

Before the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for Expedited Action)
In re: Grocery Manufacturers)
of America Petition to FDA:)
Withdraw Revise Pearson v. Shalala) Docket No. 00N-0598
Implementation Strategy,)
Re: Disease Claim Rules)

CITIZENS PETITION OF
DURK PEARSON and SANDY SHAW;
JULIAN M. WHITAKER, M.D.;
PURE ENCAPSULATIONS, INC.;
AMERICAN PREVENTIVE MEDICAL ASSOCIATION;
XCEL MEDICAL PHARMACY, INC.,
and
WEIDER NUTRITION INTERNATIONAL, INC.
IN SUPPORT OF GMA PETITION TO FDA AND
REQUEST FOR EXPEDITED ACTION

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Durk Pearson and Sandy Shaw; Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; the American Preventive Medical Association; XCEL Health Care, Inc.; and Weider Nutrition, International, Inc. (collectively, "Joint Commenters"), by counsel pursuant to 21 U.S.C. §§ 321(n) and 343(r) and 21 C.F.R. 10.30 and in support of the Grocery Manufacturers of America's (GMA) citizen petition filed on April 27, 2000 (hereinafter "GMA Petition"), hereby submit the following petition.

I. INTERESTS OF THE JOINT PETITIONERS

Durk Pearson and Sandy Shaw. Pearson and Shaw are scientists residing in Nevada. They design dietary supplement formulations and license them to manufacturing and retailing companies. They also license for sale three specialty food products and currently have three more in development (packaged foods and food ingredients for home preparation; snacks, and beverages). They are authors of four books

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on aging and age-related diseases, including the #1, million plus copy best seller *Life Extension: A Practical Scientific Approach* (1982). They have also published three other health books, two of which were best sellers: *The Life Extension Companion* (1984); *The Life Extension Weight Loss Program* (1986); and *Freedom of Informed Choice—FDA Versus Nutrient Supplements* (1993). Durk Pearson and Sandy Shaw were plaintiffs in the *Pearson v. Shalala* case. Pearson and Shaw believe the First Amendment principles in *Pearson v. Shalala* are fully applicable not only to the labels and labeling of dietary supplements but also to the labels and labeling of foods, including the foods they license for sale.

Julian M. Whitaker, M.D. Julian M. Whitaker, M.D. is a physician licensed to practice medicine in the states of California and Washington. He graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the Whitaker Wellness Institute in Newport Beach, California. He is the author of five books: *Reversing Heart Disease* (1985), *Reversing Diabetes* (1987), *Reversing Health Risk* (1989), *Natural Healing* (1994), and *What Your Doctor Won't Tell You About Bypass* (1995). Since August of 1991 he has been the editor of *Health & Healing*, currently the nation's largest single editor health newsletter. In 1998, *Health & Healing* had over 500,000 subscribers. He has formulated and sold at the Whitaker Wellness Institute, a specialty food containing fiber and antioxidant vitamins. He will also receive royalties from the distribution and sale of several specialty food products containing

omega-3 fatty acids and folic acid, which he plans to formulate and license for sale in the near future. Dr. Whitaker believes the First Amendment principles in *Pearson v. Shalala* are fully applicable not only to the labels and labeling of dietary supplements but also to the labels and labeling of foods, including the specialty foods he licenses or plans to license for sale.

Pure Encapsulations, Inc. Pure Encapsulations, Inc. (Pure) is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling over 250 pharmaceutical grade dietary supplements for human and companion animal consumption. Pure intends in the near future to formulate, manufacture, sell and distribute a food product that contains folic acid, antioxidant vitamins and fiber. Pure wants to place the health claims listed in *Pearson*, disclaimed as necessary to avoid misleadingness, on the labels and in the labeling of the food product and, thus, seeks allowance of the health claims for the food it plans to sell as well as for dietary supplements it currently sells. Pure believes the First Amendment principles in *Pearson v. Shalala* are fully applicable not only to the labels and labeling of dietary supplements but also to the labels and labeling of foods, including the specialty food it plans to sell.

American Preventive Medical Association. The American Preventive Medical Association (APMA) is a non-profit organization located in Virginia. APMA was founded in October of 1992 and is dedicated to ensuring consumer access to preventive therapies and the rights of health care providers to offer those therapies. APMA was a plaintiff in the *Pearson v. Shalala* case. Several APMA physicians sell dietary supplements and specialty foods that contain antioxidant vitamins, fiber, omega-3 fatty acids, and folic acid. APMA and its practitioner members, and their hundreds of

thousands of patients, would benefit from approval of the health claims proposed in *Pearson* on dietary supplements and foods because it would enable those practitioner members to communicate, and their patients to receive, nonmisleading health information on labels and in labeling concerning the effects of dietary supplements and foods upon disease. APMA believes the First Amendment principles in *Pearson v. Shalala* are fully applicable not only to the labels and labeling of dietary supplements but also to the labels and labeling of foods.

XCEL Medical Pharmacy, LTD d/b/a XCEL Health Care. XCEL Medical Pharmacy, Ltd. d/b/a XCEL Health Care (XCEL) is a California corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human consumption. XCEL manufactures and produces several dietary supplements containing antioxidant vitamins, fiber, omega-3 fatty acids, and folic acid. XCEL would manufacture and sell a beverage that contains antioxidant vitamins and folic acid if it were assured that the First Amendment principles in *Pearson v. Shalala* applied to the labels and the labeling of that food product. XCEL would place the health claims listed in *Pearson* for antioxidant vitamins and folic acid, disclaimed as necessary to avoid misleadingness, on the labels and in the labeling of its new food product. XCEL believes the First Amendment principles in *Pearson v. Shalala* are fully applicable not only to the labels and labeling of dietary supplements but also to the labels and labeling of foods.

Weider Nutrition International, Inc. Weider Nutrition International, Inc. (Weider) develops, manufactures, markets, distributes and sells branded private label vitamins, nutritional supplements and sports nutrition products in the United States and

throughout the world. Weider offers a broad range of capsules and tablets, powdered drink mixes, bottled beverages and nutrition bars consisting of approximately 1,000 SKUs domestically and internationally. Weider markets branded products in four principal categories: sports nutrition; vitamins; minerals and herbs; weight management; and healthy snacks. The company is located in Salt Lake City, Utah.

II. INTRODUCTION

In its petition, GMA asks FDA to take the following steps without delay:

1. FDA must immediately withdraw and revise its proposed strategy to implement the Pearson decision.
2. FDA must apply Pearson to all food, including but not limited to dietary supplements, because the Pearson case interpreted the NLEA standard for approval of disease claims for food (which FDA extended without change to dietary supplements).
3. FDA must withdraw the significant scientific agreement guidance because it does not permit FDA to authorize all truthful, nonmisleading claims (including claims for which the level of scientific support can be set forth meaningfully in disclaimers or other explanatory information).
4. FDA must withdraw the authoritative statement guidance because it indicates that FDA will use its unconstitutional interpretation of "significant scientific agreement" to determine whether a statement is "authoritative."
5. FDA must amend all existing disease claim regulations (both procedural and substantive) in 21 C.F.R. § 101.14 and 21 C.F.R. Part E to comply with Pearson.
6. FDA must immediately suspend all enforcement action against claims that are truthful, accurate, and not misleading.

In this Petition, the Joint Petitioners explain (1) that 21 U.S.C. §343(r)(3)(B) applies "significant scientific agreement" to proposed, specific health claims not overall substance-disease relationships; (2) that under the canons of statutory construction FDA must interpret 21 U.S.C. § 343(r)(3)(B) in a constitutional manner, if at all possible; (3)

that the First Amendment precludes FDA from denying and suppressing food health claims if those claims can be rendered non-misleading through the addition of a disclaimer; (4) that there is nothing in 21 U.S.C. § 343(r)(3)(B) which precludes FDA from authorizing health claims for foods with disclaimers designed to cure misleadingness; and (5) that to avoid an unconstitutional interpretation, FDA must interpret the standard in 21 U.C.S. § 343(r)(3)(B) to be in complete harmony and accord with the First Amendment.

III. ACTION REQUESTED AND STATEMENT OF GROUNDS

A. REQUEST FOR EXPEDITED ACTION TO HALT FIRST AMENDMENT RIGHTS VIOLATION

The Joint Petitioners hereby request that this agency act immediately on this citizen petition and the one it endorses earlier filed by the Grocery Manufacturers Association (GMA) (Docket No. 00N-0598). Immediate action is needed to ensure that the First Amendment rights of the Joint Petitioners and all similarly situated are given the protection that is their due at the earliest possible moment. Administrative delay in the face of First Amendment rights violations is intolerable. See *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) (“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”). See also *Riley v. National Federation of the Blind*, 784 U.S. 781, 793-94 (1988). (“Speakers. . . cannot be made to wait for years before being able to speak with a measure of security” (internal quotes omitted)).

B. THE HEALTH CLAIMS PROVISIONS FOR FOODS APPLY “SIGNIFICANT SCIENTIFIC AGREEMENT” TO PROPOSED, SPECIFIC CLAIMS, NOT OVERALL SUBSTANCE-DISEASE RELATIONSHIPS
FDA’S CONTRARY INTERPRETATION VIOLATES THE ADMINISTRATIVE PROCEDURE ACT AND RESULTS IN RIGHTS VIOLATION

21 U.S.C. § 343(r)(3)(B) reads in pertinent part:

The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of 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.

In its April 26, 2000 letter to the Chairman of the House Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs (hereinafter “House Subcommittee”) (attached as Exhibit 1 at 2-3), FDA explained that it has interpreted the foregoing section to require application of the significant scientific agreement standard “to the overall substance-disease relationship, rather than to a proposed specific health claim,” explaining that the Subcommittee Chairman was “correct that FDA applies the significant scientific agreement standard to the validity of the substance-disease relationship that is the subject of the claim, not to the wording of the claim.” FDA further states that it “*inferred* from Congress’ definition of a health claim as a statement of a relationship between a substance and a disease or health-related condition, that the significant scientific agreement standard should apply to the relationship.” Exhibit 1 at 2. FDA recites that in the following agency orders it has explained this rationale for evaluation of health claims for conventional foods: 56 Fed Reg 60537 at 60539; 60547-60548 (Nov. 27, 1991) and 58 Fed Reg 2478 at 2503-2505 (Jan. 6, 1993). In its May 16, 2000 letter to the Chairman of the House Subcommittee

(attached as Exhibit 2 at 6), FDA further explained that it perceived but one interpretation possible from 21 U.S.C. § 343(r)(3)(B), i.e., its current interpretation, writing:

There is a statutory requirement that FDA authorize health claims for conventional foods only when there is significant scientific agreement that the nutrient-disease relationship is valid. Therefore, 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.

Thus it is that FDA has exercised its interpretive power to cause the definition given 21 U.S.C. § 343(r)(3)(B) to be one that limits the extent of claims capable of authorization to ones that are not only truthful and nonmisleading but are also based on nutrient-disease relationships that are proven to a near conclusive degree.

That interpretation is inconsistent with the plain language of the statute; is not in fact the only, or even the most appropriate, interpretation of the language; and is inconsistent with the First Amendment. Indeed, FDA's interpretation deviates from the plain language of 21 U.S.C. § 343(r)(3)(B) and from the legislative intent concerning interpretation of that section.¹ The plain language requires that FDA determine, based on the totality of publicly available evidence (including, but not limited to, well-designed studies); whether there is "significant scientific agreement, among experts . . . that the *claim is supported* by such evidence" (Emphasis added). Read according to its plain, literal meaning, the statute compels FDA to determine if a claim is supported by scientific evidence based on the agreement of a significant segment of the scientific community. Nowhere in the statute is there a requirement that FDA determine that the substance-disease relationship itself is established to a near conclusive degree. Rather,

¹ The *Pearson* Court plainly recognized that the statutory language may be interpreted consistent with the First Amendment when it wrote, ". . . the general regulation [significant scientific agreement] does not *in*

the statute's focus is upon "support" for the "claim," not upon near conclusive proof of the substance-disease relationship.

Thus, FDA's current interpretation of the statutory provision deviates from the plain language of the statute. It therefore has a natural competitor: the interpretation consistent with the plain language of the statute. Indeed, to the extent that FDA's interpretation deviates not only from the plain language but also from the legislative intent, it constitutes arbitrary and capricious agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706 and *Chevron* steps one and two. *See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3, 104 S. Ct. 2778 (1984).

FDA's interpretation of "significant scientific agreement" contradicts Congress's intent concerning how the health claims provision for foods is to be interpreted. Unlike the agency's interpretation, Congress's focuses upon support for the claim, not on establishment of the substance-disease relationship to a near conclusive degree. In committee Congress wrote:

The Committee notes that the significant scientific agreement standard is, by design, more flexible than the standard established by law for FDA to review and approve drugs, which requires a demonstration of safety and effectiveness based on "adequate and well-controlled clinical investigations." While the intake of a nutrient on which a health claim is based must be safe, there is no requirement that health claims be derived from clinical trials, and, by its terms, the standard recognizes that scientific agreement on the validity of the claim does not have to be complete. Evidence from a broad range of reliable scientific sources should be considered in determining the adequacy of scientific support.

In implementing the significant scientific agreement standard, FDA will be expected to take full advantage of the flexibility of the standard to maximize the availability on food and dietary supplement labels and labeling of disease-related information consumers can prudently use to affect their risk of disease.

haec verba preclude authorization of qualified claims, *see* Melinda Ledden Sidak, *Dietary Supplements and Commercial Speech*, 48 FOOD & DRUG L.J. 441, 455 (1993)."

This includes recognizing that there will nearly always be some remaining scientific uncertainty about the validity of any diet-related health claim; that some individuals consuming or avoiding a nutrient in response to a health claim may benefit, while others may not; and that the benefits for any individual may consist not of absolutely avoiding a disease, but rather of reducing her or his risk of a disease.

The end point for evaluation of the adequacy of support for a claim should not be definitive proof that the nutrient has the stated effect for all populations, but that the nutrient will produce the stated effect in the majority of a target population the majority of the time. In addition, the scientific evidence supporting a claim should not be held to the same standard used in evaluating new drug applications.

Under the significant scientific agreement standard, the FDA should authorize claims when a significant segment of scientists having relevant expertise agree, based on relevant scientific evidence, that consumers are reasonably likely to obtain the claimed health benefit. This is consistent with the NLEA's goal of assuring that consumers have access on food and dietary supplement labels to health claims that are scientifically supported, without having to wait until the degree of scientific certainty contemplated by the drug standard has been achieved.

S. Rep. No. 103-410, at 24.

In lieu of its current interpretation, FDA could choose to interpret 21 U.S.C. § 343(r)(3)(B) in accordance with the plain meaning of the statute and the intentions of Congress. Doing so would cause FDA to apply significant scientific agreement to the specific claim as worded and to determine if relevant evidence from all available sources (not just well-designed studies) revealed that a significant segment of scientists having relevant expertise agreed that consumers were reasonably likely to obtain the claimed health benefit (i.e., that the claim was supported by the evidence). The word "support" in the statute should be contrasted with the word "established" or "proven" which does not appear in the statute but is substantively required by FDA as a condition precedent to claim authorization. Little, if anything, of what is now accepted as true is considered "established" or "proven" in science except after often a lengthy period of intense debate.

Moreover, even accepted knowledge is always incomplete, in that there is always more to learn about it. Nevertheless, when a significant segment of scientists believe the claim as worded supported by the evidence, this agency can (and must) authorize a health claim in full accord not only with the plain language of the statute but also with the intent of Congress (as quoted supra).

Aware since 1994 that Congress expected the health claims standard to be interpreted more flexibly than the drug approval standard, FDA has consistently resisted those expectations, erecting instead an anti-competitive regime that favors its drug approval provisions over the plain and intended meaning of the health claims provisions for foods and dietary supplements. In its Guidance on “Significant Scientific Agreement,” FDA reveals its continuing unwillingness to follow Congress’s intentions. The only message responsive to the *Pearson* Court’s order that comes from the Guidance is that proof to near certainty, the same proof that FDA expects for the approval of new drug applications under 21 U.S.C. § 355(d), will suffice for authorization of health claims. FDA gives no clear direction concerning what evidence short of large and expensive double-blind, placebo controlled clinical trials, it will accept as sufficient for claim authorization, yet the statute, as intended by Congress, clearly requires FDA to authorize claims based on evidence of less weight.

In holding FDA’s failure to define a standard for dietary supplement health claims review invalid under the Administrative Procedure Act, the *Pearson* court reasoned that “it must be possible for the regulated class to perceive the principles which are guiding agency action. Accordingly, on remand, the FDA must explain what it means by significant scientific agreement or, at minimum, what it does not mean.” 164 F.3d at 661.

The Court also faulted FDA for “never explain[ing] just how it measured ‘significant’ or otherwise defined the phrase.” 164 F.3d at 653-654. The decision focused on FDA’s failure to provide FDA regulatees information necessary to discern what FDA expects to receive to find a health claim supported by “significant scientific agreement.” In particular, the Court responded to the plaintiffs’ argument that the FDA had failed to define the level, degree, quality, and quantity of scientific evidence necessary for health claim authorization.

In its Guidance, FDA did not define the term “significant scientific agreement” or explain what combinations of scientific evidence (other than intervention studies) would suffice to satisfy its standard. FDA did reiterate the obvious: that intervention studies providing a direct causal link between a nutrient and an effect on disease, of a kind comparable to that acceptable under the new drug standard, would likely satisfy its health claims standard. Intervention studies on specific dietary compounds are extremely costly. Evidence equivalent to that FDA favors in its Guidance would easily cost a company \$500,000 or more, depending on the nature of the nutrient-disease interaction studied. Few companies can afford that kind of cost, particularly because most supplements cannot be patented. Moreover, there is considerable uncertainty whether after spending these large sums the FDA would be willing to approve qualified health claims, and investors hate uncertainty. Those nutrients that can be patented usually involve use patents for synergistic combinations. Proof of the efficacy of synergistic combinations, via intervention studies acceptable to FDA, would be extremely difficult, if not impossible.

In sum, then, FDA can (and must) reinterpret 21 U.S.C. § 343(r)(3)(B) as Congress intended and as the plain language of the statute dictates. Such an interpretation will ensure that the statute is consistent, rather than in conflict, with the First Amendment principles that govern Government regulation of commercial speech.

**C. UNDER THE CANONS OF STATUTORY CONSTRUCTION
FDA MUST INTERPRET 21 U.S.C. § 343(r)(3)(B) IN A CONSTITUTIONAL
MANNER, IF AT ALL POSSIBLE**

In its letter to the Chairman of the House Subcommittee (attached as Exhibit 2 at 6), FDA states 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 is in error. Indeed, the agency has already authorized food claims with disclaimers designed to cure misleadingness. See 21 C.F.R. § 101.72 (c)(2)(E) (FDA requires the claim to include the qualification “that a total dietary intake of greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health”); §§101.73 (c)(2)(F), 101.76 (c)(2)(D), 101.78 (c)(2)(J) (FDA requires that the claims include the qualification that “development of cancer depends on many factors”); §101.75 (c)(2)(D) (FDA requires that the claim include the qualification “coronary heart disease risk depends on many factors”); §101.77 (c)(2)(F)(FDA requires that the claim include the qualification that “the development of heart disease depends on many factors”);§101.79 (c)(2)(H) (FDA requires that the claim include the qualification that “folate needs to be consumed as part of a healthful diet”). In the quoted statement from its letter to the Chairman of the House Subcommittee, the agency reveals (1) that FDA is unwilling to interpret (indeed it purports to believe it lacks authority to interpret) 21

U.S.C. § 343(r)(3)(B) in a manner that would cause that section to be constitutional under the First Amendment and (2) that FDA will enforce, and insist on compliance with, its interpretation of the statute despite the constitutional invalidity of that interpretation.

As explained above, the plain language of the statute and Congress's intended meaning reveal that the section can, and therefore must, be interpreted in accordance with the First Amendment. *In short, there is no statutory provision, and no expression of legislative intent, that would deny FDA the authority to employ corrective disclaimers to cause health claims for foods to be rendered nonmisleading.* In addition, there is no statutory provision, and no expression of legislative intent, that would deny FDA the authority to authorize health claims, so corrected, based on the conclusion that, as worded, the claims were supported by the scientific evidence. In sum, FDA can (and, therefore, must), as a less restrictive alternative to outright suppression, interpret 21 U.S.C. § 343(r)(3)(B) to permit authorization of health claims, corrected for potential misleadingness with disclaimers, on the labels and in the labeling of foods, as well as dietary supplements.

Under the canons of statutory construction, if a constitutional interpretation of a statute is possible, that interpretation must be preferred over an unconstitutional interpretation. In short, far from having no authority to interpret Section 343(r)(3)(B) to effect outcomes required by the First Amendment, FDA has no choice but to interpret the statute to achieve a constitutional outcome because, by the statute's plain language and intended meaning, a constitutional interpretation is possible. The inherent power to interpret the meaning of statutory language contains within it the legal duty to interpret that meaning in a *constitutional* way. FDA must, therefore, reject its current

unconstitutional interpretation and adopt the one explained above because that latter interpretation is constitutional and avoids the necessity of invalidating the statute. See *De Bartolo Corp. v. Florida Guild Coast Building & Construction Trades Council*, 485 U.S. 568, 573 (1988).

Although it defies credulity to argue, as does this agency, that only one interpretation, an unconstitutional interpretation, is possible for the language in 21 U.S.C. § 343(r)(3)(B), FDA further errs when it tells the House Subcommittee having oversight over its conduct that “absent a court ruling finding the statute unconstitutional” FDA must enforce an unconstitutional law.

As an initial matter, *Pearson* rests upon a body of constitutional law that applies across governments, federal and state, to protect commercial speech from blanket suppression when that same speech can be rendered nonmisleading through the addition of a corrective disclaimer. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh’g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999), *citing Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206 n.20; *Shapero*, 486 U.S. 466 at 478, 100 L.Ed.2d 475, 108 S.Ct. 1916.

The FDA’s argument that First Amendment protection extends only to health claims on dietary supplements, and does not extend to those same health claims when placed on foods, erects a distinction without a principled difference. The overarching First Amendment principle of disclosure over suppression and of permitting even potentially misleading commercial speech if it can be rendered nonmisleading through the addition of a disclaimer transcends the artificial distinctions this agency maintains between food and dietary supplement labels.

The First Amendment is traduced whenever FDA prohibits a health claim for a food that would otherwise be permitted, when properly disclaimed, under the First Amendment. As a matter of constitutional law, consistent with the oaths of office taken by every decision maker in this agency, FDA is duty bound to support and defend the Constitution first and foremost. See, e.g., *Syracuse Peace Council*, 2 FCC Rcd. 5043 (1987) (wherein the Commissioners of the FCC voted unanimously to discontinue enforcement of the FCC's "Fairness Doctrine" on grounds that enforcement would violate the First Amendment). This is not only a condition precedent to employment in the civil service under 5 U.S.C. § 3331, it is a solemn oath that must be honored in practice.

D. THE FIRST AMENDMENT PRECLUDES FDA FROM DENYING AND SUPPRESSING HEALTH CLAIMS FOR FOODS IF THOSE CLAIMS CAN BE RENDERED NON-MISLEADING THROUGH THE ADDITION OF A CORRECTIVE DISCLAIMER

Under the Supremacy Clause of the United States Constitution, U.S. Const. Art. VI. Cl. 2, the Constitution and the laws in pursuance of it are the Supreme law; all laws contrary to the Supreme law are null and void. See generally *Marbury v. Madison*, 5 U.S. 137, 178-180 (1803). FDA's refusal to extend First Amendment protection to health claims for foods, and its insistence on enforcement of contrary regulations, violates the Supremacy Clause by turning the constitutional order upside down: FDA's unconstitutional regulation is made supreme over the First Amendment.

To set the matter aright, FDA must recognize that its refusal to extend First Amendment protection to health claims for foods violates not only the First Amendment but also the Supremacy Clause.

The First Amendment precedent relied upon in *Pearson* applies on all fours to health claims for foods. The speech in issue is commercial. See generally 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (Stevens, J., concurring in judgment); *Pearson*, 164 F.3d at 659. Concerning commercial speech, the Supreme Court has held that Government “may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive.” *In re R.M.J.*, 455 U.S. 191, 203 (1982); see also *Ibanez v. Florida Dep’t of Business and Prof’l Regulation*, 512 U.S. 136, 144-46 (1994); *Peel v. Attorney Registration and Disciplinary Comm’n of Illinois*, 496 U.S. 91, 99-111 (1990). The Court has reasoned that Government prohibitions on the communication of commercial speech that can be rendered non-misleading constitute acts of state paternalism verboten under the First Amendment. That is because the First Amendment favors disclosure over suppression (“the preferred remedy is more disclosure, rather than less”). See *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-375 (1977) (“[W]e view as dubious any justification that is based on the benefits of public ignorance”); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (“The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good”). To ensure fulfillment of the First Amendment principle favoring disclosure over suppression, the Supreme Court has placed a high burden of proof on the Government to establish in every instance of commercial speech suppression that no disclaimer will suffice to cure for misleadingness.² When the Government restricts speech, the Government bears the

² As the *Pearson* Court put it:

burden of proving the constitutionality of its actions. *Playboy Entertainment Group, Inc., v. United States*, U.S. Supreme Court, No. 98—1682 at 6, (decided, May 22, 2000). citing *Edenfield v. Fane*, 507 U.S. 761, 770—771 (1993) (“[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree”); *Board of Trustees of State Univ. of N. Y. v. Fox*, 492 U.S. 469, 480 (1989) (“[T]he State bears the burden of justifying its restrictions ...”). See also *Ibanez*, 512 U.S. at 146 (“If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words ‘potentially misleading’ to supplant the [government’s] burden to demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree”). As the *Pearson* Court informed this agency, “disclaimers [are] constitutionally preferable to outright suppression,” 164 F. 3d at 657, citing *Peel*, 496 U.S. at 110; *In Re R.M.J.*, 455 U.S. 191, 206 n 20 (1982); *Shapero*, 486 U.S. 466 at 478, 108 S.Ct. 1916.

FDA must therefore accept as a matter of constitutional law that the First Amendment principles in *Pearson* apply to health claims on every regulated forum (be it a dietary supplement or a food label). That is the only principled decision this agency can reach, the only decision consistent with the First Amendment, and the only decision consistent with the plain and intended meaning of the statute and the Administrative Procedure Act’s prohibition on arbitrary and capricious agency action.

It is clear, then, that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a “far less restrictive” means.
164 F.3d at 658.

IV. CONCLUSION

For the foregoing reasons, the Joint Petitioners implore this agency to take immediate action to grant the relief requested in the Grocery Manufacturers of America's citizens' petition.

V. ENVIRONMENTAL IMPACT

The actions requested herein are subject to categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32.

VI. ECONOMIC IMPACT

The Joint Petitioners will submit an economic impact statement upon request of the Commissioner of FDA.

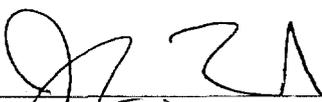
VII. CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition contains all information and views on which the petition relies, and there are no data or information known to the Petitioners unfavorable to the petition.

Respectfully submitted,

DURK PEARSON and SANDY SHAW
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Dated: May 26, 2000

EXHIBIT 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 16 2000

The Honorable David M. McIntosh
Chairman
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
House of Representatives
Washington, D.C. 20515-6134

Dear Mr. Chairman:

Thank you for your interest in the Food and Drug Administration's (FDA or the Agency) "Strategy for Implementation of Pearson Court Decision" (64 F.R. 67289, December 1, 1999). This is in response to your March 13, 2000 letter, to Jane E. Henney, M.D., Commissioner of Food and Drugs, requesting information. Your questions are restated, followed by our response.

Q1. The Pearson court, following well-established Supreme Court jurisprudence, held that the Food and Drug Administration's (FDA) regulation of health claims is premarket review of commercial free speech protected by First Amendment and, therefore, must be justified by a substantial governmental interest and withstand close scrutiny (Pearson, 164 F.3d 650, 655 D.C. Cir. 1999). How does FDA justify its continued suppression of truthful speech that helps consumers make educated decisions to improve their own health? Could FDA avoid violating the First Amendment by approving, as the Pearson court suggested, qualifying language or disclaimers that would ensure that the proposed health claims are truthful and not misleading?

We are in the process of implementing the part of Pearson that requires FDA to consider use of disclaimers to render dietary supplement claims non-misleading when they fail to meet the significant scientific agreement standard of scientific validity. Now that the comment period for submitting new scientific data on the four Pearson health claims has closed, we have begun to reconsider these claims. Our reconsideration will include an evaluation of whether the evidence supporting the claims now

meets the significant scientific agreement standard and, if not, whether qualifying language could prevent the claims from being misleading. The implementation process includes public input through a public meeting (held April 4, 2000) and notice-and-comment rulemaking. (Docket Number 00N-0598)

Q2. Does the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) (and particularly § 403(r)(5)(D), 21 U.S.C. § 343(r)(5)(D), concerning the standard for approving health claims for dietary supplements), authorize FDA to approve truthful, nonmisleading, and adequately-substantiated health claims that include qualifying language or disclaimers? Is this standard compatible with the First Amendment and the Pearson decision? Please provide any evidence in FDA's possession that adoption of such standard would endanger consumers. Has FDA considered adopting this standard? If not, why not?

Section 403(r)(5)(D) contains no specific language concerning the standard for authorizing health claims for dietary supplements. With the Nutrition Labeling and Education Act of 1990 (NLEA), Congress entrusted FDA with the discretion to establish an appropriate standard for the validity of dietary supplement health claims. Congress left this discretion intact through several rounds of amendments to the Federal Food, Drug and Cosmetic (FD&C) Act, (Dietary Supplement Act of 1992, Dietary Supplement Health and Education Act of 1994, and the FDA Modernization Act of 1997 (FDAMA)). By requiring for conventional foods that there be significant scientific agreement among experts qualified by training and experience to evaluate health claims (21 U.S.C. 343(r)(3)(B)(i)), Congress recognized that consumers can make educated decisions to improve their own health if they can rely on health claims about nutrient/disease relationships that qualified experts agree are valid. FDA's implementation of NLEA, including its decision to apply the significant scientific agreement standard to dietary supplement health claims, reflected the Agency's belief that Congress did not intend to place consumers in a position of evaluating the relative merits of health claims in the absence of such expert assistance.

We are evaluating how Pearson might be best implemented to ensure that health claims are truthful and do not mislead consumers. This evaluation will include consumer research.

Q3. In section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress set deadlines for FDA consideration and completion of rulemakings for health claims for conventional foods (i.e., 100 days for FDA to initiate a rulemaking and 540 days to complete a rulemaking). In 1997, FDA adopted a similar deadline framework for health claims for dietary supplements (21 C.F.R. § 101.70). By what authority can FDA now refuse to comply with these statutory and regulatory deadlines?

FDA has not refused to comply with any statutory or regulatory deadlines for health claim petitions. On the contrary, we have met the deadlines established in FDAMA since the passage of that legislation¹, either in the authorization of those proposed health claims that met the significant scientific agreement standard, or in the denial of those that did not. In FDAMA, Congress not only set deadlines for FDA to initiate and complete rulemaking in response to health claim petitions, but also provided a number of options for denial of petitions, extension of deadlines, and for FDA discretion not to act on health claim petitions. Under section 403(r)(A)(i) of the FD&C Act, if FDA does not act by either filing or by denying a health claim petition within 100 days after the petition is received, then the petition shall be deemed denied unless an extension is mutually agreed upon by FDA and the petitioner. Further, if after filing a health claim petition FDA does not act by either proposing a regulation or by denying the petition within 90 days of the date the petition is filed, then the petition shall be deemed denied unless an extension is mutually agreed upon by FDA and the petitioner. Complying with statutory and regulatory deadlines continues to be a top priority with FDA (CFSAN 2000 Program Priorities, Strategy 2.3 § A.2(d)).

Q4. Part II.A. of FDA's January 2000 "Dietary Supplement Strategy (Ten Year Plan)" indicates that implementation of the Pearson decision is a program goal FDA aims to achieve by the year 2010, which is 16 years after enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Neither FDA's Ten Year Plan nor FDA's February 10, 2000 "Center for

¹ There is one possible exception, namely the rulemaking authorizing the use of a health claim relating psyllium husk and reduced risk of coronary heart disease (21 CFR 101.81), which was not completed until 614 days from the date the petition was received. Section 403(r)(4)(A)(i), added by FDAMA, requires rulemaking to be completed within 540 days. Receipt of the health claim petition and issuance of a proposed rule for psyllium husk and reduced risk of coronary heart disease occurred prior to passage of FDAMA. The final rule was completed and published after passage of FDAMA.

Food Safety and Applied Nutrition (CFSAN) Year 2000 Program Priorities" include any interim implementation deadlines. Please explain why it will take 16 years to implement Pearson, when the court held FDA's health claims policy suppresses free speech protected by the First Amendment? Please provide a timetable that implements the health claims provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), DSHEA, and FDAMA in accordance with the First Amendment and Pearson decision, including interim steps and specific deadlines for compliance.

This question has misconstrued the Dietary Supplement Strategic Plan. The plan lays out all dietary supplement-related issues FDA has identified to be addressed and accomplished over the next decade. The ten-year time frame applies to the plan as a whole, not to each individual item in the plan. The plan does not state or imply that Pearson implementation will take ten years to complete. Indeed, the fact that Pearson implementation is listed first under the Labeling section of the plan shows the importance FDA places on it.

FDA has made significant progress on implementing the decision under the plan described in our Pearson implementation strategy notice (64 FR 67289; December 1, 1999). We have issued guidance on significant scientific agreement (64 FR 71794) and held a meeting to obtain public input on Pearson implementation (65 FR 14219). Time lines for Pearson implementation are under development. The time lines will be consistent with the Administrative Procedure Act requirements and FDAMA time frames. FDA has already committed to issue a decision on the four health claims that were the subject of the Pearson litigation by October 10, 2000. This date, which is 190 days following the close of the comment period requesting scientific evidence supporting the claim, is consistent with the time frame for FDA action on health claim petitions provided for in FDAMA. Section (r)(4)(A)(i) of the FD&C Act, added by FDAMA, requires FDA to act by either denying or publishing a proposal within 190 days after receipt of a health claim petition. Accordingly, the process of implementing the Pearson decision will not require anywhere near 16 years to complete.

Q5. Section 2.d of FDA's February 2000 CFSAN Year 2000 priorities for dietary supplements states that FDA will "[c]ontinue to review health claim petitions within the statutory timeframe." Does this more recent commitment overrule the denial of all pending health claims FDA announced in its December 1999 "Strategy for Implementation of Pearson

Court Decision"? If not, please explain what steps FDA will take (including specific deadlines for each step) to resolve this inconsistency and to inform stakeholders and the public about FDA's actual intended practice.

This question has misconstrued the Pearson implementation strategy. FDA has not said that it is denying all pending health claims. Rather the December 1999 Pearson implementation strategy notice states: "Until the rulemaking to reconsider the general health claims regulations for dietary supplements is complete, FDA intends to deny, without prejudice, any petition for a dietary supplement health claim that does not meet the significant scientific agreement standard in 21 CFR § 101.14(c)." (64 FR 67289 at 67290 (emphasis added)) New health claim petitions will continue to be evaluated, within the statutory and regulatory time frames, under the significant scientific agreement standard during this interim period. New health claim petitions that fail to meet the significant scientific agreement standard will continue to be denied under that standard, but will be reconsidered once the general health claim regulations for dietary supplements have been reconsidered in light of the Pearson decision.

Q6. In contrast to FDA's 1994 policy adopting the same standard for approving health claims for dietary supplements and conventional foods (59 F.R. 395, 405, 422-23, January 4, 1994), FDA's Pearson implementation strategy does not address conventional foods. Moreover, in Strategy 2.2 § A.3 of FDA's CFSAN Year 2000 priorities, FDA announced its intention to promulgate this year a final rule amending the health claims regulations governing conventional foods but does not mention the First Amendment or the Pearson decision. Please explain the timeframe and specific steps FDA is taking to ensure that this final rule governing health claims for conventional foods will comply with the First Amendment and the court's reasoning in Pearson.

Pearson implementation is on the Year 2000 CFSAN Priority A list (Strategy 2.3 § A.2(b)) and is discussed in our responses to your previous questions.²

² The Year 2000 CFSAN Program Priorities Strategy 2.2 § A.3 pertains to developing a final rule on infant formula Good Manufacturing Practices. Strategy 2.2 § A.4 pertains to a final rule amending the regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims. This latter strategy component does not mention Pearson because the issues raised in the citizen petitions to which this rulemaking responds were independent of those addressed in Pearson, and the proposed rule was published prior to the Pearson litigation.

The claims that were the subject of Pearson were for dietary supplements. The court's mandate did not direct FDA to reconsider any health claims for conventional foods. There is a statutory requirement that FDA authorize health claims for conventional foods only when there is significant scientific agreement that the nutrient-disease relationship is valid. Therefore, 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. For these reasons, the Pearson implementation strategy announced in the December 1, 1999, Federal Register did not address health claims for conventional foods.

Q7. Does the FD&C Act allow FDA to provide safe harbors of approved label text, instead of specific, government-mandated text? Has FDA considered the benefits of such an approach in terms of establishing a system of model claims that would guide industry and consumers and help conserve FDA resources? If not, please explain why not.

Use of government mandated text is not required when making a health claim. For each authorized health claim, the authorizing regulation specifies (1) elements of the claim that must be included in manufacturer-crafted text (e.g., heart disease claims must identify the disease as either coronary heart disease or heart disease); (2) optional elements that may be included in manufacturer-crafted text; and (3) model claims, or "safe harbor" wording that may be used to ensure that the claim complies with the regulation.

Q8. Please provide a summary of FDA's enforcement activities against illegal health claims for each fiscal year from 1996 to the present, including the number of claims FDA reviewed and the number of enforcement actions FDA took by type, e.g., issuing a warning letter or initiating judicial action. Please also provide the number of full-time equivalent personnel assigned to such enforcement during each fiscal year from 1996 to the present.

FDA does not index its compliance review actions by the alleged violations; therefore, we are not certain we determined the total number of health claims reviewed in the context in question. We did review compliance files within CFSAN and were able to identify records of two Warning Letters issued in 1996 (one for an unauthorized health claim, the other for use of an authorized health claim on a product failing to meet the

eligibility criteria for the claim); one Warning Letter issued in 1999 (encompassing five different products using unauthorized health claims); and one Warning Letter issued and one Import Detention approved in 2000. Both the 2000 Warning Letter and the 2000 Import Detention were for the use of unauthorized health claims. These are the only enforcement actions we are able to identify at this time.

FDA does not have a position assigned specifically to health claim enforcement activities. Activities involving health claim labeling issues would be one of many responsibilities of the approximately two compliance and enforcement full-time equivalents assigned to handle both domestic and import cases within the CFSAN Office of Nutritional Products, Labeling and Dietary Supplements, or this Office's predecessors, over the previous four years. In addition, other offices are involved with the process of issuing Warning Letters (i.e., field investigators, supervisory investigators, chemists, supervisory chemists, Center consumer safety officers (CSO) and supervisory CSOs, Office of Chief Counsel attorneys).

Q9. Has any FDA official responsible for approving health claims had any contact or correspondence with any government scientists or other government personnel (including advisory committee scientists) outside of FDA who have objected to or commented negatively on any of the health claims at issue in Pearson? If so, please provide the name, title, and office of the official; dates of each contact or correspondence; and an explanation of the circumstances surrounding each contact or correspondence.

At the invitation of FDA, one of the panelists at our April 4, 2000 public meeting was from another government agency, Michelle Rusk, Bureau of Consumer Protection, Federal Trade Commission.

Ms. Rusk did not voice concerns or objections on any of the health claims at issue in Pearson. Our contact with Ms. Rusk consists of our correspondence regarding participation in the meeting.

Q10. The Pearson court found that FDA's failure to give any definitional content to the "significant scientific agreement" standard used to evaluate proposed health claims violated the Administrative Procedure Act (5 U.S.C. § 500 et seq.) (APA) (Pearson at 334). In the evaluation of the health claims at issue in Pearson, did FDA comply with all other aspects of APA,

the Government in the Sunshine Act (5 U.S.C. § 552b), and the Federal Advisory Committee Act (5 U.S.C. § App. 2)? If not, please explain.

To the best of our knowledge, we have in each case complied with all other aspects of APA, the Government in the Sunshine Act, and the Federal Advisory Committee Act (FACA). All information upon which FDA relied in denying the Pearson claims is included in the administrative record for these rules. Folic acid and neural tube birth defects have been the topic of three FDA Advisory Committee or Subcommittee meetings. All were open to the public. There were no closed meetings. Requirements of FACA were met. There have been no FDA Advisory Committee meetings on the nutrient-disease relationships that are the subject of the other three Pearson health claims.

Q11. Did the FDA restrict public access under the APA to any documents in connection with the evaluation of the health claims at issue in Pearson? If so, please provide copies of those documents and explain why access was restricted. If FDA wishes to withhold [sic] access from Congress, please provide a description of each withheld document, including date.

FDA is statutorily required to consider the totality of the publicly available scientific evidence in evaluating a proposed health claim. All the information in a health claim petition is made publicly available after FDA files the petition, except that names and other identifying information are redacted from clinical investigation reports, adverse reaction reports, and the like. There were no non-public documents for the health claims at issue in Pearson. All material relied upon in the rulemakings on the claims at issue in Pearson is in the administrative record. The administrative record is public information and is maintained by the FDA Dockets Management Branch under the Docket number of the original rulemaking.

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|--|---------------------|
| (1) antioxidant vitamins/cancer | Docket No. 91N-010 |
| (2) dietary fiber/colorectal cancer | Docket No. 91N-0098 |
| (3) omega-3 fatty acids/coronary heart disease | Docket No. 91N-0103 |
| (4) folic acid comparative claim | Docket No. 91N-0100 |

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Thank you again for your comments. If you have additional questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Melinda K. Plaisier". The signature is fluid and cursive, with a long horizontal stroke at the end.

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable Dennis J. Kucinich
Ranking Minority Member
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
House of Representatives

EXHIBIT 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 26 2000

The Honorable David M. McIntosh
Chairman
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
House of Representatives
Washington, D.C. 20515-6134

Dear Mr. Chairman:

Thank you for your interest in the Food and Drug Administration's (FDA or the Agency) December 22, 1999, "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." This is in response to your letter of February 22, 2000, addressed to Jane E. Henney, M.D., Commissioner of Food and Drugs. We apologize for the delay.

The January 1999 court of appeals decision in *Pearson v. Shalala* (Pearson) held in part that the Administrative Procedure Act requires FDA to explain what it means by "significant scientific agreement." The FDA guidance document, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, was issued in response to this part of *Pearson*.

You asked FDA to explain how the guidance's application of the significant scientific agreement standard reconciles with the First Amendment, Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), Food and Drug Administration Modernization Act of 1997 (FDAMA), and the *Pearson* case. The guidance is consistent with *Pearson* in that it fulfills the court's directive to clarify the meaning of significant scientific agreement. We are unaware of any inconsistency between the significant scientific agreement guidance and NLEA, DSHEA, FDAMA or the First Amendment, and neither did your letter point out any such inconsistency. This guidance does not purport to respond to the First Amendment holding of *Pearson* or to address the use of qualified health claims, however, these issues were addressed in a public meeting held April 4, 2000 and will be addressed in a subsequent rulemaking to reevaluate our general health claim regulations, as was explained in the Federal Register (FR) notice announcing FDA's *Pearson* implementation strategy (Volume 64 FR 67289).

At the public meeting we heard comments representing a wide range of viewpoints on implementing the requirements of Pearson. We are now carefully considering how best to incorporate these comments into appropriate rulemaking to implement the Pearson decision. We will also consider the meeting comments in developing an interim policy on qualified health claims pending finalization of rulemaking.

You also questioned FDA's rationale for applying the significant scientific agreement standard to the overall substance-disease relationship, rather than to a proposed specific health claim. You are correct that FDA applies the significant scientific agreement standard to the validity of the substance-disease relationship that is the subject of the claim, not to the wording of the claim. This approach derives from the NLEA, which provides that FDA shall authorize a health claim to be used on conventional foods only when 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." Title 21, United States Code (U.S.C.) § 343(r)(3)(B)(i). Thus, the statute requires there be significant scientific agreement that the claim is supported by the totality of the publicly available scientific evidence.

FDA extensively discussed the validity of science needed to support a health claim, as well as significant scientific agreement as the standard of validity, in the preambles to the general health claim requirements proposal and final rule (Volume 56 FR 60537 at 60539 and 60547 - 60548, November 27, 1991; Volume 58 FR 2478 at 2503 - 2505, January 6, 1993). In these discussions, FDA indicated that significant scientific agreement addressed the validity of the scientific support for the claim (e.g., see Volume 56 FR 60537 at 60540 and 60547). FDA inferred from Congress' definition of a health claim as a statement of a relationship between a substance and a disease or health-related condition, that the significant scientific agreement should apply to the relationship. The Agency stated that a health claim is to describe the scientifically established relationship between a substance and a disease, and

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not the state of evidence that might support such a claim (Volume 58 FR 2478 at 2505). The Agency also cited legislative history in support of these conclusions (e.g., Volume 56 FR 60537 at 60540 and 60547 - 60548; Volume 58 FR 2478 at 2504 - 2505).

In light of the foregoing considerations, FDA concluded that the significant scientific agreement standard should apply to the validity of the substance-disease relationship, not to the specific wording of the claim (see Volume 58 FR 2478 at 2504 - 2505).

Applying the significant scientific agreement standard to the substance-disease relationship, rather than to the specific claim is also consistent with *Pearson*. The court said that FDA might be justified in rejecting a proposed health claim outright where the evidence for a claim is outweighed by evidence against the claim. If the court had focused on significant scientific agreement for a claim rather than for the relationship, there would not be any need for the weighing of evidence because the petitioner (or FDA) could always adjust the wording of the claim to reflect the available evidence, however limited or contrary.

In summary to the points you raise in your letter, we believe our guidance on significant scientific agreement is consistent with the *Pearson* decision and other applicable law. As another element in implementing *Pearson*, we are working towards the development of criteria to allow qualified health claims for dietary supplements when evidence supporting a relationship between a substance in the supplement and a disease or health-related condition does not meet the significant scientific agreement standard.

Thank you again for your comments. We trust this responds to your questions. If you have further questions, please let us know.

Sincerely,



Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable Dan Burton
Chairman
Committee on Government Reform

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The Honorable Dennis J. Kucinich
Ranking Minority Member
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

The Honorable Helen Chenoweth-Hage
Member, Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

Dockets Management Branch
(Docket No. 99D-5424)