demonstrated before having access to a new genetic test?

Issue 5: What Is an Appropriate Level of Oversight for Each Category of Genetic Test?

Different levels of oversight may be appropriate for tests that present different or unknown levels of risk, have different purposes, and are at different stages of development. Until SACGT has had an opportunity to consider public comment, it is premature for SACGT to formulate or offer any views on whether additional oversight is needed, and if so, what form it should take. SACGT welcomes public comment on this subject.

Question Related to Issue 5:

5.1 How can oversight be made flexible enough to incorporate and respond to rapid advances in knowledge of genetics?

Issue 6: Are There Other Issues in Genetic Testing of Concern to the Public?

6.1 Is the public willing to share, for research purposes, genetic test results and individually identifiable information from their medical records in order to increase understanding of genetic tests? For example, tumors removed during surgery are often stored and used by researchers to increase understanding of cancer. Should samples from individuals with genetic disorders or conditions be managed in a manner similar to cancer specimens? Or does the public feel that this could cause confidentiality problems? If so, are there special informed consent procedures that should be used?

6.2 Research studies involving human subjects or identifiable human tissue samples that are funded by the Government or are subject to regulations of the FDA must be reviewed by an Institutional Review Board (IRB). (An IRB is a specially constituted review body established or designated by an organization to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.) Some studies involving genetic tests do not fall into either of these categories and, therefore, are not required to be reviewed by an IRB. For example, a private laboratory developing a test for its own use would not be required to obtain IRB review. Should all experimental genetic tests be required to be reviewed by an IRB?

6.3 When some medical tests (e.g., routine blood counts) are performed, patients do not sign a written consent to have the test performed. Should health care providers be required to obtain written informed consent before proceeding with a genetic test? Should this apply to all tests or only certain tests? Should testing laboratories be required to obtain an assurance that informed consent has been obtained before providing test services?

6.4 Does the public support the option of being able to obtain a genetic test directly from a laboratory without having a referral from a health care provider? Why or why not?

6.5 Should any additional questions or issues be considered regarding genetic testing?

Part VI. Conclusion

SACGT was chartered to advise the DHHS on the medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests. At SACGT's first meeting in June 1999, the Assistant Secretary for Health and Surgeon General asked the Committee to assess, in consultation with the public, whether current programs for assuring the accuracy and effectiveness of genetic tests are satisfactory or whether other measures are needed. This assessment requires consideration of the potential benefits and risks (including socioeconomic, psychological, and medical harms) to individuals, families, and society, and, if necessary, the development of a method to categorize genetic tests according to these benefits and risks. Considering the benefits and risks of each genetic test is critical in determining its appropriate use in clinical and public health practice.

The question of whether more oversight of genetic tests is needed has significant medical, social, ethical, legal, economic, and public policy implications. The issues may affect those who undergo genetic testing, those who provide tests in health care practice, and those who work or invest in the development of such tests. SACGT is endeavoring to encourage broad public participation in the consideration of the issues. Such public involvement in this process will enhance SACGT's analysis of the issues and the advice it provides to DHHS. SACGT looks forward to receiving public comments and to being informed by the public's perspectives on oversight of genetic testing.

Comment Period and Submission of Comments

In order to be considered by SACGT, public comments need to be received by January 31, 2000. Comments can be submitted by mail or facsimile. Members of the public with Internet access can submit comments through email or participate in the SACGT website consultation.

Secretary's Advisory Committee on Genetic Testing, National Institutes of Health, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892, 301–496–9839 (facsimile), sc112c@nih.gov (email), http://www4.od.nih.gov/oba/sacgt.htm (website).

Dated: November 24, 1999.

Sarah Carr,

Executive Secretary, SACGT.

[FR Doc. 99–31226 Filed 11–30–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of *Pearson* Court Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is informing the public of its strategy to implement a recent court decision in *Pearson* v. *Shalala* (*Pearson*). The agency is taking this action to ensure that interested persons are aware of the steps it plans to follow to carry out the decision. FDA is also announcing how it plans to process petitions for dietary supplement health claims during the interim implementation period.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Background

On January 15, 1999, the U.S. Court of Appeals for the D.C. Circuit issued its decision in *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In *Pearson*, the plaintiffs had challenged FDA's health claim regulations for dietary supplements and FDA's decision not to authorize health claims for four specific nutrient-disease relationships: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 mg of folic acid in dietary supplement form is more effective in

reducing the risk of neural tube defects than a lower amount in conventional food form.

The court held in *Pearson* 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. Accordingly, the court invalidated the regulations prohibiting the four health claims listed above and directed the agency to reconsider whether to authorize the claims. The court further held that the Administrative Procedure Act requires FDA to clarify the ''significant scientific agreement'' standard for authorizing health claims, either by issuing a regulatory definition of significant scientific agreement or by defining it on a case-by-case basis.

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.

After the petition for rehearing was denied, FDA's Center for Food Safety and Applied Nutrition updated its 1999 Program Priorities document to state that developing a strategy to implement the *Pearson* decision would be a high priority for calendar year 1999.

II. Components of the Implementation Strategy

The components of the strategy are to: (1) Update the scientific evidence on the four claims at issue in *Pearson*; (2) issue guidance clarifying the ''significant scientific agreement'' standard; (3) hold a public meeting to solicit input on changes to FDA's general health claim regulations for dietary supplements that may be warranted in light of the *Pearson* decision; (4) conduct a rulemaking to reconsider the general health claims regulations for dietary supplements in light of the *Pearson* decision; and (5) conduct rulemakings on the four *Pearson* health claims. Because of FDA's obligation to implement the court decision promptly, the agency intends to work on the components of the strategy concurrently whenever possible. As noted above, implementation of *Pearson* is one of the items on the Center for Food Safety and Applied Nutrition's (CFSAN's) 1999 Program Priorities list, which constitutes CFSAN's priority work plan for the year, and CFSAN will include *Pearson* implementation as one of its high priority items for fiscal year 2000.

III. Updating the Scientific Evidence on the Four *Pearson* Claims

As a first step toward re-examining the evidence supporting the four claims at issue in *Pearson*, FDA published a notice in the **Federal Register** of September 8, 1999 (64 FR 48841), requesting that interested persons submit any available scientific data concerning the substance-disease relationships that are the subject of the four claims. In that notice, FDA requested that written comments be submitted to the agency by November 22, 1999. In addition, CFSAN entered into a contract with a nongovernment firm to conduct a literature review for the four claims to identify relevant scientific information that became available after the agency's initial 1990 to 1993 review of these claims. This data gathering and literature review is needed for FDA to determine the current nature of the scientific evidence relating to the four claims and is an essential step in re-considering the claims. The contracted literature review for the four claims is due to the agency this fall.

In response to a request from several of the *Pearson* plaintiffs, the agency has agreed to extend or reopen the comment period on the September 8, 1999, notice for 75 days after the agency issues its guidance on the significant scientific agreement standard (described below). The agency will give careful consideration to any additional data it receives during the second 75-day comment period.

IV. Guidance on the Significant Scientific Agreement Standard

The agency is preparing to issue guidance clarifying the meaning of the significant scientific agreement standard. FDA expects to issue such guidance before the end of calendar year 1999.

V. Rulemakings and Public Meeting

FDA is planning to initiate several rulemakings in response to *Pearson*. First, the court's decision requires the agency to reconsider whether to authorize the four claims that were at issue in the case. The agency intends to conduct four rulemakings, one for each claim. In each instance, the agency will first evaluate whether the evidence supporting the claim meets the significant scientific agreement standard; if not, the agency will then proceed to consider whether there is any qualifying language that could render the claim nonmisleading. If FDA believes that the answer to either question is yes, the agency will propose to authorize the claim; otherwise, the agency will propose not to authorize it.

Second, FDA intends to initiate rulemaking to consider changes to its general health claims regulations for dietary supplements that may be warranted in light of *Pearson*. A public meeting during the first quarter of calendar year 2000 will precede this rulemaking. FDA will publish a **Federal Register** notice announcing the date and location of the public meeting. In that notice, FDA will provide a list of topics or questions to focus public input on how the agency's approach to the regulation of health claims for dietary supplements could be changed in light of *Pearson*.

Written comments received in response to the notice, and participation at the public meeting, will assist the agency in the rulemaking to reconsider its general health claims regulations for dietary supplements.

VI. Interim Process for Petitions

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). Once the rulemaking is complete, the agency will, on its own initiative, reconsider any petitions denied during the interim period. Petitions will be reconsidered in the order they were originally received. This process does not apply to the four claims at issue in *Pearson*, which will be handled as previously described.

FDA takes seriously its obligation to implement *Pearson*. The agency believes that the fastest and most efficient way to fully implement the decision is to conduct a rulemaking to reconsider the general procedures and standards governing health claims for dietary supplements before ruling on individual petitions that do not meet the current regulatory standard for health claim authorization. If the agency attempted to proceed case-by-case without establishing a regulatory framework applicable to all petitions, confusion among regulatees, inconsistent agency action, and waste of private and agency resources could result.

This practice is consistent with the practice FDA adopted immediately following the passage of the Nutrition Labeling and Education Act of 1990, which provided explicit statutory authority for health claims on conventional foods and dietary supplements. In a **Federal Register** notice

published March 14, 1991 (56 FR 10906), the agency announced that it would deny, without prejudice, any health claim petition that was submitted before issuance of final regulations concerning the submission and content of such petitions.

Dated: November 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31122 Filed 11–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5013]

Draft Guidance for Industry on Labeling of Over-the-Counter Human Drug Products Using a Column Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling of Over-the-Counter Human Drug Products Using a Column Format.'' This draft guidance is intended to provide information on the use of columns as part of the standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug and drug-cosmetic products.

DATES: Submit written comments on the draft guidance for industry by January 31, 2000.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance entitled ''Labeling of Over-the-Counter Human Drug Products Using a Column Format'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow or Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling of Over-the-Counter Human Drug Products Using Column Format.'' This is the first of a series of guidances the agency plans to issue to help manufacturers, packers, and distributors implement the recently issued final rule establishing standardized format and content requirements for the labeling of all OTC drug products.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing a standardized format and standardized content requirements for the labeling of all OTC drug products including drug-cosmetic products (products that consist of both drug and cosmetic components or a single component marketed for both drug and cosmetic uses). This rule is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulatory requirements for this new standardized labeling require manufacturers to present OTC drug and drug-cosmetic labeling information in a certain prescribed order and format. This new format will require the revision of all existing labeling.

The final rule did not include examples where Drug Facts information (presented in a defined box or similar enclosure) appeared in column format on the same side of the outside container of a retail package, or side-by-side on the immediate container label. This draft guidance is intended to explain how Drug Facts information can be presented using a column format that is consistent with the final rule. This draft guidance includes examples of such labeling in columns.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency's current thinking on using a column format in the labeling of OTC human drug products (21 CFR part 201). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may, on or before January 31, 2000, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31124 Filed 11–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–285]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Request for Retirement Benefit Information.

Form No.: HCFA–R–285 (OMB# 0938–0769).

Use: This form will be used to obtain information regarding whether a beneficiary is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan subsidizes the beneficiary's Part A premium. The purpose in collecting this information is to determine and provide those eligible beneficiaries, with free Part A Medicare coverage.

Frequency: On occasion.