Food and Drug Administration
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Department of Health and Human Services
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Rockville, Maryland 20852

Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims	)))	Docket No. 2007D-0125

COMMENTS OF TREA SENIOR CITIZENS LEAGUE
(September 7, 2007)

TREA Senior Citizens League, through its undersigned counsel, submits the following comments pursuant to 21 CFR 10.115(h) and 72 Fed. Reg. 37246-47 (July 9, 2007). These comments relate to the following documents in Docket No. 2007D-0125:

1. Food and Drug Administration ("FDA") "Draft Guidance for Industry on Evidence-Based Review System for the Scientific Evaluation of Health Claims" (June 2007). http://www.cfsan.fda.gov/~dms/hclmgui5.html (note: this html version of the Draft Guidance is dated July 2007) ("Draft Guidance").

2. FDA Notice,"Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims; Availability," 72 Fed. Reg. 37246-47 (July 9, 2007) (providing public notice of the issuance of this Draft Guidance).

3. FDA Notice,"Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims; Availability; Correction," 72 Fed. Reg. 49723-24 (August 29, 2007) (correcting certain errors in the July 9, 2007 notice).

If finalized, this new Draft Industry Guidance would replace two documents (see Industry Guidance, p. 2-3, n. 3):

1. FDA "Interim Evidence-based Ranking System for Scientific Data" (July 2003), and

2. FDA "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" (December 20, 1999).

However, even if finalized, the Draft Guidance apparently would **not** replace:

3. FDA "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (July 2003).

For reasons discussed below, TSCL requests the FDA to: (i) decline to finalize the current Draft Guidance; (ii) withdraw and reconsider all three of the above previous publications; and (iii) withdraw and rewrite its regulations in this area, most specifically 21 CFR 101.14(c).

I. TREA SENIOR CITIZENS LEAGUE, AS WELL AS ITS MEMBERS AND SUPPORTERS, HAS GREAT INTEREST IN THE FDA'S DRAFT GUIDANCE AND HAS IN THE PAST COMMENTED TO THE FDA ON OTHER RELATED MATTERS.

TREA Senior Citizens League ("TSCL") is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquartered in Alexandria, Virginia, is known as one of the largest U.S. seniors groups, engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has more than three quarters of a million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens' rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

TSCL also previously demonstrated its interest in the activities of the Food and Drug Administration relating to seniors when, on May 29, 2007, TSCL filed comments with the FDA regarding its "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration" in Docket No. 2006D-0480.

The Draft Guidance under review in this proceeding provides that it applies to health claims relating to the elderly which are of particular interest to TSCL:

> Health claims are directed to the general population or designated subgroups (e.g., **the elderly**) and are intended to assist the consumer in maintaining healthful dietary practices. [Draft Guidance, at 3 (emphasis added).]

TSCL's members and supporters, as well as all American citizens, have a vital interest in the Food and Drug Administration's current "Draft Guidance for Industry on Evidence-Based Review System for the Scientific Evaluation of Health Claims." Indeed, TSCL is greatly concerned that the FDA could restrict access to important information about nutritional supplements, as well as the supplements themselves, and that industry compliance with the FDA's Draft Guidance will unduly increase the cost of dietary supplements.

II. THE FDA'S DRAFT GUIDANCE FAILS TO COMPLY WITH THE REQUIREMENTS OF THE NUTRITION LABELING AND EDUCATION ACT OF 1990

The FDA Federal Register of July 9, 2007, presents background information with respect to the Draft Guidance which reveals that the Draft Guidance badly misrepresents the requirements of the underlying statute, the Nutrition Labeling and Education Act of 1990 ("NLEA").

A. FDA's View of NLEA

Underlying the Draft Guidance is the FDA's apparent belief that it is authorized by the NLEA to treat health claims for conventional food and health claims for dietary supplements in the same manner. The Draft Guidance states:

> This scientific standard ["significant scientific agreement"] was prescribed by **statute** for **conventional food** health claims; by **regulation**, FDA adopted the **same standard** for **dietary supplements** health claims. See 21 CFR 101.14(c). [72 Fed. Reg. 37246 (emphasis added).]

This accurately describes what has occurred to date. In 1990, Congress adopted a "significant scientific agreement" standard applicable to "conventional food health claims" and the FDA subsequently purported, by regulation, to extend that same standard to "dietary supplements health claims." The FDA regulation provides a single "validity requirement" for health claims applicable to health claims for both conventional foods and dietary supplements, as follows:

> (c) Validity requirement. FDA will promulgate regulations authorizing **a health claim** only when it 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. [21 CFR 101.14(c) (emphasis added).]

The FDA Draft Guidance contains numerous other statements which indicate that it has conflated its treatments of health claims for conventional foods and health claims for dietary supplements.

1. The FDA views dietary supplements as a mere subset of conventional foods under NLEA, taking the position that health claims for either can be treated the same, both requiring prior FDA review and approval:

> … NLEA directed FDA to issue regulations providing for the use of statements that describe the relationship between a substance and a disease ("health claims") in the labeling of **foods**, including **dietary supplements after** such statements have been reviewed and authorized by FDA. [72 Fed. Reg. 37246 (emphasis added).]

2. The FDA seems to merge, not distinguish, health claims for conventional foods vis-a-vis health claims for dietary supplements:

> An authorized health claim may be used on both **conventional foods** and **dietary supplements**, assuming that the substance in the product and the product itself meet the appropriate standards in the authorizing regulation. [*Id*. (emphasis added).]

3. Although the FDA regulation reveals an identical standard, the Draft Guidance states that the FDA's review process for conventional foods and dietary supplements are only "very similar."

> it became apparent to the agency that components of the scientific review process for an **SSA health claim** and **qualified health claim** are **very similar**. Because of the similarity between the scientific reviews for SSA and qualified health claims, FDA intends to generally use the approach set out in this draft guidance for evaluating the scientific evidence in petitions that are submitted for an SSA health claim or qualified health claim. [72 Fed Reg. 37247 (emphasis added).]

As seen above, the term "SSA health claim" derives from the NLEA, but the FDA creates a new term — "qualified health claim" — without providing any definition — and this term has not been located in NLEA or FDA regulations. It ascribes the origin of this term to a decision of the U.S. Court of Appeals for the D.C. Circuit, but as discussed below in Section III, "qualified health claim" is never used by the court in the cited case. One can only speculate

that it could describe health claims accompanied by disclaimers as discussed in Judge Silberman's opinion. However, the Draft Guidance is completely silent as to identifying the type of scientific evidence which would permit disclaimers to be used.

4. Indeed, the FDA describes the primary purpose of the Draft Guidance as follows:

> The primary purpose of this document is to set out FDA's current thinking on the process for evaluating the scientific evidence for a health claim, the meaning of the **SSA standard** in section 403(r)(3) of the act [NLEA] [for conventional foods], and § 101.14(c) [of FDA regulations], and **credible scientific evidence** to support a **qualified health claim** [for dietary supplements]. [*Id*. (emphasis added).]

Unfortunately, the Draft Guidance only addresses the first point — "the process for evaluating the scientific evidence for a health claim." Rather than clarify the differences between the SSA standard for conventional foods, and the standard for dietary supplements, the FDA fuses the two in a way which violates NLEA.

In the only portion of the Draft Guidance which purports to distinguish between the "significant scientific agreement" test and a test that at one point is described as "credible evidence," the FDA wholly fails to describe how these tests differ, or how a different, lower standard would apply to dietary supplements. Draft Guidance, p. 21.

B. Statutory Analysis of NLEA

Contrary to the FDA's views, stated above, NLEA does not treat dietary supplements as a subset of conventional foods, NLEA does not require prior FDA review of health claims about dietary supplements, NLEA does not view health claims about conventional foods and dietary supplements as interchangeable, and the scientific review process for conventional foods is not very similar to that for dietary supplements.

Indeed, the manner in which NLEA authorizes the FDA to regulate health claims concerning food is completely different from the manner in which this statute addresses nutritional supplements. This single but fundamental misunderstanding infects and undermines the totality of the FDA's Draft Guidance (and regulations).

NLEA Section 3(a) deals with labeling required for food health claims, amending Section 403 of the Federal Food, Drug, and Cosmetic Act which deals with "misbranded food." 21 U.S.C. section 343. It adds a new subsection (r), which the U.S. Code entitles "Nutrition levels and health-related claims," and which provides in pertinent part as follows:

> … if it is a **food** intended for human consumption which is offered for sale and for which a **claim** is made **in the label** or labeling of the food which expressly or by implication — …
>
> > (B) characterizes the **relationship** of any nutrient which is of the type required … to be in the label or labeling of the food to a **disease** or a **health-related condition** unless the claim is made in accordance with subparagraph (3) or (5)(D)….

The **first** way in which claims can be made under the statute (subparagraph (3)) applies to foods, the statute specifying that health claims for foods can only be made if "the claim meets the requirements of the regulations of the Secretary promulgated under clause (B) …" as follows:

> (B)(i) 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. [21 U.S.C. § 343(r)(3) (emphasis added).]

On the other hand, the **second** way that claims can be made under the statute (subparagraph (5)(D)) applies not to foods, establishing an entirely separate rule for claims regarding a "dietary supplement":

> A subparagraph (1)(B) claim made with respect to a **dietary supplement** of vitamins, minerals, herbs, or similar nutritional substances shall **not** be subject to subparagraph (3) [relating to foods] but shall be subject to **a procedure and standard** respecting the validity of such claim, established by regulation of the Secretary. [21 U.S.C. § 343(r)(5)(D) (emphasis added).]

C. FDA's Review Is Flawed

From this review of the statutory language, we see at the outset that the FDA's premise for this Draft Guidance is flawed:

First, rather than treating dietary supplements as a subset of conventional foods, NLEA goes to great lengths to establish different rules relating to health claims for the two types of

products. In fact, NLEA specifically states that dietary supplements "shall **not** be subject to subparagraph (3)" which establishes the "significant scientific agreement" standard for foods. (21 U.S.C. § 343(r)(5)(D), emphasis added.) A different standard was envisioned — and indeed required — by NLEA. It is wholly inconsistent with NLEA for the FDA to apply the "significant scientific agreement" standard to dietary supplements "by regulations" as the FDA explained that it has. Indeed, it would appear axiomatic that the standard that the FDA should develop would be less stringent than that for foods.[1]

Second, there is no requirement whatsoever for **prior** FDA review of claims relating to dietary supplements. The only requirement is that health claims for dietary supplements "be subject to a procedure and standard respecting the validity of such claim, established by regulation." It would be completely consistent with this statutory mandate for the FDA to hear and rule upon complaints about health claims after the fact. Indeed, without any authorization for pre-claim review, it would not appear that authority for such an extraordinary burden on dietary supplements should be assumed.

III. THE DRAFT GUIDANCE FAILS TO MEET CONSTITUTIONAL STANDARDS.

According to the Draft Guidance, "[t]he genesis of qualified health claims was the court of appeals decision in *Pearson v. Shalala*." Draft Guidance, p. 3 (II. Background, Para. 3). The Draft Guidance is mistaken. Although the court of appeals in Pearson used the term "qualified claims" to describe the contents of a published article (164 F.3d at 655), it did not coin the term "qualified health claim" as an alternative to a "significant scientific agreement" health claim. Rather, it is the Draft Guidance that creates the two kinds of health claims, and it apparently does so, in part, in professed reliance upon Pearson to create the impression that the Draft Guidance is designed to meet the First Amendment freedom of speech standards laid out in Pearson v. Shalala, 614 F.3d 650 (D.C. Cir. 1999).[2]

Although purporting to implement those constitutional standards, the Draft Guidance fails to identify them, and consequently completely fails to ascertain whether its proposed evidence-based review system for the scientific evaluation of health claims satisfies the commercial speech doctrine of the First Amendment.

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[1] The Draft Guidance states that "Health claims represent a continuum of scientific evidence that extends from very limited or inconclusive evidence to consensus, with evidence supporting SSA health claims lying closer to consensus." Although the FDA's explanation appears in a paragraph relating to food, the FDA apparently has invented the phrase "credible evidence" to "suggest a [less strong] relationship" applicable to dietary supplements, in alleged conformity with the Pearson ruling. *See* Draft Guidance, p. 21.

[2] *See* Draft Guidance, pp. 3-4 (II. Background, Paras. 3-5).

When measured by those standards, the proposed evidence-based review system falls short of FDA's constitutional responsibilities to facilitate "the commercial speech doctrine [that] embod[ies] a preference for disclosure [by means of disclaimers] over outright suppression." *See id.,* 614 F.3d at 657. Instead, the Draft Guidance characterizes the FDA's constitutional responsibilities in a negative, rather than a positive, light, stating "that the First amendment does **not** permit FDA to reject health claims that the agency deems to be potentially misleading unless the agency determines that a disclaimer would **not** eliminate the potential deception." Draft Guidance, p. 3 (II. Background, Para. 3) (emphasis added).

Because the FDA views the First Amendment protections afforded commercial speech in such a negative way, the Draft Guidance fails to provide guidance that would assist a petitioner on how to phrase a health claim, as well as any disclaimers, either to meet the FDA SSA standard supporting a FDA ruling that the health claim is "authorized," or the FDA "credible" evidence standard supporting a "qualified health claim" as stated in a "letter regarding its intent to consider enforcement discretion." *Id.*, p. 4 (II. Background, Para. 7). Yet, at the heart of the court of appeals ruling in Pearson v. Shalala is the constitutional preference for "disclaimers," as a means whereby potentially misleading claims might be cured. *Id.*, 164 F.3d at 657-58. The Draft Guidance, however, does not even offer assurance that previous FDA acceptance of a "qualified health claim," including an appropriate disclaimer, will limit the exercise of FDA discretion in the future.

Nor does the Draft Guidance offer any assistance in the kind of review that disclaimers may be subjected to should a "qualified health claim" be sought. According to the Draft Guidance, "the components of the scientific review process for an SSA health claim and a qualified health claim are very similar" and, for that reason alone, the Draft Guidance states that the "FDA intends to use" the same approach to both. *See* Draft Guidance, p. 4 (II. Background, Para. 7). Thus, even a petitioner seeking a qualified health claim must run the gauntlet of FDA review that is clearly calculated to ascertain whether the claim meets the SSA standard, thereby imposing significant costs and unnecessary time delays which, themselves, would abridge the free speech interests of the petitioner and the consuming public.

Furthermore, the Draft Guidance fails to provide any meaningful definition of SSA, even though the court of appeals ruling in Pearson v. Shalala called for some infusion of "definitional content" to the term. *See id.*, 164 F.3d at 660-61. Even though the Draft Guidance, if adopted, will replace the FDA's December 22, 1999 Guidance Statement on the meaning of the term,[3] it offers only that the SSA standard lies somewhere on a "continuum of scientfic evidence that extends from very limited or inconclusive evidence to consensus, with evidence supporting SSA health claims lying closer to consensus." Draft Guidance, p. 19 (III. Specificity of the Health Claim Language). The "closer to consensus" demarcation hardly

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[3] *See* Draft Guidance, p. 1, n.3 (I. Introduction, Para. 2).

satisfies the court of appeals standard in Pearson calling for an explanation of what SSA "means … or, at minimum, what it does not mean." Pearson v. Shalala, 164 F.3d at 661.

Such a tepid attempt at making more specific the meaning of SSA spills over into the Draft Guidance's feeble effort to define the "credible" standard required to support a "qualified health claim." According to the FDA, a health claim is "credible" although "it does not meet the SSA standard," because the scientific evidence does not generate the "high level of confidence" that comes from "a sufficient body of relevant scientific evidence that shows consistency across different studies and among different researchers." *See* Draft Guidance, p. 19 (III. Specificity of the Health Claim Language). While this language might tell a petitioner what a "qualified health claim" is not, it offers precious little guidance as to what "credible scientific evidence" is.

In sum, the response of this Draft Guidance, like the actions of the FDA in response to the court of appeals order in Pearson v. Shalala, is half-hearted, with little regard for the First Amendment speech interests of the manufacturers of foods and dietary supplements and of the information needs of the consumers of such products to meet real health needs. *See* Pearson v. Shalala, 130 F. Supp. 2d 105, 118, 120, n.34 (D.D.C. 2001).

IV. THE SCIENTIFIC METHODOLOGY APPLIED BY THE DRAFT GUIDANCE IS BIASED AGAINST HEALTH CLAIMS FOR BOTH FOODS AND DIETARY SUPPLEMENTS.

In one respect the FDA's Draft Guidance is flawed from the standpoint of both conventional foods and dietary supplements. The FDA adopts an evidence-based scientific model more suitable to tracing the cause and effect between a single, potentially-toxic pharmaceutical and a disease, rather than to the identification of the complex manner in which foods and dietary supplements are used by the body in achieving overall health wellness. Accordingly, the evidence-based review system proposed by the Draft Guidance is biased against health claims that are made on behalf of conventional foods and dietary supplements.

Instead of submitting such claims to a review process that would assess the series of interconnections, cross-connections, and recombinations of nutrition in order to assess the effectiveness of appropriate combinations to achieve health wellness, health claims for foods and dietary supplements are assessed by studies that evaluate "the relationship between a substance and a disease." *See* Draft Guidance, p. 5 (III.B. Evidence-Based Review System, Para. 1).

Thus, only "[w]hen there is credible evidence available to suggest a relationship between the substance and disease" does the proposed system then take into account "whether the substance has an independent role in the relationship or whether its role is based on

inclusion or replacement (i.e. substitution) of other substances." *See* Draft Guidance, p. 19 (III.G. Evidence-Based Review, Para. 3).

By isolating, in the first instance, the tested substance from what would otherwise be taken in combination with other substances, in order to ascertain if there is a relationship between the combination and a disease or state of health wellness, the system could miss the very combination that a dietary supplement might have when taken in conjunction with other supplements or conventional foods.

V. THE DRAFT GUIDANCE FAILS TO TAKE INTO CONSIDERATION ITS POTENTIAL ADVERSE EFFECT ON MEDICARE.

TSCL is concerned that the FDA is exceeding its statutory authority, and violating its members' constitutional right to have important information about dietary supplements on the label of the product. The following words of Justice Silberman in the Pearson case should be recalled: "Although a dietary supplement manufacturer remains free to publish articles and books concerning health claims, and may market its dietary supplements with certain physically separate peer-reviewed scientific literature … those channels of communication reach consumers less effectively than does a claim made directly on the label because they impose higher search costs on consumers." 164 F.3d 464, 658, n.7.

The FDA should consider the impact that such an over-reaching regulation would have upon the financial stability of the Medicare program.[4] Dietary supplements are taken by seniors to maintain good health and to prevent health problems, as well as to address certain on-going conditions. Dietary supplements are consistent with a preventative approach to health care, where a small investment in one's health can reap large savings in unnecessary suffering and medical costs down the road. Currently, seniors pay for their own dietary supplements, which are almost never reimbursed by Medicare.[5] FDA restrictions on important information about health care would necessarily lead to lower levels of utilization of important dietary supplements, and higher medical expenses for drugs for which Medicare must pay.

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[4] Medicare, it should be noted, already is facing increasingly large unfunded obligations. *See* "2006 Annual Report of The Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," Centers for Medicare & Medicaid Services, Department of Health and Human Services, April 23, 2007. http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf.

[5] "Medicare Drug Coverage under Medicare Part A, Part B, and Part D," CMS Pub. No. 11315-P, Centers for Medicare and Medicaid Services, August, 2007, p. 4. www.cms.hhs.gov/partnerships/downloads/11315_P.pdf.

Similarly, consumers who were not aware that certain dietary supplements could assist in their health care might choose to pursue conventional, toxic, and often more expensive treatments. For example, instead of trying to combat a common cold with Echinacea[6] or Vitamin C, a person might choose instead to obtain a prescription drug, further increasing the cost to Medicare.

CONCLUSION

For the foregoing reasons, TSCL respectfully submits that the Draft Guidance and other related regulations and FDA publications should be withdrawn, and not reissued until the concerns discussed above be addressed, requesting public comments and establishing meetings and workshops in which such matters can be further addressed.

The FDA website designates this Draft Guidance as "Level 1 guidance" under 21 CFR 110.115(g)(1)-(3). Accordingly, the FDA can "hold public meetings or workshops," and may issue "another draft of the guidance document." *See* 21 CFR 10.115(g)(1)(iii) and (v). We urge that the FDA hold these meetings and workshops in order to better understand the problems associated with such guidance.

Respectfully submitted,

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[6] See "Echinacea Halves Chances of Getting Cold, Review Finds," June 25, 2007, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=amECqXK1DYMk.