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.