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

Re: Guidance for Industry - Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements

On behalf of Public Citizen and the Center for Science in the Public Interest ("CSPI"), we are writing to address certain statutory and regulatory violations inherent in the agency's December 2002 guidance on qualified health claims.

As the agency is aware, the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343(r)(3)(B)(i), authorizes the FDA to approve health claims for conventional foods and dietary supplements without requiring that these products go through the drug approval process. The agency may do so, however,

> only if the Secretary determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

If the FDA determines that a proposed health claim meets the statutory requirement quoted above—a requirement also repeated verbatim in the agency's regulations, 21 C.F.R. § 101.14(c)—the FDA must propose a regulation to authorize the claim and to accept public comment on the proposal. 21 U.S.C. § 343 (r)(3)(B)(i); 21 C.F.R. § 101.14(d)(1), § 101.70. Only after the FDA reviews the comments and issues a final regulation authorizing the claim may companies make that health claim. 21 C.F.R. § 101.14(e). Although an individual manufacturer may trigger the rulemaking process by filing an appropriate petition with the FDA, any manufacturer may make approved claims, subject to any requirements set forth in the final rule. 21 U.S.C. §§ 343(r)(1)(B), 343(r)(3)(B).

The statute permits only two exceptions to the prohibition against making health claims in the absence of a final rule. Neither exception applies here. First, claims based on an "authoritative statement" of either a federal agency with relevant expertise or the National Academy of Sciences may be made upon 120 days notice to the FDA, without notice-and-comment rulemaking. 21 C.F.R.

§ 403(r)(3)(C). A claim based on an authoritative statement is permitted unless and until the FDA issues a final regulation prohibiting the claim, the FDA determines that the requirements for using authoritative statements have not been met, or a district court in reviewing an enforcement action determines that the requirements for using an authoritative statement have not been met. 21 U.S.C. § 403(r)(3)(D).

Second, in some circumstances, the statute permits the FDA "to make proposed regulations issued under [the health claims provisions] effective *upon publication pending consideration of public comment and publication of a final regulation*." 21 U.S.C. § 343(r)(7) (emphasis added). That provision is designed to permit the Secretary to review and act promptly on petitions that provide information about healthy dietary practices or important new knowledge regarding nutritional or health benefits of food, or to ensure that "scientifically sound nutritional and health information is provided to consumers as soon as possible." *Id.* As is clear from the statutory language, however, a request for public comment is a prerequisite to issuance of an "interim" regulation allowing a health claim not yet authorized by a final regulation.

Notwithstanding the statutory and regulatory prohibitions against making health claims that are not authorized by regulation (final or interim), the agency's December 2002 Guidance for Industry announces that the agency intends to forgo the rulemaking process for "qualified" health claims. That is, under the Guidance, health claims supported by the weight of scientific evidence but not by significant scientific agreement will be permitted, *without* notice-and-comment rulemaking, as long as the claims are qualified by a disclaimer. More specifically, after the agency receives a petition requesting authorization of a specific health claim, the agency will either (1) initiate a rulemaking to authorize an unqualified claim (one that meets the significant scientific agreement standard) and make the petition available to the public, (2) send the petitioner a letter stating that the FDA will allow use of the claim if it is qualified by a disclaimer, presumably without providing public access to the petition,[1] or (3) deny the petition. Guidance at 4; FDA, Letter to Stakeholders, Jan. 15, 2003, at 2. Although the agency states that under this process qualified health claims are "subject to the statutory requirement of FDA authorization" (FDA Letter at 2), that statement is not accurate. The statutory requirement of FDA authorization is a requirement of notice-and-comment rulemaking, subject to the exceptions described above (neither of which is applicable here). The procedure announced in the Guidance takes qualified health claims outside of that authorization process and permits such claims to be made without any public process at all, let alone the notice-and-comment rulemaking prescribed by Congress.

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[1] The statute does not permit the FDA to make available to the public petitions that have been denied. 21 U.S.C. § 343(4)(A); *see* 21 C.F.R. § 101.70(j)(2). This provision seems to foreclose the possibility that the FDA could make public petitions that it does not approve but as to which it allows health claims by "exercising enforcement discretion." Allowing companies to make health claims without providing public access to the basis for the claims would run counter to Congress's purpose of ensuring public input and public access to information about health claims.

The FDA's new policy undermines the protections afforded to consumers by encouraging companies to seek permission to make health claims based on preliminary evidence, as opposed to waiting until the evidence demonstrates the existence of significant scientific agreement. Under the statute, the FDA has 540 days to issue a final regulation after it receives a petition demonstrating the existence of significant scientific agreement for a particular health claim.[2] By contrast, if a claim cannot meet the statutory standard—that is, the claim is not supported by significant scientific agreement—the Guidance would permit the FDA to allow the claim to be made after 190 days.[3] The perverse incentive created by the Guidance further demonstrates that this new policy is contrary to the structure and purpose of the NLEA, as well as principles of sound science.[4]

As the agency has stated, "a food is misbranded when its label or labeling bears a health claim unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D)." 58 Fed. Reg. 2478, 2423 (1993). Those statutory provisions require "that the health claim be made in accordance with regulations." *Id.* In fact, contrary to the procedure described in the December 2002 Guidance, the agency stated in the Federal Register commentary accompanying the issuance of its final regulations on this topic that it lacked the authority to allow health claims not authorized by regulation, even claims as to which the agency has proposed a regulation—that is, claims that the FDA has initially determined are most likely to meet the statutory standard for approval. *Id*. ("Proposed rules are not 'regulations.'"). Although the statute has since been amended to allow the FDA to authorize claims on an interim basis during the pendency of the notice-and-comment period, the FDA's prior reading of the basic statutory structure remains accurate: In the absence of a regulation, either final or interim (pending completion of a public comment period), the statute does not authorize the FDA to countenance health claims.

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[2] *See Nutritional Health Alliance v. Shalala*, 144 F. 3d 220 (2d Cir. 1998); *Nutritional Health Alliance v. Shalala*, 953 F. Supp. 526 (S.D.N.Y. 1998).

[3] Under section 343(r)(4)(A), FDA has 100 days to decide whether to "file" a petition, allowing it to consider it further, or to deny it. Within 90 days after filing a petition, the FDA must deny it or issue a proposed rule to take the action requested in the petition. Mutual extensions may be agreed upon during the 90 and 100-day periods.

[4] Notably, the National Academy of Sciences' Institute of Medicine (IOM) recently urged the FDA not to permit the use of preliminary health claims: "Claims about nutrient-disease relationships are more easily made than scientifically supported. Because the implications for public health are so important, caution is urged prior to accepting claims without supporting evidence from appropriately designed, typically large clinical trials." National Academy of Sciences, Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships,* at 58 (2002). The IOM cautioned that further study of an "appealing hypothesis" may result in a finding that the nutrient actually causes harm. For example, despite preliminary evidence that beta-carotene supplements could reduce the risk of lung cancer, clinical intervention trials later demonstrated that beta-carotene supplements actually increased the risk of lung cancer in smokers. *Id.* at 6.

Now, however, the FDA has decided as a matter of policy to ignore the NLEA's procedural requirements and its own regulations. To be sure, the FDA attempts to justify its departure from the statutory and regulatory requirements by characterizing its new policy as an exercise of "enforcement discretion." And "the decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). The December 2002 Guidance, however, goes well beyond a decision not to pursue enforcement action in a particular case. By announcing as a matter of policy that companies may make a category of health claims without a prior regulation authorizing the claim, the Guidance demonstrates that the agency has "consciously and expressly adopted a general policy [that] is in effect an abdication of its statutory duty." *Adams v. Richardson*, 480 F.2d 1159, 1162 (D.C. Cir. 1973) (en banc). As the Supreme Court has admonished, congressional delegation of authority does "not set agencies free to disregard legislative direction in the statutory scheme that the agency administers." *Heckler*, 470 U.S. at 833.

The present circumstances are similar to those at issue in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), in which the court overturned the FDA's decision to allow marketing of certain new drugs without prior approval of a new drug application. The court's decision in that case could easily be applied to the policy announced in the December 2002 Guidance:

> This [procedure] flies in the face of the statutory scheme. Under the Act, with very limited exceptions not here relevant, drugs can be lawfully marketed in only two ways. They are either new drugs which must be licensed, or they are generally recognized by experts as safe and effective, and are therefore not subject to active regulation. The goal of the Act is to insure that every marketed drug is both safe and effective. [footnote omitted] There are no other possibilities, no interim provisions under which safe, but only potentially effective drugs can be marketed pending testing. Even assuming that defendants are correct that Category III drugs are not necessarily unlawful new drugs, there is no question that they are potentially unlawful new drugs. To say that the Commissioner has the authority under the Act to affirmatively sanction the marketing of such drugs, effectively exempting them from the enforcement provisions of the Act for periods ranging from two to at least five years, is nothing less than a frontal assault on the premarket licensing scheme of the Food, Drug, and Cosmetic Act.

Id. at 854.

As in *Cutler,* the statute at issue here sets forth specific procedures. Just as the FDA lacked authority to approve drugs that were safe but of questionable efficacy, the FDA lacks authority to waive requirements for "qualified health claims." Whether or not the agency's existing regulation implementing the *substantive* standard is proper (and we are not convinced that the regulation is invalid in any respect), the agency exceeds its authority by allowing—effectively

inviting—companies to make health claims prior to receiving specific authorization via notice-and-comment rulemaking.

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), the stated impetus for the December 2002 Guidance, in no way calls the NLEA's procedural requirements into question. In fact, the FDA's October 6, 2000, Federal Register notice regarding implementation of *Pearson* indicated that the agency believed the D.C. Circuit's decision required reconsideration of the *substantive* health claim regulations as to dietary supplements, but did not suggest that the agency believed that the decision called into question the validity of any requirements applicable to health claims for conventional foods, let alone imply that any First Amendment concerns override the *procedural* safeguards built into the NLEA. 65 Fed. Reg. 59855; *see also supra* note 2 (citing cases sustaining procedural requirements). Put simply, neither the NLEA, current FDA regulations, nor *Pearson* give the FDA authority to disregard the requirement of notice-and-comment rulemaking before a health claim, whether qualified or unqualified, is permitted. *See also Lopez v. FAA*, 318 F.3d 242, 247 (D.C. Court 2003) (court's duty to enforce administrative regulations is "most evident when compliance with the regulation is mandated by . . . federal law") (quoting *United States v. Caceres*, 440 U.S. 741, 749 (1979)).

The FDA's decision consistently to forgo enforcement action in instances where a company makes a "qualified" health claim after failing to receive formal authorization to make that claim "is a dereliction of duty." *Adams*, 480 F.2d at 1163. Indeed, it is a dereliction of duty "reviewable in the courts." *Id.*; *see Heckler*, 470 U.S. at 839 (Brennan, J., concurring) (pattern of non-enforcement of clear statutory language subject to judicial review under APA); *cf. Better Gov't Ass'n v. Department of State*, 780 F.2d 86 (D.C. Cir. 1986) (agency guidance document subject to judicial review).

Accordingly, Public Citizen and CSPI urge the agency to withdraw the December 2002 Guidance, not to sanction health claims (qualified or otherwise) unauthorized by regulation, and to continue its previous policy of enforcing the NLEA's procedural requirements, according to Congress's mandate and current regulations. If the agency believes that its substantive regulations warrant revision in light of *Pearson*, it should initiate notice-and-comment rulemaking to amend them, subject to the requirements of the NLEA. We look forward to your prompt response.

Sincerely,

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