

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]

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## 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]

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## 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]

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## 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.