UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, 1875 Connecticut Avenue, NW Washington, DC 20009, and PUBLIC CITIZEN HEALTH RESEARCH GROUP, 1600 20th Street, NW Washington, DC 20009, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane Rockville, Maryland 20009, Defendant.	)	Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action is brought under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), by two public interest membership organizations to challenge regulatory guidance recently issued by the Food and Drug Administration ("FDA"). The guidance sets forth a new regulatory regime in which the FDA, under the guise of enforcement discretion, will permit certain claims about purported health benefits of foods, without following the procedural requirements or meeting the substantive standard of the Nutritional Labeling and Education Act of 1990 ("NLEA").

2. This Court has jurisdiction under 28 U.S.C. § 1331.

PARTIES

3. Plaintiff Center for Science in the Public Interest ("CSPI") is a non-profit consumer education and advocacy organization with approximately 750,000 members nationwide. CSPI conducts research, educates the public, and represents the interests of consumers before Congress and federal agencies in the areas of food safety and nutrition. CSPI has a strong and continuing interest in ensuring that the government enforces the laws concerning food quality and the dissemination of accurate and useful nutritional information to the public. Likewise, CSPI and its members have an interest in ensuring that the government properly interprets, implements, and enforces the NLEA's provisions regarding claims that foods can aid in the cure, prevention, or treatment of disease. CSPI brings this action on behalf of its members who shop for food for themselves and their families. These members will be injured by the FDA's guidance, described below, in that they will not be able to rely on food labels to provide accurate and non-misleading information about the health benefits of foods and may be induced to make choices that adversely affect their health based on preliminary or misleading information. CSPI also brings this action on behalf of itself and its members to protect their right to the procedural protections of the notice-and-comment rulemaking process required by the APA when the FDA issues a new substantive rule and required by the NLEA for FDA approval of health claims for foods, as further described below.

4. Plaintiff Public Citizen is a non-profit consumer advocacy organization with approximately 125,000 members nationwide. Through its Health Research Group, Public Citizen works to promote consumer health and safety through research and public education on matters including food, drugs, and health care delivery systems. The work of the Health Research Group focuses in large part on monitoring the government's enforcement of the Food, Drug, and Cosmetic

Act, including the laws concerning food quality and the dissemination of nutritional information to the public. Public Citizen and its members have an interest in ensuring that the government properly interprets, implements, and enforces the NLEA's provisions regarding claims that foods can aid in the cure, prevention, or treatment of disease. Public Citizen brings this action on behalf of its members who shop for food for themselves and their families. These members will be injured by the regulatory scheme set forth in the FDA's guidance, described below, in that they will not be able to rely on food labels to provide accurate and non-misleading information about the health benefits of foods and may be induced to make choices that adversely affect their health based on preliminary or misleading information. Public Citizen also brings this action on behalf of itself and its members to protect their right to the procedural protections of the notice-and-comment rulemaking process required by the APA when the FDA issues a new substantive rule and required by the NLEA for FDA approval of health claims for foods, as further described below.

5. Defendant FDA is an agency of the United States. The FDA is charged by Congress, through its parent agency the Department of Health and Human Services ("HHS"), with implementing and enforcing the NLEA.

STATUTORY AND REGULATORY BACKGROUND

6. Under the Food, Drug, and Cosmetic Act, a drug is defined as, among other things, an "article[] intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" and an "article[] (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 201(g)(1)(B), (C).

7. Prior to 1984, food companies made few, if any, "health claims" for their products—that is, claims characterizing the relationship of any nutrient in a food to a disease or health-related

condition. Until that time, the FDA's view was that to make a health claim for a food was to bring that food within the Food, Drug, and Cosmetic Act's definition of a drug ("intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease"), and thus that a food company must submit and receive FDA approval of a new drug application prior to making such a claim.

8. During the mid-1980s, companies began making health claims for foods, without requesting FDA approval. The FDA did not take enforcement action against the companies, but instead published a proposed rule addressing health claims by food companies. 52 Fed. Reg. 28843 (1987). That rule was never finalized.

9. In 1990, the FDA again published a proposed regulation to establish rules regarding health claims for food. 55 Fed. Reg. 5176 (1990).

10. Later that year, Congress passed the NLEA, which prohibits any health claim for foods unless the claim is authorized by the Secretary of HHS, subject to certain substantive and procedural criteria. Unless made in accordance with these criteria, a health claim for a food renders the food misbranded. 21 U.S.C. § 343(r)(1), (r)(3). The Secretary delegated this authority to the FDA.

11. The House Committee Report on the NLEA observed that, without the authority established in the NLEA, "there is a serious question as to whether the Agency has the legal authority to . . . permit health claims regarding the usefulness of a food in treating a disease, without also requiring that the claim meet the premarket approval requirements applicable to drugs." H.R. Rep. No. 101-538, at 9 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3339.

12. The NLEA restricts FDA approval of food health claims to instances in which the agency "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." 21 U.S.C. § 343(r)(3)(B)(i). As the House Report stated: "The standard is intended to be a strong one. The bill requires that the Secretary have a high level of confidence that the claim is valid." 1990 U.S.C.C.A.N. at 3351.

13. The statutory standard—significant scientific agreement—is repeated verbatim in a regulation the agency issued to implement the NLEA. 21 C.F.R. § 101.14(c). In promulgating the regulation, the FDA expressly rejected suggestions that it define a lower substantive standard so as to allow claims with disclaimers or other language to express a lesser degree of scientific certainty that the claim was accurate. The FDA stated: "FDA does not have authority to modify the scientific standard for health claims . . . . [T]he requirement objected to by several of the comments, that there be significant scientific agreement that the claim is supported by the publicly available evidence, derives directly from the act." 58 Fed. Reg. 2478, 2504 (1993).

14. After receipt of a petition asking the FDA to authorize a health claim, the FDA must either deny the petition or "file" it "for further action." 21 U.S.C. § 343(r)(4)(A)(i). The NLEA instructs the FDA that, if it preliminarily determines that the proposed health claim in a filed petition meets the statutory requirement ("significant scientific agreement"), the FDA must "issue a proposed regulation" to authorize the claim. *Id.* The agency must then accept public comment on the proposal. If, taking into consideration the comments received, the agency makes a final determination that the statutory standard has been met, it must then issue a final rule allowing the claim. 21 C.F.R. §§ 101.14(d)(1), 101.14(e), 101.70.

15. When issuing its regulations to implement the NLEA, the FDA recognized that, as a general matter, "the comment period following publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption" and that, with regard to health claims for foods, "significant information concerning the validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period," and that "the comment period may bring to light a previously unforeseen potential for the health claim to be misleading to consumers" if adopted as proposed. 58 Fed. Reg. 2523.

16. Although an individual manufacturer may trigger the rulemaking process by filing an appropriate petition with the FDA, any manufacturer of the same food may make an approved claim, subject to any requirements set forth in the final rule. 21 U.S.C. §§ 343(r)(1)(B), 343(r)(3)(B).

17. The statute permits only two exceptions to the prohibition against making health claims in the absence of a final rule. 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).

18. 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). That provision enables 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 and to ensure that "scientifically sound nutritional and health information is provided to consumers as soon as possible." *Id*.

THE *PEARSON* DECISION

19. Under the NLEA, health claims for dietary supplements, like those for foods, are forbidden, unless the FDA approves such claims. However, rather than specifying the substantive standard applicable to such claims (as it does for foods), the statute directs the FDA to adopt a standard and procedures to apply for approval of health claims for dietary supplements. 21 U.S.C. § 343(r)(65)(D). Congress intended that the standard be no less rigorous than the "significant scientific agreement" standard applied to foods; and the FDA chose to apply the "significant scientific agreement" standard, implemented through the same notice-and-comment rulemaking process that the NLEA mandates for foods. 21 C.F.R. § 101.14(c).

20. In 1997, a manufacturer of dietary supplements brought a challenge to the FDA's refusal to approve health claims for certain of its products. On appeal from a district court ruling in favor of the agency, the United States Court of Appeals D.C. Circuit held that, based on the rulemaking record with respect to those supplements, the First Amendment did not permit the FDA to reject outright the health claims at issue in that case. The court held that if the agency found that a claim was not supported by significant scientific agreement, but was supported by the weight of the evidence, the FDA could not prohibit the claim if it found that a disclaimer would eliminate the potential for deception of consumers. The court also stated, however, that health claims could be prohibited outright based on health or safety concerns, or where the quality or quantity of the evidence in support of the claim outweighed the quality or quantity of the evidence against it.

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). That case did not involve a health claim with respect to a food; the court did not consider the constitutionality of the regulatory regime set forth by Congress for food claims, and the court's opinion did not suggest that the statutory procedure requiring the FDA to use notice-and-comment rulemaking to allow a health claim was invalid.

21. After *Pearson*, some food industry groups and supporters urged the FDA to apply the holding of the case to conventional foods. The FDA rejected those suggestions. In a May 2000 letter to Congressman McIntosh, the FDA explained that "absent a court ruling finding the statute unconstitutional, FDA does not have authority to authorize health claims for conventional foods when such a claim would require a disclaimer to render it truthful and nonmisleading."

FDA'S DECEMBER 2002 GUIDANCE

22. With respect to foods, the FDA followed the NLEA's procedural requirements and substantive standard from the time of the NLEA's enactment through December 2002. During that time, the FDA authorized food health claims in response to petitions only after notice-and-comment rulemaking and a determination that the claims were supported by significant scientific agreement or in accordance with the statutory exceptions set forth in paragraphs 17 and 18, above.

23. Notwithstanding the statutory and regulatory prohibitions against making food health claims that are not authorized by regulation (final or interim), on December 20, 2002, the FDA issued a document entitled Guidance for Industry ("December Guidance"), in which the agency announced its intention to forgo the notice-and-comment rulemaking process for "qualified" health claims. Under the December Guidance, health claims for foods that were supported by the weight of scientific evidence, but not by significant scientific agreement, would be permitted, *without*

notice-and-comment rulemaking, as long as the claims were qualified by a disclaimer. 67 Fed. Reg. 78002 (2002).

24. On December 24, 2002, the U.S. District Court for the District of Columbia issued a decision concerning the FDA's denial of a petition seeking authorization to make a health claim for a dietary supplement—specifically, the claim that antioxidant vitamins help to prevent cancer. In that case, the district court held that, where a health claim for a dietary supplement was supported only by "credible" evidence, but not by the weight of the evidence, the FDA had to allow it, subject to an appropriate disclaimer. *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002). Like *Pearson*, the *Whitaker* case did not involve a food and, therefore, did not concern the statutorily mandated regulatory standard. The FDA did not appeal the *Whitaker* decision.

25. In a letter to the FDA dated April 10, 2003, plaintiffs CSPI and Public Citizen complained that the procedure described in the December Guidance violated the procedural requirements of the NLEA and the FDA regulations implementing the NLEA. The letter asked the agency to withdraw the December Guidance, not to sanction health claims unauthorized by regulation, and to continue enforcing the NLEA's procedural requirements. It also stated that if the FDA believed that the substantive standard set forth in the its regulations warranted revision and that the NLEA permitted such a revision, the agency was required to initiate notice-and-comment rulemaking to make changes.

FDA'S JULY 2003 GUIDANCE

26. On July 11, 2003, the FDA issued a notice announcing the availability of two additional guidance documents, entitled Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data, and Guidance for Industry and FDA: Interim Procedures for Health

Claims in the Labeling of Human Food and Human Dietary Supplements (collectively "July Guidance"). *See* 68 Fed. Reg. 41387 (2003).

27. The July Guidance supersedes the December Guidance. The July 11 *Federal Register* notice explains that, after the district court decision in *Whitaker*, the "weight of the evidence standard" set forth in the December Guidance "must be tempered by the test of credible evidence." That is, as described in more detail below, in the July Guidance, the FDA announced that it is asserting authority to permit a health claim for food as long as some credible evidence supports it, even where the weight of the credible evidence does not.

28. The July Guidance states that the agency will continue to follow the NLEA and its regulations implementing the NLEA only for "unqualified" health claims—that is, for health claims that meet the statutory standard set forth in the NLEA and, accordingly, are not accompanied by a disclaimer. The July Guidance refers to these statutorily authorized health claims as "Category A" claims.

29. The July Guidance identifies three categories of "qualified" health claims—that is, health claims accompanied by a disclaimer: Category B claims will be qualified by language stating that "although there is scientific evidence supporting the claim, the evidence is not conclusive." Category C claims will be qualified by language stating that "Some scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive." Category D claims will be qualified by language stating that "Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim." The exact language may vary from case to case.

30. The NLEA, as implemented by the FDA through final regulations promulgated through notice-and-comment rulemaking, does not permit health claims of the sort now categorized by the FDA as B, C, and D claims. Nonetheless, the Guidance announces that the FDA will use "enforcement discretion" to allow qualified claims in categories B, C, and D, subject to certain procedures.

31. The FDA will accept petitions for qualified health claims beginning in September 2003. If a petition is not complete, the FDA will inform the petitioner within 45 days of the deficiencies and of what steps the petitioner should take to complete the petition. If the petition is complete, the FDA will "file" it.

32. Upon filing a petition, the FDA will post it on the FDA's website and request public comment for 60 days. After the 60 days have ended, the FDA will conduct its own scientific review, either internally, through an advisory committee, or using a third-party reviewer under contract to the agency. The FDA expects the review to take up to 120 days.

33. The July Guidance states that, after completion of the review, the FDA will decide whether to "exercise enforcement discretion" to allow the proposed claim. The FDA expects to notify the petitioner of its decision within 270 days of filing the petition, although it may extend the time 30-60 days for "good cause." The FDA will notify the petitioner by letter of its decision whether to allow the claim, and it plans to post its letter and any third-party review report on its website.

34. The FDA does not intend to issue a proposed rule before allowing a qualified health claim. The FDA does not intend to respond to public comments on a qualified health claim petition.

The FDA does not intend to provide an opportunity for public comment on its internal or third-party review of the petition or on its decision to allow a particular qualified claim.

35. The July Guidance states that the agency plans to conduct consumer research studies to explore the ability of consumers to understand the differences between the categories of qualified claims and to find the appropriate words to convey the differences. Thereafter, the FDA plans to issue a proposed rule to address qualified health claims.

36. The regulatory regime for consideration and approval of Category B, C, and D health claims for foods, as set forth in the July Guidance, went into effect on September 1, 2003. The FDA has already accepted and begun processing at least one petition for approval of a qualified claim, and it expects to complete processing that petition and others prior to the issuance of any proposed rule addressing qualified health claims.

37. The July Guidance and the harms discussed in paragraphs 3 and 4, above, threaten irreparable injury to plaintiffs and their members, who will be deprived of the substantive and procedural protections established by Congress to protect them against injuries to their health and the waste of their money on foods that make inaccurate or misleading health claims. No adequate remedy at law exists for consumers who are induced to purchase foods based on inaccurate or misleading qualified health claims and whose health may suffer as a result.

FIRST CAUSE OF ACTION

(For violation of NLEA's substantive requirements)

38. Plaintiffs incorporate paragraphs 1 through 37, as though fully set forth herein.

39. The July Guidance announces a policy of authorizing certain health claims not supported by significant scientific agreement, in violation of the substantive requirements of the NLEA.

SECOND CAUSE OF ACTION

(For violation of FDA regulations)

40. Plaintiffs incorporate paragraphs 1 through 37, as though fully set forth herein.

41. The July Guidance announces a policy of authorizing certain health claims not supported by significant scientific agreement, in violation of the substantive requirements of FDA regulations implementing the NLEA.

THIRD CAUSE OF ACTION

(For violation of NLEA's procedural requirements)

42. Plaintiffs incorporate paragraphs 1 through 37, as though fully set forth herein.

43. The July Guidance establishes a procedure for authorizing certain health claims without notice-and-comment rulemaking, in violation of the procedural requirements of the NLEA.

FOURTH CAUSE OF ACTION

(For violation of FDA regulations)

44. Plaintiffs incorporate paragraphs 1 through 37, as though fully set forth herein.

45. The July Guidance establishes a procedure for authorizing certain health claims without notice-and-comment rulemaking, in violation of the procedural requirements of the FDA regulations implementing the NLEA.

FIFTH CAUSE OF ACTION

(For violation of Administrative Procedure Act)

46. Plaintiffs incorporate paragraphs 1 through 37, as though fully set forth herein.

47. The July Guidance is, in substance, a legislative rule, issued without notice-and-comment rulemaking, in violation of section 553 of the Administrative Procedure Act.

WHEREFORE, Plaintiffs pray that this Court:

(A) Declare that defendant's policy, as announced in the July Guidance, violates the substantive requirements of the NLEA and FDA regulations insofar as it allows health claims for foods that are not supported by significant scientific agreement;

(B) Declare that defendant's policy, as announced in the July Guidance, violates the procedural requirements of the NLEA and FDA regulations with respect to the process for review and approval of health claims for foods;

(C) Order defendant to withdraw the July Guidance and not to sanction health claims for foods other than claims approved under the procedures and standards set forth in the NLEA and FDA regulations implementing the NLEA;

(D) Award plaintiff its costs and reasonable attorneys' fees pursuant to 28 U.S.C. § 2412(d); and

(E) Grant such other relief as this Court may deem just and proper.

Dated: September 23, 2003

Respectfully submitted,

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