Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 67 FR 62475–77, dated October 7, 2002) is amended to reorganize the Office of the Director, CDC.

Section C–B, Organization and Functionss, is hereby amended as follows:

After the *Office of Management and Operations (CAD),* insert the following:

Office of Science Policy and Technology Transfer (CAE). (1) Advises the CDC Director and Senior Staff on science matters and represents CDC in these areas to the Department, other agencies, and Congress; (2) maintains the integrity and productivity of CDC's scientists by resolving controversial scientific issues, developing scientific policies and procedures, supporting training and information exchange, and presenting awards for outstanding scientific efforts; (3) assures the protection of human subjects in public health research; (4) integrates behavioral and social sciences research into public health research; (5) provides advice and guidance on the management of intellectual property; interprets policies, rules, and regulations, especially those related to the Federal Technology Transfer Act; (6) promotes and facilitates the timely transfer of technology, knowledge, products, and processes that improve public health through the use of patents, trademarks, Biological Materials Licensing Agreements, and Cooperative Research and Development Agreements; (7) coordinates governmental and non-governmental vaccine activities, including vaccine research, development, and safety and efficacy testing trough the National Vaccine Program Office and the National Vaccine Advisory Committee; (8) advises the Secretary of HHS and the Director of CDC about the most appropriate use of vaccines and immunization practices for effective disease control in the population through the Advisory Committee for Immunization Practices; and (9) manages the CDC and ATSDR Specimen and Data Bank, an archive of biological materials, including blood components, tissue, bacterial isolates, DNA, and other biological and environmental specimens.

Office of Minority Health (CAG). (1) Serves as the principal advisor to the Director, CDC/Administrator ATSDR on all minority health issues affecting the agency; (2) serves as the focal point for CDC minority health programs, projects, and issues including coordination of CDC/ATSDR activities with the PHS, other U.S. Government Agencies, health agencies of other nations, other national and international government and non-government organizations, community-based organizations, and the public at large; (3) provides leadership and coordination in the development and implementation of long-term plans for minority health activities within the Centers, Institute, and Offices of CDC; (4) provides leadership, in collaboration with senior managers, for policy initiatives to improve the health of ethnic populations, setting agency priorities, goals and objectives, defining appropriate interventions, and monitoring progress toward meeting these goals and objectives; (5) advocates for minority health issues, including presentation at scientific or programmatic meetings, publication of important findings, and dissemination of information via electronic or other means; (6) assesses the progress to improve minority health by establishing tracking mechanisms, and assuring the use of minority health measures to set goals and track accomplishments; (7) coordinates health initiatives including CIO and ATSDR support of Executive Branch and Departmental Minority Health Initiatives; (8) coordinates the planning, design and implementation of minority health research and oversees studies related to understanding and improving health disparities; (9) assists the CIOs and their constituents in identifying and improving the collection and analysis of data on race and ethnicity needed to develop policy, formulate research agendas, set program priorities, and monitor progress in achieving health outcomes; (10) assures minority health issues are incorporated in to the CIO and ATDSR research agendas and ongoing systematic reviews of the literature on intervention effectiveness; (11) assists CIOs and ATSDR in developing and implementing an agency-wide system to apply standards for evaluation and quality assurance, and monitor, evaluate, and measure the cost-benefit/effectiveness and prevention effectiveness of programs to reduce health disparities; (12) assists in the review and clearance of manuscripts, medical studies, or technical papers for publication, and recommends changes as needed to ensure the quality of the work and consistency with HHS and CDC minority health policies and goals, (13) assists the CIOs and their constituents to increase the competence and diversity of the public health workforce by supporting minority student internships, fellowships and Institutions of Higher Learning; and (14) identifies and fosters partnerships and collaborative activities with public, non-profit, private organizations and organizations and agencies, and academia to improve their organizational capacity to execute public health policy, programs, and the CDC and ATSDR agenda.

Office of the Executive Secretariat (CAH). (1) Anticipate potential problems and plans for processing future decisions and issue analyses; (2) coordinate the review and clearance of all controlled correspondence and other documents including announcements, position papers, briefing documents, and report to Congress regarding current Departmental and CDC/ATSDR policy considerations to facilitate consistency and adherence to HHS and agency policy across Centers/Institutes/Offices; (3) control the communications flow by communicating the actions taken by the Director on documents and at meetings, including revisions needed and follow-up action; (4) manage the flow of decision documents and correspondence for action by the Director of CDC; (5) assure that the Director has the views of OGC and the Deputy Director before making program or management decisions; (6) represent CDC in relations with the Executive Secretary of the Department, other HHS executive secretariats, and with outside document management organizations; (7) set editorial standards and processing policies for documents acted on by the Director; (8) track incoming documents and makes action and review assignments to appropriate staff; and (9) maintain all official records relating to the decisions and official actions of the Director, CDC and his immediate staff.

Dated: November 27, 2002.

David Fleming,

Acting Director.

[FR Doc. 02–32009 Filed 12–19–02; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee on Mental Retardation; Notice of Meeting

AGENCY: President's Committee on Mental Retardation (PCMR), HHS.

ACTION: Notice of meeting.

DATES: Monday, January 27, 2003, from 1 p.m. to 7 p.m., and Tuesday, January 28, 2003, from 8 a.m. to 4 p.m. The entire meeting of the PCMR will be open to the public.

ADDRESSES: The meeting will be held at the Aerospace Center Building, Aerospace Auditorium, 6th Floor East, 370 L'Enfant Promenade, SW., Washington, DC 20447. Individuals who will need accommodations for a disability in order to attend the meeting (*i.e.,* interpreting services, assistive listening devices, materials in alternative format) should notify Sally Atwater at (202) 619–0634 no later than January 13, 2003. We will attempt to meet requests after that date, but cannot guarantee availability. All meeting sites are barrier free.

Agenda: The Committee plans to discuss critical issues relating to individuals with mental retardation concerning education and transition, family services and supports, public awareness, employment, and assistive technology and information.

FOR FURTHER INFORMATION CONTACT: Sally D. Atwater, Executive Director, President's Committee on Mental Retardation, Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, telephone: 202–619–0634, fax: 202–205–9591, e-mail: *satwater@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs and supports for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

Dated: December 6, 2002.

Sally D. Atwater,

Executive Director, President's Committee on Mental Retardation.

[FR Doc. 02–32002 Filed 12–19–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0515]

Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements.'' This guidance updates the agency's approach to implementing the court of appeals decision in *Pearson* v. *Shalala* (*Pearson*) to include conventional foods. FDA is taking this action to inform interested persons of the circumstances under which the agency intends to consider exercising its enforcement discretion to permit qualified health claims for conventional foods and dietary supplements.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Kathleen Ellwood, Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (the 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),(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 (21 CFR 101.14(d),(e); 21 CFR 101.70)). The standard requires a finding of ''significant scientific agreement'' before FDA may authorize a health claim by regulation § 101.14(c) (21 CFR 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 significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, 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 (21 CFR 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)).

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)). 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. 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)).

In the **Federal Register** of October 6, 2000 (65 FR 59855), FDA published a