question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 7, 1995.

A. Federal Reserve Bank of New York (William L. Rutledge, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. 401 K Plan and ESOP of United States Trust Company of New York New York, New York; to become a bank holding company by acquiring between 25 and 35 percent of the voting shares of New USTC Holdings Corporation, New York, New York (''New Holdings''), and thereby indirectly acquire New U.S. Trust Company of New York, New York, New York; U.S. Trust Company of Texas, N.A., Dallas, Texas; and U.S. Trust Company of California, N.A., Los Angeles, California.

In connection with this application, Applicant also has applied to acquire U.S. Trust Company of Florida Savings Bank, Palm Beach, Florida, and thereby engage in trust company, investment and financial advisory, community development, and savings association operations activities, pursuant to §§ 225.25(b)(3), (4), (6), and (9), of the Board's Regulation Y; [2] through CTMC Holding Company and its wholly-owned subsidiaries, U.S. Trust Company of the Pacific Northwest, and CTC Consulting, all of Portland, Oregon, in trust company, and investment and financial advisory activities pursuant to §§ 225.25(b)(3) and (4) of the Board's Regulation Y, respectively, [3] through Campbell, Cowperthwait & Co., Inc., New York, New York, in investment or financial advice pursuant to § 225.25(b)(4) of the Board's Regulation Y, [4] through U.S. Trust Company of New Jersey and its wholly-owned subsidiary, U.S.T. Securities Corp., both of Princeton, New Jersey, in trust company, investment and financial advisory, securities brokerage, and riskless principal activities pursuant to §§ 225.25(b)(3), (4), (15) of the Board's Regulation Y and previous Board order (U.S. Trust Corporation, 78 *Federal Reserve Bulletin* 336, (1992)), respectively, and [5] through U.S. Trust Company of Connecticut, Stamford, Connecticut, in trust company and investment and financial advisory activities pursuant to §§ 225.25(b)(3) and (4) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 8, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19985 Filed 8–11–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Evaluation of Medical Technology

The Agency for Health Care Policy and Research (AHCPR), through the Center or Health Care Technology (CHCT) (formerly OHTA), announces that it is conducting an evaluation of the safety, effectiveness, and clinical utility of positron emission tomography (PET), using fluorine 18 labelled 2-deoxy-2-fluoro-D-glucose (FDG), as a diagnostic and management tool for use in patients with focal or partial epilepsy.

This evaluation will be concerned with the use of FDG–PET in the localization of seizure focus for possible surgical excision and seeks to answer the following questions: (1) Does FDG–PET provide information of value to a clinician that is not otherwise available? (2) What is the extent of any incremental benefit obtained from the use of FDG–PET when the information obtained is comparable to that available from other diagnostic modalities? (3) How does the sensitivity and specificity of FDG–PET compare with other diagnostic modalities currently in use? (4) Where does FDG–PET fit in the overall scheme of diagnostic testing? Should it be used in lieu of, or in addition to other diagnostic modalities? (5) What patient selection criteria should be applied?

AHCPR is interested in receiving information based on review and assessment of past, current, and planned research related to this technology, as well as a bibliography of published, controlled clinical trials and other well-designed clinical studies. Also requested is information related to the characteristics of the patient population most likely to benefit from the use of FDG–PET as well as information on the clinical acceptability, effectiveness, and the extent of use of this technology. Information relevant to this review should be submitted in writing to CHCT at the address below.

To enable the interested scientific community to evaluate the information included in this review, AHCPR will discuss in the review only those data and analyses for which a source(s) can be cited. Respondents are therefore encouraged to include with their submission a written consent permitting AHCPR to cite the source of the data and comments provided. Otherwise, in accordance with the confidentiality statute governing information collected by AHCPR, 42 U.S.C. 299a–1(c), no information received will be published or disclosed which could identify an individual or entity described in the information or could identify an entity or individual supplying the information.

Dependent upon the quality and quantity of the scientific data, CHCT will prepare an assessment, review, or other evaluation of the technology under consideration. (The AHCPR Technology Assessment process was described in the December 3, 1993 **Federal Register** (58 FR 63988)).

Written material should be submitted to: Thomas V. Holohan, M.D., Acting Director, Center for Health Care Technology, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Suite 309, Rockville, MD 20852, Phone: (301) 594–4023, Fax: (301) 594–4030.

Dated: August 8, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–19991 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 95N–0228]

Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding pharmaceutical marketing and information exchange in managed care environments. FDA is seeking information and views concerning the potential impact of

changing organizational structures and information dissemination channels in the managed care setting on the agency's responsibilities to regulate drug marketing and promotion. The agency is particularly interested in exploring the issues surrounding new modes and techniques of drug information dissemination (e.g., the communication of cost-effectiveness claims) and the formation of alliances between manufacturers and prescription benefit management companies (PBM's).

DATES: The public hearing will be held on October 19, 1995, from 1:30 p.m. to 5:30 p.m., and October 20, 1995, from 8:30 a.m. to 5:30 p.m. Submit written notices of participation *by September 15, 1995*. Written *comments* will be accepted *until December 29, 1995*.

ADDRESSES: The public hearing will be held at the Quality Hotel–Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N–0228. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act, FDA has responsibility for regulating the labeling and advertising of prescription drugs. Specifically, the agency reviews promotional materials disseminated by, or on behalf of, prescription drug manufacturers for consistency with approved drug product labeling, and to ensure that these materials are accurate, contain proper disclosures, and ''fair balance'' in terms of benefit and risk information. Underlying this responsibility is a public health concern that health care professionals and patients base their decisions about drug products on sound scientific data and information.

Traditionally, health care providers, patients, pharmacists, and pharmaceutical manufacturers have been separate entities with independent functions. However, the relationships among health care providers, pharmaceutical manufacturers, and health benefits managers are changing. The rapid growth of managed health care, with its emphasis on managing the quality of care while controlling costs, has dramatically changed pharmaceutical purchasing. Consequently, pharmaceutical marketing has also changed to emphasize value in addition to safety and effectiveness. Direct comparative effectiveness, safety, and cost-effectiveness information has become more prevalent as a basis for promotional claims.

Furthermore, the audience for prescription drug promotion has also changed. The importance of institutional decisionmakers as recipients of marketing communications has increased. Over the past several months, several pharmaceutical manufacturers have formed business relationships with or have purchased companies that manage pharmacy benefits (i.e., PBM's). FDA has received reports that these entities are disseminating information to formulary decisionmakers, prescribers, and users about the allied manufacturer's drug products. Moreover, pharmacist employees of certain PBM's have telephoned prescribers to request that they switch their patients to the drug products of their employer's allied manufacturer.

Several pharmaceutical manufacturers have approached FDA about its policies regarding the dissemination of pharmacoeconomic information, especially comparative cost-effectiveness analyses of pharmaceutical products. In response to these inquiries, FDA has stated that ''effectiveness'' elements of cost-effectiveness claims must be based on adequate and well-controlled studies and cost elements should be substantiated by adequate disclosure of both prices and methods used to derive the cost estimates. In addition, the Division of Drug Marketing, Advertising and Communications (DDMAC) has circulated a draft set of principles for use in evaluating pharmacoeconomic claims.

Some have asserted that the dissemination of information by the pharmaceutical industry to managed care providers (e.g., formulary managers) need not meet traditional standards of substantiation because the audience is highly educated and able to regulate the process by creating a demand for supporting studies that display scientific rigor.

In addition, they maintain that these audiences may impose corrective measures (e.g., formulary exclusions), which would drive up the quality of pharmacoeconomic analyses. However, the proponents also suggest that the increased costs and time needed to conduct multiple studies with sufficient methodological rigor are prohibitive and that their customers are demanding information that, in some instances, may only be provided by the use of less expensive techniques such as administrative data base analysis and modeling.

The agency recognizes that these issues affect both the manufacturers' desire to provide drug information and the managed health care industry's need for this information. Accordingly, FDA seeks to investigate the implications of these issues on its regulatory responsibilities.

II. Scope of the Hearing

In light of the many complex scientific and public health issues raised by the evolution of the health care environment, FDA is soliciting broad public participation and comment on the potential implications of these changes on pharmaceutical regulation. The agency encourages individuals with information relevant to these changes to respond to this notice. FDA is interested in a broad range of issues including:

(1) *Changing business relationships*. What are the implications of the changing health care market on pharmaceutical communications and promotion? Should FDA regulations be modified? If yes, how should the agency's regulations be modified? How would these modifications affect FDA's public health responsibilities?

(2) *Changing marketing claims*. How are pharmacoeconomic claims different from traditional comparative claims between therapeutically similar drugs or therapies? What should be FDA's goal in monitoring cost-effectiveness claims? What level of support is necessary to substantiate cost-effectiveness claims?

(3) *Changing audiences for industry-supplied pharmaceutical information*. Who is receiving/asking for industry-supplied pharmaceutical information? Is this audience more sophisticated (highly educated) than traditional audiences? What type of comparative information is sought? How is this comparative information utilized and interpreted? What should be FDA's goal in monitoring the communication of comparative drug information to healthcare providers and patients within managed care organizations?

(4) *Changing channels for communication of pharmaceutical information*. What constitutes sufficient evidence of ''independence'' to give

confidence of unbiased decisions in formulary development? How can FDA protect scientific-exchange between the pharmaceutical company and the target audience while protecting the audience from false and misleading pharmaceutical promotion? How should FDA address methods employed by pharmaceutical manufacturers to ''switch'' patients from one drug therapy to another similar product? How should FDA address communications from the PBM's to the target audience? What specific types of information and services do managed health care organizations commonly request from the pharmaceutical industry? Examples of such services may include provider/patient education or formulary coordination between organizations (''pull-through'').

III. Notice of Hearing under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) by September 15, 1995. To ensure timely handling, any outer envelope should be clearly marked with docket number 95N–0228 and the statement ''Pharmaceutical Marketing and Information Exchange in Managed Care Environments.'' Groups should submit two copies of materials. The notice of participation should contain the speaker's name, address, telephone number, affiliation, if any, brief summary of the presentation, and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under docket number 95N–0228.

Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as required by § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped person requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–19947 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OPL–006–N]

Medicare Program; September 11, 1995 Meeting of the Practicing Physicians Advisory Council

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 Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for September 11, 1995, from 8 a.m. until 4 p.m. e.d.t. An additional meeting is tentatively scheduled for December 11, 1995.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel Shekar, Executive Director, Practicing Physicians Advisory Council, Room 425–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, (202) 260–5463.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act as added by section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508, enacted on November 5, 1990), to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and under served urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.