development protocol. This portion of the meeting is closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–34826 Filed 12–30–98; 12:28 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 21, 1998 (63 FR 56195), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0389. The approval expires on May 31, 1999.

Dated: December 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–34735 Filed 12–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0494]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Registration and Listing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 1998 (63 FR 55132), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0387. The approval expires on December 31, 2001.

Dated: December 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–34736 Filed 12–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3889–N]

Medicare Program; Open Town Hall Meeting to Discuss the Positron Emission Tomography

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting to present and discuss the current medical and scientific evidence regarding the clinical use of positron emission tomography scans for cancers of the head and neck, colorectal malignancy, melanoma, lymphoma, and brain tumors. We will discuss the clinical comparability of dedicated positron emission tomography scanners compared to coincident imaging cameras. This meeting represents an aspect of the evolving process for making our coverage reviews more open and responsive to the public.

DATES: The meeting is scheduled for January 20, 1999 from 8:00 a.m. until 5:00 p.m., E.S.T. and January 21, 1999 from 8:30 a.m. until 4:00 p.m., E.S.T.

ADDRESSES: The meeting will be held in the HCFA headquarters auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Mitchell I. Burken, M.D., (410) 786–6861.

SUPPLEMENTARY INFORMATION:

Background

Currently, Medicare covers positron emission tomography (PET) scanning for the diagnostic evaluation of solitary pulmonary nodules and for staging of primary lung cancer. The purpose of the PET Scan Town Hall Meeting is to convene dialogue on PET scanning for the evaluation and management of head and neck, brain, and colorectal cancers; melanoma; and lymphoma. We anticipate participation by national professional medical organizations; medical equipment manufacturers; experts in technology assessment, health policy, and clinical research; other federal agencies; managed care organizations; national cancer organizations; and other members of the public with an interest in future oncology applications of PET.

The format of the meeting will include short (10–20 minutes) public presentations on PET scanning for the above oncology applications. It is our intent for invited panelists to stimulate further discussion based on the presentations. This discussion will be free-flowing and will *not* result in a set of advisory recommendations, or consensus statements.

The PET Scan Town Hall Meeting will assist us in reviewing the state of evidence for PET scanning in malignancies, as well as understanding the viewpoints of stakeholders with an interest in PET coverage policy.

The meeting will conclude with a question-and-answer session during which the public may raise any issues related to the topics discussed. While the meeting is open to the public, attendance is limited to space available.

Individuals must register in advance as described below.

Registration

AFYA, Incorporated in Takoma Park, Maryland will handle registration for the meeting. Individuals may register by contacting Cathy Freeland at AFYA, Incorporated by mail or fax. Please provide your name, title, firm name, address, telephone number, fax number, and Internet electronic mail address (if applicable).

- For mail registration, the address is: AFYA, Incorporated, 6930 Carroll Avenue, Suite 820, Takoma Park, Maryland 20912, Attention: *Cathy Freeland*.
- For fax registration, the number is (301) 270–3441.

AFYA, Inc. will provide all registrations with a confirmation packet and background papers before the meeting.

Participants who wish to display an exhibit or make a presentation at the meeting, must contact Maria Ellis at (410) 786–0309 or via E-Mail at MEllis@HCFA.GOV or Mitchell I. Burken, M.D. at (410) 786–6881 or via E-Mail at MBURKEN@HCFA.GOV no later than December 30, 1998.

We will accept written questions, comments, or other materials, either before the meeting, or up to 14 days after the meeting. Address comments to: Health Care Financing Administration, ATTN: Mitchell I. Burken, M.D., Office of Clinical Standards and Quality/CAG, Room S3–02–01,7500 Security Boulevard, Baltimore, Maryland 21244–1850, Telephone Number: (410) 786–6861, Fax Number: (410) 786–0169; E-Mail: MBurken@HCFA.GOV.

There is no special format for the materials; however, we request that commenters be clear about the issue or aspect of the proposed process on which they have a question, comment, or suggestion.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 98.773, Medicate—Hospital Insurance; and Program No. 93.774, Medicate—Supplementary Medical Insurance Program)

Dated: December 18, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–34739 Filed 12–31–98; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: http://www.health.org

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SPECIAL NOTE: Our office moved to a different building on May 18, 1998. Please use the above address for all regular mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840 (formerly: Bayshore Clinical Laboratory)

Advanced Toxicology Network, 15201 East I–10 Freeway, Suite 125, Channelview, TX 77530, 713–457–3784 / 800–888–4063 (formerly: Drug Labs of Texas, Premier Analytical Laboratories)

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931 / 334–263–5745

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–9000 (formerly: Jewish Hospital of Cincinnati, Inc.)

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866 / 800–433–2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787 / 800–242–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5784

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652 / 417–269–3093 (formerly: Cox Medical Centers)