premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On March 10, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 22, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 6, 1995.

Joseph A. Levitt,

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

[FR Doc. 95–9950 Filed 4–20–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Subcommittee Meeting of the Food Advisory Committee

Date, time, and place. May 8 and 9, 1995, 8:30 a.m., Days Inn—Downtown Convention Center, Franklin Square I Ballroom, 1201 K St. NW., Washington, DC.

Type of meeting and contact person. Open subcommittee discussion, May 8, 1995, 8:30 a.m. to 5:15 p.m.; open subcommittee discussion, May 9, 1995, 8:30 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; open subcommittee discussion, 11 a.m. to 2 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by close of business May 1, 1995, 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 required to make their comments. If necessary, comments may be limited to 5 minutes.

Open committee discussion. The subcommittee will review the Center for Food Safety and Applied Nutrition's Microbiology Research Program in the context of the Center's science program. A peer review panel will be asked to present its findings to the subcommittee. More detailed information regarding the meeting agenda that may become available prior to the meeting will be provided to the public via the 800 number listed above.

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. May 8 and 9, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Walker and Whetstone Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, May 8, 1995, 8:30 a.m. to 9:30 a.m., unless public

participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; open public hearing, May 9, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory System Devices Panel, code 12625.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 28, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss general issues relating to the review of four premarket approval applications; on May 8, 1995, the committee will discuss two hemostasis devices and on May 9, 1995, two pacemaker devices.

Veterinary Medicine Advisory Committee

Date, time, and place. May 10 and 11, 1995, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballroom III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, May 10, 1995, 8:30 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 4:30 p.m.; open committee discussion, May 11, 1995, 8:30 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 12 m.; Gary E. Stefan, Center for Veterinary Medicine (HFV–244), 7500 Standish Pl., Rockville, MD 20855, 301–594–1769, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Veterinary Medicine Advisory Committee, code 12546.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 9, 1995, 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 amount of time required to make their comments.

Open committee discussion. On May 10, 1995, the committee will discuss veterinary medical issues related to implementation of the Animal Medicinal Drug Use Clarification Act of 1994 (extra-label animal drug use). On May 11, 1995, the committee will discuss options for obtaining approvals for minor use (orphan) animal drugs.

Science Board to the Food and Drug Administration

Date, time, and place. May 16, 1995, 8:30 a.m., Holiday Inn—Eisenhower Metro, Eisenhower Ballroom, 2460 Eisenhower Ave., Alexandria, VA.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Anita O'Connor, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5839, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before May 2, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely manner will be provided to the board.

Open committee discussion. The board will discuss issues related to the testing strategy for toxicity and carcinogenicity of substances regulated by FDA. The discussion is designed to give the agency direction for future program development.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 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.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–9889 Filed 4–20–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0005]

Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 27, 1995 (60 FR 10594). The document published guidance on the regulation of positron emission tomography (PET) radiopharmaceutical drug products and announced a public workshop to facilitate an understanding of regulatory requirements regarding these products. The document was published with some typographical errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 95–4691, appearing on page 10594 in the **Federal Register** of February 27, 1995, the following corrections are made:

1. On page 10594, in the third column, in the title heading, ''TomographyRadiopharmaceutical'' is corrected to read ''Tomography Radiopharmaceutical''.

2. On page 10595, in the third column, in the third full paragraph, in the 4th line from the bottom, ''§ 1A207.10'' is corrected to read ''§ 207.10''.

3. On page 10596, in the first column, in the first full paragraph, in line 8, ''§ 1A361.1'' is corrected to read ''§ 361.1''.

4. On page 10596, in the first column, in the second paragraph, in lines 4 and 20, ''§ 1A361.1(c)'' is corrected to read ''§ 361.1(c)''.

5. On page 10596, in the second column, in the first full paragraph, in line 3, ''§ 1A361.1(c)(3)'' is corrected to read ''§ 361.1(c)(3)''.

Dated: April 14, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9844 Filed 4–20–95; 8:45 am]

BILLING CODE 4160–01–F

SOCIAL SECURITY ADMINISTRATION

Agency Forms Submitted to the Office of Management and Budget for Clearance

Normally on Fridays, the Social Security Administration publishes a list of information collection packages that have been submitted to the Office of Management and Budget (OMB) for clearance in compliance with Public Law 96–511, The Paperwork Reduction Act. The following clearance packages have been submitted to OMB since the last list was published in the **Federal Register** on Friday, April 7, 1995.

(Call Reports Clearance Officer on (410) 965–4142 for copies of package.)

1. Measuring Public Perception of the Value of Social Security—0960–0551. The information on these questionnaires is used by the Social Security Administration (SSA) to measure public perception of the value of Social Security and to determine whether the Personal Earnings and Benefit Statement (PEBES) affects public confidence in Social Security. The control group respondents are members of the general public who have not received an SSA-initiated PEBES. The study group respondents are members of the general public who have received recently an SSA-initiated PEBES.

SSA has requested and received expedited approval for this collection of information (both the study group collection instrument and the control group collection instrument) from OMB and is, accordingly, publishing in the **Federal Register** a copy of each of the collection instruments (5 CFR 1320.18(g)).

Number of Respondents: 6,000
Frequency of Response: 1
Average Burden Per Response: 15 minutes
Estimated Annual Burden: 1,500 hours
OMB Desk Officer: Laura Oliven

Written comments and recommendations regarding these information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: Office of Management and Budget, OIRA, New Executive Office Building, Room 10230, Washington, DC 20503.

Dated: April 17, 1995.

Charlotte Whitenight,

Reports Clearance Officer, Social Security Administration.

Measuring Public Perception of the Value of Social Security (Control Group)

Your Name _____

Your Social Security Number _____-____-_____

1. Are you aware that Social Security pays benefits (circle all that you are aware of):
   a. To you when you retire?
   b. To you if you became disabled?
   c. To your spouse if you became disabled or retired?
   d. To your young children if you became disabled or retired?
   e. To your widow if you should die?
   f. To your young children should you die?
2. How important is it for you to plan financially for your retirement?
   a. Very important
   b. Somewhat important