

articulate the science and to better define the substance that is the subject of the claim). However, as a general matter, comments have not persuaded the agency that any particular proposed health claim should not be allowed.

In light of this consideration, after *Pearson*, FDA began using authority given to the agency by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amendments to the act to authorize some unqualified health claims faster (see 65 FR 59855 at 59856). FDA has authorized three health claims, based on a finding of SSA, through the IFR process under section 403(r)(7) of the act.¹¹ First, in the **Federal Register** of September 8, 2000 (65 FR 54686), FDA issued an IFR that authorized a health claim for plant sterol/stanol esters and reduced risk of coronary heart disease (CHD) (§ 101.83) (21 CFR 101.83)). The agency intends to issue a final rule on this claim, that includes consideration of public comment. Second, in the **Federal Register** of October 2, 2002 (67 FR 61773), FDA issued an IFR that amended the health claim regulation in 21 CFR 101.81 authorizing a health claim about the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of CHD to include an additional eligible source of whole oat beta-glucan soluble fiber (the oatrim IFR). After consideration of comments, the agency adopted as a final rule, without change, the provisions of the oatrim IFR (68 FR 44207, July 28, 2003). Third, in the **Federal Register** of December 2, 2002 (67 FR 71461), FDA issued an IFR that amended the health claim regulation in 21 CFR 101.80 authorizing a health claim about the relationship between dietary sugar alcohols and dental carries to include the sugar D-tagatose (the D-tagatose IFR). After consideration of comments,

the agency adopted as a final rule, without change, the provisions of the D-tagatose IFR (68 FR 39831, July 3, 2003).

FDA recognizes that the general rulemaking process (i.e., non-IFR process) for unqualified health claims may be lengthy; however, this process may help ensure the validity of the scientific evidence under the SSA standard before such a claim is authorized, and may help prevent the unfair market advantage that could arise if FDA were to inappropriately characterize a substance or misinterpret the publicly available scientific evidence. The agency is interested in comments on the balance between the priorities of timeliness and comprehensiveness in the agency's review of an unqualified health claim. FDA is requesting comments on whether the agency should continue to use the IFR process for some or all unqualified health claims as a means of expediting the agency's processing of these petitions. Are there specific circumstances when IFRs should or should not be considered appropriate for health claims that meet the SSA standard?

4. Use of Phrases Such as "FDA authorized" in Qualified and Unqualified Health Claims

The agency has for decades discouraged or prohibited use of such phrases as "FDA authorized" or "FDA approved" in labeling. The agency's policy on such statements was generally based on one of two reasons: (1) All products of the type were FDA approved, so that a label statement regarding one product implied a difference that did not exist; or (2) "approval" terminology was not appropriate because FDA did not approve any individual (or specific) product. FDA is requesting data or other information on whether a phrase indicating FDA authorization (e.g., "FDA says * * *") would encourage consumers to have more confidence in a claim it accompanied than in a claim without the phrase. FDA is interested in receiving evidence of data concerning any confusion or potential confusion. Should such a phrase be encouraged at all, even if it were to give the consumer confidence in the claim? Would such a phrase, when used with claims supported by different levels of science, confuse or potentially confuse consumers?

5. Consumer Education

The Task Force report noted growing evidence of a public health gap in knowledge and behavior with respect to substance/disease relationships. Even

when the scientific evidence for substance/disease relationship does not meet the standard of SSA, there may be considerable evidence of a relationship between the substance and the disease, and consumers may find this information useful in planning their diets. FDA is requesting comments on how the agency could best educate consumers about the role of qualified health claims on food labeling, and how such claims may be used by consumers to advance their own understanding of diet and health matters.

6. Evaluations of Outside Scientific Groups

FDA has been requested on several occasions to consider accepting the evaluations of outside scientific groups as representing scientific consensus that could justify health claims. Some wanted to be able to convene their own groups of experts. Others wanted FDA to rely on such organizations as the American Heart Association or the American Dietetic Association, which evaluate scientific information and provide advice to their constituents on diet and health. In its report, the Task Force asked FDA to consider the recommendations of such groups as evidence of the strength of the science underlying a health claim. However, to make such a system work fairly to the benefit of all, including consumers, FDA would need to have confidence in the scientific validity of the group's conclusions about the particular claim in question. Some groups would have more expertise than others, and FDA is not aware of a mechanism for evaluating them fairly and accurately. FDA is requesting comment on whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim. If the agency should give weight to the evaluations of these groups, how should this weight be determined?

FDA's Food Advisory Committee (FAC) is a body of experts chartered to advise the agency on scientific issues upon request; however, FDA does not believe that the FAC is an appropriate body to conduct the initial evaluation of the data supporting a proposed health claim. Because of the limited number of meetings in the FAC's charter and other issues that may be brought before the FAC, FDA does not believe that the FAC could conduct a timely evaluation of such data. On an interim basis, FDA has chosen to use experts identified by another Federal agency (i.e., Agency for Healthcare Research and Quality (AHRQ)) whose mission includes retaining large numbers of such experts

¹¹ Section 403(r)(7) of the act (21 U.S.C. 343(r)(7)) authorizes FDA (by delegation from the Secretary of Health and Human Services) to make regulations issued under section 403(r) of the act effective upon publication pending consideration of public comment and publication of a regulation that considers such comment, if the agency determines that such action is necessary for public health reasons. This authority enables FDA to act promptly on petitions that provide information that is necessary to: (1) Enable consumers to develop and maintain healthy dietary practices, (2) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food, or (3) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible. Regulations made effective upon publication under this authority are deemed to be final agency action for purposes of judicial review. The legislative history indicates that such regulations should be issued as interim final rules (H.R. Rep. No. 105–399, at 98 (1997), reprinted in 1997 U.S.C.A.N. 2880, 2888).