

October 2000 **Federal Register** notice and the December 2002 guidance must be tempered by the test of credible evidence. Communication of that or any other level of evidence to consumers in a nonmisleading way remains of critical importance.

The reason for the decision to apply *Pearson* to conventional foods is to provide consumers with better health/nutrition information so they can make better dietary choices. By making clear that manufacturers may label foods with truthful and nonmisleading health claims, FDA believes that the guidance will precipitate greater communication in food labeling of the health benefits of consuming particular foods, thereby enhancing the public's health, because consumers will respond to health claims in food labeling by making better informed dietary choices (67 FR 78002).

The decision announced in the December 2002 notice was also based on a desire to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims. As explained previously, the appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. The agency, however, did not have any consumer data to show that a disclaimer would not eliminate the potential deception.

Pearson and subsequent related cases including *Whitaker*, concern dietary supplement labeling, but as stated previously, FDA by regulation adopted the same procedure and standard for health claims for dietary supplement labeling that Congress prescribed in the NLEA for health claims in conventional food labeling. These dietary supplement regulations, like the NLEA provisions in question, do not provide for qualified claims. Hence, based on *Pearson* and related cases, a court faced with a decision by FDA to not permit a qualified health claim for a conventional food might well find the same tension between the NLEA provisions and the first amendment. It is possible that consumer data will show that potentially misleading health claims cannot be cured by disclaimers in at least some cases, but the agency does not have such data for conventional foods, as it did not (and does not) have such data for dietary supplements. Within the next year, the

agency will be completing research in this area. The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, and evaluation of any additional alternatives, will inform any rulemaking FDA initiates.

In the interim, FDA intends to use the procedures and evidence-based ranking systems for scientific data set out in the below-described guidances on these matters, and consider the exercise of enforcement discretion on a case-by-case basis with respect to qualified health claims in conventional human food and human dietary supplement labeling under certain circumstances. (See *Heckler v. Chaney*, 470 U.S. 821 (1985); *Community Nutrition Institute v. Young*, 818 F.2d 943, 949–50 (D.C. Cir. 1987)).

FDA believes that its interim approach to qualified claims is a reasonable effort to combine the spirit of the NLEA with the current public health and legal circumstances, and one that reflects practical common sense. And, as the Court of Appeals for the District of Columbia Circuit observed in *Niagara Mohawk Power Corp. v. FPC*, 379 F.2d 153, 160, “Courts are loath to say that good sense is not good law.”

B. Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data

This interim evidence-based ranking system describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a petition for a qualified health claim. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease relationship can be assigned to one of four ranked levels. The evidence-based ranking system presupposes that FTC's requirement of “competent and reliable scientific evidence” to substantiate an advertising claim related to health or safety has been met. FTC defines “competent and reliable scientific evidence” as “tests, analyses, research, studies, or other evidence” based upon the expertise of professionals in the relevant area, that has been “conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted” in the profession to “yield accurate and reliable results.” *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988). In applying the system, FDA intends to consider scientific evidence only if it is competent and reliable. FDA intends to use this interim system, beginning in September 2003, for

qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

C. Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

FDA intends to use these interim procedures, beginning in September 2003, for qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

D. The Final Guidances Are Being Issued as Level 1 Guidance under FDA's Good Guidances Practices (GGPs) Regulation (§ 10.115 (21 CFR 10.115))

Consistent with GGPs, the agency will accept comment, but it is implementing these guidance documents immediately in accordance with section 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. FDA tentatively concludes that the guidances contain no new collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidances. Submit a single copy of the electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The Task Force report, two final guidances, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Interested persons may also access the guidance documents at <http://www.cfsan.fda.gov/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

VI. Future Agency Activities

FDA emphasizes that it intends to use the evidence-based ranking system and the procedures on an interim basis. In the near future, the agency intends to publish an advance notice of proposed