DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Head Start Bureau; Advisory Committee on Head Start Research and Evaluation; Meeting

AGENCY: Administration for Children, Youth and Families, ACF, DHHS.

ACTION: Notice of meeting; Advisory Committee on Head Start Research and Evaluation.

SUMMARY: The 1998 Head Start Reauthorization (42 U.S.C. 9844(g); section 649(g)(1) of the Head Start Act, as amended) called on the Secretary of Health and Human Services to form an independent panel of experts (i.e., an Advisory Committee) to offer advice concerning research designs that would provide a national analysis of the impact of Head Start Programs. The July 26–27, 1999 meeting will be the last of three meetings of the Advisory Committee that will culminate in a report to the Secretary due September 30, 1999.

DATES: July 26, 1999, 9 a.m.–5 p.m. and July 27, 1999, 9 a.m.–5 p.m.

PLACE: Holiday Inn Hotel and Suites, 625 First Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION: This meeting is open to the public and is barrier free. Meeting records will also be open to the public and will be kept at the Switzer Building located at 330 ''C'' Street, SW, Washington, DC 20447. The Head Start Bureau also intends to make material related to this meeting available on the Head Start web site http://www2.acf.dhhs.gov/programs/hsb. An interpreter for the deaf and hearing impaired will be available upon advance request by calling Ellsworth Associates at 703/821–3090 (ext. 282).

FOR FURTHER INFORMATION CONTACT: Deborah Roderick Stark at 301/889–0430 for substantive information. ACF Office of Public Affairs at 202/401–9215 for press inquiries. Ellsworth Associates at 703/821–3090 (ext. 282) for logistical information.

Dated: July 1, 1999.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 99–17237 Filed 7–6–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0268]

Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations on the container closure systems information that applicants should provide to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in support of new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. 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: W. Mike Adams, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310, or John D. Finkbohner, Center for Biologics Evaluation and Research (HFM–676), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301827–3031.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations on the container closure system information that applicants should provide to CDER or CBER for initial applications and supplements. In addition, the document provides guidance on qualification and quality control of packaging components used for particular dosage forms and routes of administration, including the following: Drug products for injection and ophthalmic drug products, liquid-based oral and topical drug products and topical delivery systems, solid oral dosage forms and powders for reconstitution, and other dosage forms. This guidance supersedes the agency's ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics,'' issued February 1987.

This Level 1 guidance is being issued consistent with FDA's good guidance practice (62 FR 8961, February 27, 1997). In the **Federal Register** of July 15, 1997 (62 FR 37925), FDA announced the availability of a draft version of this guidance. The July 1997 document gave interested persons an opportunity to submit comments through September 15, 1997. On September 5, 1997, in response to requests from the public, the agency extended the comment period until November 14, 1997 (62 FR 46980). All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of public input during the comment period, the final guidance is clearer and more concise than the draft version. The guidance represents the agency's current thinking on submitting information in drug applications on container closure systems used in packaging human drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the 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. A copy of the 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: June 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–17157 Filed 7–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1082–N]

Medicare Program; July 22, 1999, Meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City Metropolitan Area

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) and the Area Advisory Committee (AAC) for the Kansas City metropolitan area on July 22, 1999. The CPAC and the Kansas City metropolitan area AAC will meet both independently and in a joint session.

The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The BBA also requires the Secretary to appoint AACs in the demonstration sites to advise on the implementation of the project. CPAC and AAC meetings are open to the public.

DATES: The CPAC is scheduled to meet on July 22, 1999, from 10 a.m. until 4 p.m., c.d.s.t. The Kansas City metropolitan area AAC is scheduled to meet on July 22, 1999, from 8:30 a.m. until 5:30 p.m. Both committees will meet together in a joint session from 12 noon until 4 p.m.

ADDRESSES: The meeting will be held at the Kansas City Airport Marriott, 775 Brasilia, Kansas City, MO, 64153, (816) 464–2200.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, MD 21244–1850, (410) 786–6451 (for information about the CPAC). Richard P. Brummel, Deputy Regional Administrator, Health Care Financing Administration, Richard Bolling Federal Building, Room 235, 601 East 12th Street, Kansas City, MO 64106, (816) 426–5233 (for information about the Kansas City metropolitan area AAC).

SUPPLEMENTARY INFORMATION: Section 4011 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research designs for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, and May 13, 1999.

The CPAC consists of 15 individuals who are independent actuaries, experts in competitive pricing and the administration of the Federal Employees Health Benefit Program, representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, Health Care Financing Administration; John Bertko, Actuary Principal, Reden & Anders, Ltd.; Dave Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., former CEO, The Oschner Clinic; Samuel Havens, Healthcare Consultant and Chairman of Health Scope/United; Margaret Jordan, President and CEO, The Margaret Jordan Group; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, Senior Fellow, The Brookings Institution; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL–CIO; and Jay Wolfson, Director, Florida Health Information Center, University of South Florida. The chairperson of the CPAC is James Cubbin and the co-chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5) of the BBA, the CPAC will terminate on December 31, 2004.

Section 4012(b) of the BBA requires the Secretary to appoint an Area Advisory Committee (AAC) in each demonstration site to advise the Secretary on the implementation of the project. The CPAC has designated the Kansas City metropolitan area and Maricopa County in Arizona as the initial demonstration sites. The Kansas City metropolitan area AAC has previously met on March 26, 1999, April 8, 1999, April 22, 1999, and May 12, 1999. The Maricopa County AAC has previously met on March 31, 1999, April 20, 1999, May 18 and 19, 1999, and June 7 and 8, 1999. Additional meetings for the Maricopa County AAC are scheduled for June 30 and July 1, 1999.

The Kansas City metropolitan area AAC consists of 17 members who represent health plans, providers, and Medicare beneficiaries. The members of the Kansas City metropolitan area AAC are: E.J. Holland, Jr., Assistant Vice President for Corporate Benefits, Sprint; Robert Bonney, Vice President, Managed Care, St. Luke's Shawnee Mission PHO; Hazel Borders, beneficiary; Richard Brown, President and CEO, Health Midwest; Cynthia Finter, President and Executive Director, Kaiser Permanente, Kansas City Region; Tresia Franklin, Director of Benefits Administration, Hallmark Cards, Inc.; Alan Freeman, CEO, Cass Medical Center; Herman Johnson, beneficiary, John Kennedy, Senior Vice President of Blue Cross and Blue Shield of Kansas City; Mike Oxford, Executive Director, Topeka Independent Living Resource Center; Jean Rumbaugh, Vice President, Government Programs, HealthNet; Kathleen Sebelius, Kansas Insurance Commissioner; Zarina Shockley-Sparling, Executive Director, Humana, Inc.; Jan Stallmeyer, R.N., President, Principal Health Care of Kansas City, Inc.; Charles Van Way III,