Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. To gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

All persons entering the building must pass through a metal detector. In addition, all items brought to the Hubert H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: October 5, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20484 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7006–N]

Medicare Program; Announcement of Meeting of the Advisory Panel on Medicare Education, December 4, 2007

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92–463), this notice announces a meeting of the Panel on December 4, 2007. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: *Meeting Date:* December 4, 2007 from 9 a.m. to 3:30 p.m., e.d.t.

Deadline for Meeting Registration, Presentations, and Comments: November 27, 2007, 12 noon, e.d.t.

Deadline for Requesting Special Accommodations: November 19, 2007, 12 noon, e.d.t.

ADDRESSES: *Meeting Location:* Doubletree Hotel 1515 Rhode Island Avenue, NW., Washington, DC 20005, (202) 232–7000.

Meeting Registration, Presentations, and Written Comments: Lynne Johnson, Designated Federal Official, Division of Forum and Conference Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–0090, by 12 noon, e.d.t., on November 27, 2007.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary to establish an advisory panel if the Secretary determines that the panel is ''in the public interest in connection with the performance of duties imposed * * * by law.'' Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for ''activities * * * to broadly disseminate information to medicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.''

The Advisory Panel is also authorized by 1114(f) of the Social Security Act, 42 U.S.C. 1311(f), and section 222 of the Public Health Service Act, 42 U.S.C. 217a. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899) and approved the renewal of the charter on November 14, 2006. The establishment of the charter and the renewal of the charter were announced in the February 17, 1999 **Federal Register** (64 FR 7899), and the March 23, 2007 **Federal Register** (72 FR 13796), respectively. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Anita B. Boles, Independent Consultant, Health Communications; Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and Chief Executive Officer, National Hispanic Council on Aging; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forte, Executive Vice President, Consumer Services, WebMD; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Dr. David Lansky, Director, Health Program, Markle Foundation; Dr. Daniel Lyons, Senior Vice President, Government Programs, Independence Blue Cross; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates; Traci McClellan, J.D., Executive Director, National Indian Council on Aging; Dr. Keith Mueller, Professor and

Section Head, Health Services Research and Rural Health Policy, University of Nebraska; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Rebecca Snead, Executive Vice President/Chief Executive Officer, National Alliance of State Pharmacy Associations; William A. Steel, President, The National Grange; Marvin Tuttle, Jr., CAE, Executive Director and Chief Executive Officer, Financial Planning Association; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition; and Grant Wedner, Vice President, Partnerships and Corporate Development, Daily Strength, Inc.

The agenda for the December 4, 2007 meeting will include the following:

- Recap of the previous (September 20, 2007) meeting.
- Medicare Enrollment, Outreach, Education, and Partnering Activities Update.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 19, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–21080 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0205]

Exocrine Pancreatic Insufficiency Drug Products; Extension to Obtain Marketing Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to continue to exercise enforcement discretion to ensure the continued availability of exocrine pancreatic insufficiency drug products after April 28, 2008. FDA intends to exercise its enforcement discretion with respect to unapproved pancreatic enzyme drug products until April 28, 2010, if the manufacturers have investigational new drug applications (INDs) on active status on or before April 28, 2008, and have submitted new drug applications (NDAs) on or before April 28, 2009. FDA is granting this extension to ensure the availability of exocrine pancreatic insufficiency drug products during the additional time needed by manufacturers to obtain marketing approval.

DATES: The period during which FDA intends to exercise its enforcement discretion against unapproved pancreatic insufficiency drug products is extended to April 28, 2010, if the manufacturer has an active IND on or before April 28, 2008, and has submitted an NDA on or before April 28, 2009.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2004 (69 FR 23410) (the 2004 notice), FDA announced that all exocrine pancreatic insufficiency drug products are new drugs and announced the conditions for continued marketing of the drug products. The 2004 notice covered pancreatic enzyme preparations containing the ingredients pancreatin and pancrelipase. Both ingredients are extracted mainly from hog pancreas and contain principally the enzymes amylase, protease, and lipase. Pancreatic extract drug products are indicated as replacement therapy to treat conditions associated with exocrine pancreatic insufficiency, including cystic fibrosis, chronic pancreatitis, pancreatic tumors, or pancreatectomy.

Pancreatic extract drug products have been marketed in the United States for many years. Marketing of some versions of these products predates the 1938 passage of the Federal Food, Drug, and Cosmetic Act (the act). Over the years, other pancreatic extract drug products have entered the market. Various dosage forms of pancreatic enzyme drug products are currently marketed as prescription drug products: Uncoated tablets, powders, capsules, enteric-coated tablets, and encapsulated enteric-coated microspheres.

Some pancreatic extract drug products were marketed over-the-counter (OTC). As part of the OTC drug review, FDA evaluated the safety and effectiveness of drug products used to treat exocrine pancreatic insufficiency. FDA's review of data and information on pancreatic extract drug products found significant variations in bioavailability among the various dosage forms and among products from different manufacturers of the same dosage form. Available data have shown that the formulation, dosage, and manufacturing process of pancreatic enzyme drug products have a critical effect on the safe and effective use of these drugs. FDA concluded that preclearance of each product to standardize enzyme bioactivity would be necessary. FDA also determined that continuous physician monitoring of patients is a collateral measure necessary to the safe and effective use of pancreatic enzyme drug products, requiring that these products be available by prescription only and that the products be approved through the new drug approval process to standardize enzyme activity (56 FR 32282, July 15, 1991; 60 FR 20162, April 24, 1995).

The 2004 notice reiterated FDA's determination that all pancreatic extract drug products are new drugs under section 201(p) of the act (21 U.S.C. 321(p)), requiring approved NDAs under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314. The document stated that FDA expects to receive only NDAs, including applications submitted under section 505(b)(2) of the act, for these products. To assist manufacturers of pancreatic extract drug products in preparing and submitting documentation to meet NDA requirements for the drug products, FDA announced the availability of a draft guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs'' in the **Federal Register** of April 28, 2004 (69