

AGENDA

**FDA PUBLIC MEETING ON IMPLEMENTING THE PEARSON COURT DECISION
AND OTHER HEALTH CLAIM ISSUES**

**DEPARTMENT OF EDUCATION AUDITORIUM
400 Maryland Avenue, SW
Washington, DC**

April 4, 2000

OPENING REMARKS AND KEY ISSUES: (10:00 - 10:30 AM)

Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition

PANEL I: (10:30 - 11:45 AM)

**SHOULD HEALTH CLAIMS BE ALLOWED ON DIETARY SUPPLEMENTS ON A
BASIS OTHER THAN SIGNIFICANT SCIENTIFIC AGREEMENT? IF SO, WHAT
SHOULD THAT BASIS BE AND WHAT ARE APPROPRIATE CRITERIA FOR
MAKING DECISIONS ABOUT ALLOWING SUCH CLAIMS?**

**Jonathan W. Emord, Emord & Associates
Bruce Silverglade, Center for Science in the Public Interest
Bruce Chassy, University of Illinois
Annette Dickinson, Council for Responsible Nutrition
Alice Lichtenstein, Tufts University**

FDA PANEL DISCUSSION:

**Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition
Christine Lewis, Director, Office of Nutritional Products, Labeling, & Dietary Supplements
Michael M. Landa, Deputy Chief Counsel
Margaret Dotzel, Acting Associate Commissioner for Policy
Rachel E. Behrman, Deputy Director, Office of Medical Policy, Center for Drug
Evaluation and Research**

LUNCH: (11:45 AM - 12:45 PM)

00N-0598

LST 1

PANEL II: (12:45 - 2:00 PM)

IF SUCH HEALTH CLAIMS ON DIETARY SUPPLEMENTS ARE TO BE APPROPRIATELY QUALIFIED SO THAT CONSUMERS ARE NOT MISLED, WHAT SHOULD BE THE CHARACTERISTICS OF SUCH QUALIFYING LANGUAGE? SHOULD FDA REQUIRE ANY OTHER INFORMATION TO ASSIST CONSUMERS IN EVALUATING HEALTH CLAIMS AND PREVENT THEM FROM BEING MISLED?

**Mario Teisl, University of Maine
Michelle Rusk, Federal Trade Commission
Scott Bass, National Nutritional Foods Association Representative
James S. Turner, Citizens for Health
Brett Kay, National Consumers League**

FDA PANEL DISCUSSION:

Levitt, Lewis, Landa, Dotzel, Behrman

PANEL III: (2:00 - 3:45 PM)

SHOULD HEALTH CLAIMS GO BEYOND CLAIMS ABOUT REDUCING THE RISK OF A DISEASE TO INCLUDE CLAIMS ABOUT MITIGATION OR TREATMENT OF AN EXISTING DISEASE, OR ARE SUCH CLAIMS DRUG CLAIMS? WHERE IS THE BOUNDARY, IF ANY, BETWEEN THESE CLAIMS?

INTRODUCTION:

Christine Lewis, Director, Office of Nutritional Products, Labeling, and Dietary Supplements

**Claudia A. Lewis-Eng, Emord & Associates
H. Logan Holtgrewe, American Urological Association
William Soller, Consumer Healthcare Products Association
Marsha Cohen, Hastings College of the Law, University of California
Regina Hildwine, National Food Processors Association**

FDA PANEL DISCUSSION:

Levitt, Lewis, Landa, Dotzel, Behrman

BREAK (3:45 - 4:00 PM)

REGISTERED SPEAKERS: (4:00 - 6:00 PM, 5 minutes per speaker)

Public Meeting 

Pearson Court Decision
Health Claim Issues

April 4, 2000

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.

**FDA PUBLIC MEETING ON IMPLEMENTING THE *PEARSON* DECISION
AND OTHER HEALTH CLAIM ISSUES**

April 4, 2000

CONVENIENT PLACES FOR LUNCH

CAFETERIA in the Building—1st floor

Hours: 7:00 a.m. to 2:00 p.m. (serving stops at 1:30)

LOCATED ON C St., S.W.

- **McDonalds—corner of 4th and C St.**
- **Wall Street Deli—2 doors down from McDonalds
400 C St., S.W.**
- **Holiday Inn
Restaurants: Smithsons and Coffee Shop
550 C St., S.W.**

LOCATED ON MARYLAND AVE/INDEPENDENCE AVE.

- **Vie de France (entrance on 6th St. or Maryland Ave.)
Capital Gallery
600 Maryland Ave., S.W.**
- **Air and Space Museum Cafeteria
6th & Independence Ave, S.W. (diagonally across from 400 Maryland Ave.)**

An electrical discharge in a fuel tank can create a spark that could ignite the fuel vapors inside the tank. The spark energy required to ignite fuel depends on the type of fuel, the fuel temperature, and the air pressure (altitude) inside a fuel tank. Under certain conditions, fuel can be ignited with spark energy levels much lower than the energy required to create a visible mark. Therefore, a spark that has enough energy to cause a mark can ignite fuel vapor under a wider range of fuel tank conditions.

In developing an appropriate compliance time for this AD, the FAA considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the modification. In light of all of these factors, the FAA finds a 36-month compliance time for accomplishing the modification to be warranted, in that 36 months represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Cost Impact

The FAA estimates that 227 airplanes of U.S. registry would be affected by this proposed AD.

It would take between 20 and 100 work hours per airplane to accomplish the proposed actions, at an average labor rate of \$60 per work hour. The cost of required parts would be negligible. Based on these figures, the cost impact of the proposed modification on U.S. operators is estimated to be between \$272,400 and \$1,362,000; or between \$1,200 and \$6,000 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44

FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 2000-NM-55-AD.

Applicability: Model A319, A320, and A321 series airplanes; certificated in any category; excluding those on which Modifications 27150 and 27955 have been installed.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent ignition sources and consequent fire/explosion in the fuel tank, accomplish the following:

Modification and Installation

(a) Within 36 months after the effective date of this AD, modify the fuel pipe couplings and install bonding leads in the specified locations of the fuel tank, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-28-1077, dated July 9, 1999.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in French airworthiness directive 2000-006-144(B), dated January 12, 2000.

Issued in Renton, Washington, on March 10, 2000.

Donald L. Riggan,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 00-6493 Filed 3-15-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-0598]

Food Labeling; Dietary Supplement Health Claims; Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Diseases May Be Made as Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments on two topics pertaining to health claims in dietary supplement labeling. The first topic concerns implementation of the recent court of appeals decision in *Pearson v. Shalala (Pearson)*. In *Pearson*, the U.S. Court of Appeals for the D.C. Circuit held that FDA's decision not to authorize four health claims for dietary supplements violated the First Amendment because the agency did not

consider whether the claims, which failed to meet the "significant scientific agreement" standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims, could be rendered nonmisleading by adding qualifying language. The second topic on which we are requesting comments is whether claims about an effect on an existing disease may be made as health claims, or whether such claims should subject the product to regulation as a drug. We are holding this meeting to give the public an opportunity to provide information and views on these topics.

DATES: The meeting will be held on April 4, 2000, from 10 a.m. to 6 p.m. Please register by close of business, March 28, 2000. Late registrations will be accepted contingent on space availability. Submit written comments by April 19, 2000.

ADDRESSES: The meeting will be held at Department of Education, Barnard Auditorium (Federal Building 6), 400 Maryland Ave., SW., Washington, DC. Building entrances are located on the Maryland Ave., SW. and C Street, SW. between 4th and 6th Streets, SW. Federal Building 6 is one block east of the L'Enfant METRO Subway Station's Maryland Ave. exit.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

FOR FURTHER INFORMATION CONTACT:

To register for the public meeting contact: Carole A. Williams, Office of Consumer Affairs (HFE-88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4421, FAX 301-827-3052, e-mail pubmtg@oc.fda.gov.

For general information: Jeanne Latham, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4697, FAX 202-205-4594, e-mail JLatham@cfstan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a number of regulations to implement the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act

(the act). We set forth general requirements for health claims in the labeling of conventional foods (58 FR 2478, January 6, 1993); authorized the use of seven health claims (58 FR 2665, 58 FR 2787, 58 FR 2820, 58 FR 2739, 58 FR 2537, 58 FR 2552, and 58 FR 2622); and denied the use of five other claims (58 FR 2537 [dietary fiber and cancer], 58 FR 2552 [dietary fiber and coronary heart disease], 58 FR 2622 [antioxidant vitamins and cancer], 58 FR 2661 [zinc and immune function in the elderly], and 58 FR 2682 [omega-3 fatty acids and coronary heart disease]). We also initially denied one claim (58 FR 2606 [folic acid and neural tube defects]) that was later authorized (59 FR 433, January 4, 1994) and then modified (61 FR 8750, March 5, 1996). In response to the 1990 amendments and the Dietary Supplement Act of 1992, we issued regulations applying the general requirements for health claims for conventional foods to dietary supplements (59 FR 395, January 4, 1994). The general health claims regulations for both conventional foods and dietary supplements are in 21 CFR 101.14 and 101.70. The regulations on individual health claims are in 21 CFR 101.71 through 101.82.

Our general health claim regulations for dietary supplements and our decision not to authorize health claims for four specific substance/disease relationships were challenged in *Pearson v. Shalala* (*Pearson*). These four substance/disease relationships include: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 milligram of folic acid in dietary supplement form is more effective in reducing the risk of neural tube defect than a lower amount in conventional food form.

In 1998, the district court ruled for FDA in all respects (14 F. Supp. 2d 10 (D.D.C. 1998)). In January 1999, 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)). The appeals court held that, based on the administrative record compiled in the challenged rulemakings, the First Amendment does not permit FDA to reject health claims that we determine to be potentially misleading unless we also reasonably determine that no disclaimer would eliminate the potential deception. As a result of the decision, we must reconsider our approach to authorizing health claims for dietary supplements. The court further held that the Administrative Procedure Act (the APA) 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.

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)). We announced in the *Federal Register* of December 22, 1999 (64 FR 71794), the availability of a guidance clarifying the significant scientific agreement standard. The guidance is available on the Internet at <http://vm.cfsan.fda.gov/dms/ssaguide.html>.

In the *Federal Register* of December 1, 1999 (64 FR 67289), we published a notice informing the public of the steps we plan to follow to carry out the *Pearson* decision. This notice announced plans to hold a public meeting before initiating rulemaking to consider what changes to the general health claims regulations for dietary supplements may be warranted in light of *Pearson* (64 FR 67289 at 67290). We believe that our reevaluation of these regulations will benefit from a public meeting and an open discussion of all possible approaches to implementing the court's decision.

Also in December 1999, we declined to issue a proposed rule for a health claim relating dietary supplements containing saw palmetto extracts and symptoms associated with benign prostatic hyperplasia (BPH). The petition requesting authorization for the claim was denied by operation of law on December 1, 1999, and we issued a letter explaining our decision on the same day. Our basis for not proposing a rule was that we were unable to resolve, within the timeframe required, the novel policy issue, which the petition entailed. This issue is whether a health claim may include claims about mitigation or treatment of disease. To date, the health claims that we have authorized have been for reducing the risk of a disease. While this issue was not considered in *Pearson*, as a topic that also relates to the regulation of health claims, it is being included for discussion in this public meeting.

On December 7, 1999, the agency was sued by the petitioners who had requested FDA to authorize a health claim for saw palmetto extract and BPH (*Whitaker v. Shalala*, No. 1:99CV0247 (D.D.C. December 7, 1999)). The plaintiffs alleged that our denial of the petition violated the First Amendment to the Constitution, the 1990 amendments, and the APA. The plaintiffs asked the court to order the

agency to evaluate their petition under the health claims regulations. The case is stayed through May 26, 2000, while we consider whether claims of effects on an existing disease may be made as health claims rather than drug claims.

II. Scope of Discussion

We are holding the public meeting on April 4, 2000, in part to identify and discuss possible changes, in light of the *Pearson* decision, to our general health claim regulations as they apply to dietary supplements. Unlike the statutory provision for the use of health claims on dietary supplements (section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(s)(D))), section 403(r)(3)(B)(i) of the act provides that FDA may authorize health claims on conventional foods only when there is significant scientific agreement among qualified experts that the totality of publicly available scientific evidence supports the claim. As a result of this statutory requirement for conventional foods and because the *Pearson* case involved only dietary supplements, this portion of the public meeting will be restricted to health claims on dietary supplements.

A second topic open for discussion is whether claims about mitigation or treatment of diseases and their symptoms may be appropriately made as health claims.

We anticipate that both discussions will include presentations from people whom we invite to participate as well as from members of the public.

A. Implementation of the *Pearson* Court Decision

We are requesting comment on how to implement the element of the *Pearson* decision addressing the use of qualified health claims on dietary supplements when the evidence supporting the claim does not meet the "significant scientific agreement" standard. In general, we request public comment on whether qualified health claim statements for dietary supplements can be made that would not mislead consumers, and, if so, what types of disclaimers or other qualifying language would be appropriate. We would specifically request that persons commenting in person and in writing consider and provide input on the questions listed below. Comments recommending a particular regulatory approach should explain how that approach is consistent with the constitutional and statutory requirements to which FDA is subject.

1. What is the best regulatory approach for protecting and promoting the public health? Specifically, what approach to regulating health claims will: (a) Protect consumers from

fraudulent and misleading claims; and (b) provide reliable, understandable information that will allow consumers to evaluate claims intelligently and identify products that will in fact reduce the incidence of diseases? By what criteria should implementation options be judged?

2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence? If so, what are the characteristics of effective qualifying language? How should the agency determine what constitutes an appropriately qualified claim? If the available information is not sufficient to answer these questions, what research needs to be done, and who should be responsible for doing it? The agency encourages those commenting to submit empirical data on the effectiveness of qualifying language.

3. Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?

4. If health claims are permitted based on a standard less rigorous than significant scientific agreement, what is the best way to distinguish among claims supported by different levels of evidence so that consumers are not misled? Does the word "may" in existing health claims accurately communicate the strength of the evidence supporting claims that meet the significant scientific agreement standard, or should other language be used?

5. If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?

6. The *Pearson* opinion mentions circumstances in which FDA might be justified in banning certain health claims outright (e.g., where the evidence in support of the claim is outweighed by evidence against the claim, or where the evidence supporting it is qualitatively weaker than the evidence against it) (*Pearson*, 164 F.3d at 659 and n.10).

a. How should FDA determine when evidence supporting a health claim is outweighed by evidence against the claim?

b. How should FDA determine when evidence supporting a health claim is qualitatively weaker than the evidence against the claim?

c. Are there other circumstances in which health claims are inevitably misleading and cannot be made nondeceptive by qualifying language?

7. What safety information is necessary to prevent a health claim from being misleading? For example, such information might include side effects, drug and food interactions, and segments of the population who should not use the product or should consult a physician before doing so. When a product may have adverse effects unrelated to the subject of a scientifically valid health claim, is the claim misleading? Under what circumstances, if any, should the product be allowed to bear the claim?

8. What actions should the agency take to ensure that consumers receive all relevant information about the safety of products that bear health claims and about research on product safety?

B. Whether Claims of Effects on Existing Diseases May Be Made as Health Claims

All health claims that we have authorized since passage of the 1990 amendments have been claims about reducing the risk of a disease. However, the saw palmetto extract health claim petition (Docket Number 99P-3030) requests authorization to make a claim about effects on an existing disease. Thus, the petition proposes a significant expansion of the scope of health claims beyond those that are currently authorized.

The issue of whether health claims may be about effects on an existing disease arose in the context of a petition for a dietary supplement health claim. For this reason and because the other issue to be discussed at the public meeting concerns health claims for dietary supplements, the focus of discussion will be the use of claims on labels or labeling of dietary supplements about effects on an existing disease. However, we recognize that this issue is likely to arise in the context of health claims for conventional foods as well. Any decision we make on this issue with respect to dietary supplements, therefore, will also affect the use of such claims for conventional foods.

The health claims provisions of the act were enacted as part of a statutory scheme that already included extensive regulatory requirements for drugs. Before the 1990 amendments, the drug provisions had been applied to foods, including dietary supplements, that made claims about effects on disease. Arguably, if Congress had intended to permit any kind of disease claim for foods, it could have exempted all foods bearing authorized health claims from the drug definition in section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), which provides that an article "intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease" is a drug. Instead, Congress provided that a product that bears an authorized health claim shall not be classified as a drug solely because of the presence of the claim (21 U.S.C. 321(g)(1)(B)). Congress' decision to proceed in this manner, rather than by creating an unconditional exemption, suggests that it may have wanted the drug provisions to continue to apply to foods in certain circumstances. Similarly when the Dietary Supplement Health and Education Act (DSHEA) was enacted in 1994, Congress did not provide that dietary supplements are deemed to be foods in all circumstances; rather, it provided that dietary supplements are deemed to be foods "except for purposes of section 201(g)" of the act, the drug definition.

In interpreting the health claim provisions of the act and their relationship to the drug provisions of the act, FDA has tried to strike a balance between recognizing that foods, including dietary supplements, can influence disease outcomes without ceasing to be foods, and honoring the statutory distinction between drugs and foods. To that end, we included in our health claims regulations the requirement that a product that bears a health claim must establish that it is a food by demonstrating nutritive value (21 CFR 101.14(b)(3)). Moreover, in the preambles to the regulations, we distinguished between nutritional effects of food substances, which we said would be an appropriate subject for a health claim, and effects that are therapeutic, medicinal, or pharmacological, which would not. (See, e.g., 56 FR 60537 at 60545 to 60546, November 27, 1991; 58 FR 2478 at 2501, January 6, 1993; and 59 FR 395 at 408, January 4, 1994.) FDA also emphasized that the relationship of a food or a food component to a disease is different from that of a drug because of genetic, environmental, and behavioral factors that affect the development of chronic diseases in addition to diet, and because of the complexity of foods themselves (58 FR 2478 at 2501). Therefore, we explained, some claims that would be appropriate as drug claims under section 201(g)(1)(B) would not be appropriate as health claims for foods because they "imply a degree of association between the substance and the disease that is not supportable for any food" (56 FR 60537 at 60552).

Further, we commented that it would be necessary for a health claim petitioner to "show that the claimed effect on disease is associated with the normal functioning of the human body"

and that claims to "correct an abnormal physiological function caused by a disease or health-related condition" would be drug claims rather than health claims (59 FR 395 at 407 to 408). With respect to claims about effects on symptoms of a disease, we said:

[T]here is no provision in the act for the agency to exempt statements about symptoms of disease from causing products to be regulated as drugs. Although such statements may not be claims that the product will treat the disease that causes the symptoms, the statements clearly pertain to the mitigation of disease by addressing the symptoms caused by the disease. Section 201(g)(1)(B) of the act provides, in part, that articles intended for use in the mitigation of disease are drugs. (59 FR 395 at 413)

Another relevant part of the statutory scheme is the medical foods definition, enacted as part of the Orphan Drug Amendments of 1988. The statutory definition of a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation" (21 U.S.C. 360ee(b)(3)). Thus, medical foods are a category of foods intended for dietary management of disease through a nutritional mechanism.

By their very nature, claims about effects on an existing disease are aimed at people who are ill. To date, authorized health claims have been aimed either at the general population or at a population subgroup whose members are at risk for a particular disease but are not yet sick. Since there are already two categories of ingested products that bear claims targeted to people suffering from a disease, drugs and medical foods, the agency believes there is reason to question whether Congress also intended health claims to encompass such claims.

FDA is open to reexamining its past statements on this issue in light of subsequent developments, such as advances in science and technology, changes in the marketplace, and the passage of DSHEA. In considering the scope of the health claims provisions of the act, we will seek an interpretation that is consistent with the statutory provisions governing drugs and medical foods and that gives effect to each part of the statute.

We are inviting public comment on this issue, and in particular we are seeking input on the following questions. Comments recommending a particular regulatory approach should

explain how that approach is consistent with the legal requirements to which FDA is subject.

1. Does the language and structure of the act restrict the permissible types of substance-disease relationships that can be described in a health claim? How should FDA interpret the health claim and drug provisions of the act and the medical food provision of the Orphan Drug Amendments in relationship to each other?

2. If FDA were to permit at least some claims about effects on an existing disease as health claims, what criteria should be used to determine when a claim is a permissible health claim and when it is a drug claim under section 201(g)(1)(B) of the act?

3. If FDA were to permit at least some disease treatment or mitigation claims as health claims, what about claims that are covered by an existing over-the-counter (OTC) drug monograph? For example, if there is an existing drug monograph on the use of a dietary ingredient in an OTC drug product to treat or mitigate disease, and the monograph concludes that the substance is not safe and effective for the intended use, should FDA still consider authorizing a health claim for the substance-disease relationship?

III. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, we request that you register in writing with the contact person by March 28, 2000, by providing your name, title, business affiliation, address, telephone and fax number. To expedite processing, this registration information also may be sent to the contact person by fax to 301-827-3052, or sent by e-mail to pubmtg@oc.fda.gov. If you need special accommodations due to disability, please inform the contact person when you register. A permanent assistive listening device (ALD) is installed in Barnard Auditorium. The ALD can be used with either a hearing aid T-coil or a headset/receiver available at the auditorium. If, in addition to attending, you wish to make an oral presentation during the meeting, you must so inform the contact person when you register and submit: (1) A brief written statement of the general nature of the views you wish to present; (2) the names and addresses of all persons who will participate in the presentation; and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each presentation. We anticipate that, if time permits, those

attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

You may submit, on or before April 19, 2000, written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to FDADockets@oc.fda.gov or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. You should annotate and organize your comments to identify the specific issues to which they refer. Please address your comment to the docket number given at the beginning of this notice. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

V. Transcripts

You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after April 14, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Internet at <http://www.fda.gov>.

VI. Reference

We have placed the following reference on display in the Dockets Management Branch. You may see it at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

REGISTRATION FORM

Public Meeting on Implementation of *Pearson* Court Decision and Expansion of Health Claims to Cover Claims of Effects on Existing Diseases

Instructions: To register, complete this form and mail or fax it to 301-827-3052 by March 28, 2000.

Name _____

Title _____

Company _____

Address _____

Telephone _____

Fax _____

E-mail _____
Please indicate the type or organization that you represent:

Industry _____

Government _____

Consumer Organization _____

Media _____

Healthcare Professional _____

Law Firm _____

Educational Organization _____

Other (specify) _____

Do you wish to make an oral presentation?

Yes _____

No _____

If yes, you also must submit the following:

1. A brief statement of the general nature of the views you wish to present.
2. The names and addresses of all persons who will participate in the presentation, and
3. An indication of the approximate time that you request to make your presentation.

Dated: March 10, 2000.

Margaret M. Dotzel,
Acting Associate Commissioner for Policy.
[FR Doc. 00-6509 Filed 3-13-00; 2:34 pm]
BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 95 and 177

[USCG-1998-4593]

RIN 2115-AF72

Revision to Federal Blood Alcohol Concentration (BAC) Standard for Recreational Vessel Operators

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the Federal Blood Alcohol Concentration (BAC) standard under which a recreational vessel operator

would be considered operating while "intoxicated." For recreational vessel operators, the proposed rule would lower the current Federal BAC threshold from .10 BAC to .08 BAC. This change is appropriate because boating accident statistics show that alcohol use remains a significant cause of recreational boating deaths and because we support a trend in State recreational boating laws toward the .08 BAC standard. Further, the proposed Federal BAC standard will not supercede or preempt any enacted State BAC standard. Additionally, the proposed rule would replace the term "intoxicated" with the phrase "under the influence of alcohol or a dangerous drug." This change would bring the regulations into conformance with current statutory language. The proposed rule is expected to reduce the number of recreational boating deaths and injuries resulting from accidents caused by operators under the influence of alcohol or a dangerous drug.

DATES: Comments and related material must reach the Docket Management Facility on or before July 14, 2000.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By hand-delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Internet Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, at the address listed above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on this proposed rule, contact