

relationship can be assigned to one of four ranked levels.

#### *C. Resources for Review of Scientific Data*

This attachment describes a process to augment the agency's limited scientific review resources on an as-needed basis by using outside contractors.

#### *D. Consumer Studies Research Agenda—Improving Consumer Understanding and Product Competition on the Health Consequences of Dietary Choices*

This attachment sets forth the consumer research studies planned, pending Office of Management and Budget (OMB) approval, to provide the agency with information about consumers' reactions to qualified health claims.

#### *E. Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*

This attachment describes the interim procedures for qualified health claims in the labeling of conventional human food and human dietary supplements.

#### *F. "One-Year" Time Line for Qualified Health Claim Activities*

This attachment consolidates the main activities for June 30, 2003, through June 1, 2004.

The Task Force report also contains the list of the Task Force members, a summary of the four stakeholder meetings the Task Force held, and a summary of public comments submitted to the docket on this initiative (see Task Force report attachments G, H, and I, respectively).

### **III. Final Guidances**

#### *A. Background*

After the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA), FDA issued regulations establishing general requirements for health claims in food labeling (58 FR 2478, January 6, 1993 (conventional foods); 59 FR 395, January 4, 1994 (dietary supplements)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see 21 U.S.C. 343(r)(3) and (r)(4)). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) (21 CFR 101.14(d) and (e) and 101.70)). The standard requires a finding of "significant

scientific agreement" (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims; and that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§ 101.14(c)). Without a regulation authorizing use of a particular health claim, a food bearing the claim is subject to regulatory action as a misbranded food (see 21 U.S.C. 343(r)(1)(B)), a misbranded drug (see 21 U.S.C. 352(f)(1)), and an unapproved new drug (see 21 U.S.C. 355(a)).

NLEA required that FDA itself initially consider health claims for 10 substance/disease relationships. FDA determined that there was SSA concerning a number of these specified substance/disease relationships and in turn authorized eight claims. Not all relationships that Congress specified to be reviewed were found to meet the standard of SSA, and so not all were authorized by FDA.

Several of the substance/disease relationships for which FDA failed to find significant scientific agreement became the subject of a lawsuit brought by a dietary supplement manufacturer. The case is known as *Pearson v. Shalala* (*Pearson*). In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. The district court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)). However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)).<sup>1</sup> 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 court of appeals further stated that it did not "rule out the possibility that where evidence in support of a

claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." (Id. at 659.) Also, the court saw "no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim." (Id. at 659 and n.10.) This language was the genesis of the "weight-of-the-evidence" criterion discussed in this document.

In the **Federal Register** of October 6, 2000 (65 FR 59855), FDA published a notice announcing its intention to exercise enforcement discretion with regard to certain categories of dietary supplement health claims that do not meet the SSA standard in § 101.14(c). The notice set forth criteria for when the agency would consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling, including as a criterion whether the scientific evidence in support of a given claim outweighed the scientific evidence against it.

As discussed previously, on December 18, 2002, FDA announced the Consumer Health for Better Nutrition Initiative to encourage the flow of high quality, science-based information regarding the health benefits of conventional foods and dietary supplements to consumers. In the **Federal Register** of December 20, 2002 (67 FR 78002), FDA announced that it would apply *Pearson* to health claims in the labeling of conventional foods as well as dietary supplements. The agency also announced the availability of guidance concerning when FDA intended to consider exercising enforcement discretion with respect to health claims that do not meet the standard of SSA. Based on *Pearson*, the December 2002 guidance, like the October 2000 **Federal Register** notice stating FDA's intention to consider exercising enforcement discretion with respect to dietary supplement health claims that do not meet SSA, included as a criterion whether the scientific evidence in support of the claim outweighs the scientific evidence against the claim.

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker v. Thompson*, 248 F. Supp.2d 1 (*Whitaker*). In *Whitaker*, the district court interpreting *Pearson*, found that "credible evidence," rather than "weight of the evidence" is the appropriate standard for FDA to apply in evaluating qualified health claims. In light of *Whitaker*, FDA believes that the weight of the evidence standard in the

<sup>1</sup> On March 1, 1999, the Government filed a petition for rehearing en banc (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).