg. at 1026.

Under FDA's preamble approach, claims of an indirect implied effect on a condition that is not "closely" or "strongly associated" with gastrointestinal disorders, heart disease, or other disease conditions would not trigger FDA's drug jurisdiction. This is fully consistent with GMA's approach, outlined in prior comments. Yet the regulation itself fails to reflect this distinction.

FDA thus failed adequately to consider GMA's view, set forth in two separate sets of comments that, as an alternative to excluding all implied disease claims from Section 405(r)(6), FDA should regulate structure/function claims by differentiating between two subcategories of implied disease claims – claims that directly imply a disease, and claims that only indirectly imply the treatment or prevention of disease. GMA's proposal to limit the disease claim definition to implied claims where there is a direct casual relationship between the structure/function parameter identified in the claim and a specific known disease satisfies the requirements of DSHEA and represents sound policy which promotes the public health objectives of the FD&C Act.

GMA's petition is not frivolous and is being pursued in good faith. GMA's member companies will suffer irreparable injury if a stay is not granted because the final regulation is tantamount to a ban on their commercial speech. Issuing a stay pending the Commissioner's reconsideration of the implied claims provision of the final regulation will assure adequate agency consideration, the need for which is particularly highlighted by pending litigation in the federal courts, including the Supreme Court, concerning FDA's authority to determine the breadth of its own drug jurisdiction and the First Amendment limitations imposed on FDA authority to prohibit commercial speech

that is not false or misleading. Because (as FDA has recognized) Section 403(r)(6) is self-executing, issuing a stay will not preclude FDA from taking enforcement action with respect to a claim that is not substantiated or a product that threatens public health, and thus will not undermine in any way the public health or other public interest. Indeed, staying the effective date of the implied claim language of Section 101.93(g)(2) will facilitate the dissemination of truthful and nonmisleading information about the effects of food on the structures and functions of the human body and thus promote the public health and the public interest.

D. Conclusion

For these reasons, GMA respectfully requests that the commissioner of Food and Drugs stay the implied claim provision of the final regulation pending reconsideration.

Respectfully,

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Regulatory Policy

James H. Skiles
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February 7, 2000

By Hand

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Re: Docket No. 98N-0044

Dear Madam or Sir:

Enclosed for filing in the above-captioned proceeding are the original and four copies of a Petition for Reconsideration and Stay of Action of FDA's final structure/function regulation submitted on behalf of the Grocery Manufacturers of America, Inc.

Kindly date-stamp one of the copies and return it to me via the awaiting messenger.

Thank you for your attention to this matter.

Sincerely yours,

Coleen E. Klasmeier

CEK/vrj
Enclosures