IV. Recommendation of the Panel

At a public meeting held on September 16 and 17, 1999, the Panel recommended that the totally implanted SCS intended for aid in the treatment of chronic intractable pain of the trunk or limbs be reclassified from class III into class II. In the **Federal Register** of September 6, 2000 (65 FR 54053), FDA published for public comment a notice of the Panel's recommendation and FDA's tentative findings on the Panel recommendation. FDA invited interested persons to comment by October 6, 2000. In response to a request, FDA later extended the comment period to November 4, 2000.

V. FDA's Decision

FDA received 22 comments in response to the September 6, 2000, notice of panel recommendation. The comments are discussed in detail in the order denying the reclassification petition and in an attachment to that order. Although FDA's earlier tentative findings supported reclassification, the agency has now concluded that class II controls are not adequate to address the risks associated with the device. The most serious risk to health presented by the device is the risk of device failure. Device failure is frequently the result of improper device design. Device failure always requires reoperation with all of the attendant risks of secondary surgery. Many of the comments suggested that general controls and special controls could not adequately control the risk of device failure.

After carefully reviewing the information in the petition, the information presented at the Panel meeting, the Panel's deliberations, the published literature, the Medical Device Reports, and the comments on the notice of panel recommendation, FDA has completed its evaluation of the risks to health associated with the use of the totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs.

FDA determined that the petitioner had not demonstrated that special controls would provide reasonable assurance of the safety and effectiveness of the device. Specifically, FDA determined that special controls, such as bench and animal testing, cannot substitute for actual clinical trials designed to demonstrate the safety and effectiveness of these devices. FDA also determined that the risks to health associated with the manufacturing process could only be addressed through the degree of regulatory oversight applied to class III devices. Therefore, on February 23, 2001, FDA issued an order to the petitioner denying the petition for reclassification.

FDA has placed a copy of the order denying the petition on display at the Dockets Management Branch (address above) in the above referenced docket. A copy of the order may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 18, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–10619 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Technical Electronic Product Radiation Safety Standards Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Technical Electronic Product Radiation Safety Standards Committee.

General Function of the Committee: To provide advice on technical feasibility, reasonableness, and practicality of performance standards for electronic products to control the emission of radiation under 21 U.S.C. 360kk(f).

Date and Time: The meeting will be held on May 17, 2001, 8:30 a.m. to 5 p.m..

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Orhan H. Suleiman, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12399. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear an informal review of ongoing activities associated with electronic products. Following the overview, FDA will specifically discuss its concern about radiation doses associated with x-ray computed tomography, digital x-ray imaging systems, and its current thinking about amending the U.S. performance standard for these systems. In the afternoon, FDA will briefly review the history and current program for products for which performance standards exist. This review will include discussion of microwave ovens, television receivers, and laser products. Following this review, FDA will discuss current research and public health concerns associated with cellular telephones.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 10, 2001. On May 17, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and between 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 10, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

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

Dated: April 23, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–10625 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3067–N]

Medicare Program; Request for Nominations for Members for the Medicare Coverage Advisory Committee (MCAC)

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

ACTION: Notice.

SUMMARY: This notice requests nominations for consideration for members of the Medicare Coverage Advisory Committee.

DATES: Nominations will be considered if we receive them at the designated address, as provided below, no later than 5 p.m. on May 30, 2001.

ADDRESSES: You may mail or deliver nominations for membership to the following address: Health Care Financing Administration, Attention: Constance Conrad, 7500 Security Blvd., Mail Stop: South Building 3–02–01, Baltimore, MD 21244.

A request for a copy of the Secretary's Charter for the Medicare Coverage Advisory Committee (MCAC) should be submitted to Maria Ellis, Office of Clinical Standards and Quality, Health Care Financing Administration, 7500 Security Blvd., Mail Stop: South Building 3–02–01, Baltimore, MD 21244, or by e-mail to mellis@hcfa.gov. The charter is also posted on the web at www.hcfa.gov/coverage, and can be readily printed from that site.

FOR FURTHER INFORMATION CONTACT: Constance A. Conrad, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244, 410–786–4631.

SUPPLEMENTARY INFORMATION:

Background

The Medicare Coverage Advisory Committee (MCAC) is governed by provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 USC Appendix 2), which sets forth standards for the formulation and use of advisory committees, and authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

The MCAC consists of no more than 120 appointed members from among authorities in clinical and administrative medicine, biologic and physical sciences, public health administration, health care data and information management and analysis, the economics of health care, medical ethics, and other related professions. A maximum of 9 members are standard voting members, and 24 are nonvoting members, 12 of which are representatives of consumer interests, and 12 of which are representatives of industry interests.

The MCAC functions on a panel basis. The panels review and evaluate medical literature, review technical assessments, and examine data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. Panel meetings generally follow an agenda that we provide that lists specific issues. The panels develop technical advice to aid us in determining reasonable and necessary applications of medical services and technology when we make national coverage decisions for Medicare.

A few vacancies exist on the current MCAC panel rosters, and terms for some members currently serving will expire before January 1, 2002. Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the MCAC. Therefore, we encourage nominations of qualified candidates from these groups.

All nominations and curricula vitae for the MCAC should be sent to Constance Conrad at the address above.

Criteria for Members

Nominees should have expertise in one or more of the following fields: clinical and administrative medicine, biologic and physical sciences, public health administration, health care data and information management and analysis, the economics of health care, medical ethics, and other related professions.

We are also seeking nominations for nonvoting consumer and industry representatives. Nominees for these positions must possess appropriate qualifications to understand and contribute to the MCAC's work.

Nominations must state that the nominee is willing to serve as a member of the MCAC and appears to have no conflict of interest that would preclude membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

Members are invited to serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the MCAC by appropriate action before its termination on November 23, 2002. A member may serve after the expiration of the member's term until a successor has taken office.

Any interested person may nominate one or more qualified persons. Self-nominations are also accepted.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: April 6, 2001.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 01–10639 Filed 4–27–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3066–N]

Medicare Program; Meeting of the Diagnostic Imaging Panel of the Medicare Coverage Advisory Committee—June 19, 2001

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Diagnostic Imaging Panel (the Panel) of the Medicare Coverage Advisory Committee. The Panel provides advice and recommendations to the agency about clinical issues. The Panel will hear and discuss presentations from interested persons regarding FDG Positron Emission Tomography imaging for breast cancer diagnosis and staging.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The meeting will be held on June 19, 2001 from 8 a.m. until 4:30 p.m., E.D.T.

Deadline for Presentations and Comments: June 5, 2001, 5 p.m., E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by May 26, 2001.

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 321 and 322, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Janet A. Anderson, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3–02–01; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at *www.hcfa.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the HCFA Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Janet A. Anderson, Executive Secretary, 410–786–2700.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR