Dated: November 8, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–29232 Filed 11–8–96; 2:37 pm]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: 8:00 a.m. (EST); November 18, 1996.

PLACE: 4th Floor, Conference Room, 1250 H Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Labor Department audit briefing.

2. Approval of the minutes of the October 21, 1996, Board meeting.

3. Thrift Savings Plan activity report by the Executive Director.

4. Review of KPMG Peat Marwick audit reports:

(a) ''Pension and Welfare Benefits Administration Review of the Policies and Procedures of the Federal Retirement Thrift Investment Board Administrative Staff.''

(b) ''Pension and Welfare Benefits Administration Review of the Thrift Savings Plan Billing Process at the United States Department of Agriculture, National Finance Center.''

(c) ''Pension and Welfare Benefits Administration Review of Backup, Recovery, and Contingency Planning of the Thrift Savings Plan at the United States Department of Agriculture, National Finance Center.''

(d) ''Pension and Welfare Benefits Administration Review of Capacity Planning and Performance Management of the Thrift Savings Plan at the United States Department of Agriculture, National Finance Center.''

5. Semiannual review of status of audit recommendations.

6. Quarterly investment policy review.

7. Annual ethics briefing.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: November 6, 1996.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 96–29124 Filed 11–7–96; 4:42 pm]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Proposed Research Agenda

AGENCY: Agency for Health Care Policy and Research, with the National Institute for Nursing Research and Health Resources and Services Administration, Division of Nursing.

ACTION: Notice of request for comments.

SUMMARY: The Agency for Health Care Policy and Research (AHCPR), the National Institute for Nursing Research (NINR), and the Division of Nursing (DN) of the Health Resources and Services Administration (HRSA) invite comments and suggestions of priority research topics related to the impact of nurse staffing on the quality of care in hospitals. These comments and suggestions will be considered by AHCPR, NINR, and DN of HRSA in planning for future research initiatives to benefit health care for the public and the health of the nation. Comments and suggestions on the proposed research agenda will be considered by the three Agencies in developing research priorities, but they will not be responded to individually.

DATES: Comments and suggestions must be postmarked by December 30, 1996.

ADDRESSES: Written comments and suggestions should be submitted to Kelly Morgan, Program Analyst, Center for Primary Care Research, Agency for Health Care Policy and Research, Suite 502, 2101 East Jefferson Street, Rockville, Maryland 20852. Respondents should provide a clear rationale and supporting evidence of the importance of the suggested topic.

All responses will be available for public inspection at the Center for Primary Care Research. Telephone 301–594–1357 ext. 1335, weekdays between 8:30 a.m. and 5:00 p.m.

SUPPLEMENTARY INFORMATION: In response to a congressional directive, the Department requested the Institute of Medicine (IOM) to conduct a study on nurse staffing levels in hospitals and nursing homes. The IOM issued a report in January 1996, *Nursing Staff in Hospitals and Nursing Homes—Is It Adequate?* [1] (the Report). The Report notes a paucity of objective research on the relationships among restructuring, nurse staffing, and quality in hospitals. One of the recommendations of the Report is that the National Institute of Nursing Research and other appropriate agencies fund scientifically sound research on the relationships between quality of care and nurse staffing levels and skill mix, taking into account organizational variables. The Report further recommends that NINR, along with AHCPR and private organizations, develop a research agenda on staffing and quality of care (See page 122 of the Report).

In July 1996, AHCPR, DN (HRSA), and NINR jointly convened a group of research experts to discuss methodological issues and key research questions on nurse staffing and quality of care in hospitals. Also discussed were selected outcomes from a conference held by the American Academy of Nursing in June 1996, sponsored by AHCPR, the American Nurses' Association, and the American Organization of Nurse Executives, entitled ''Outcome Measures and Care Delivery Systems.''

Nurse Staffing

Research efforts in this area will require refinement and standardization of conceptual as well as operational definitions of variables such as nurse staffing level and nursing skill mix. Included in this process must be an evaluation of the characteristics of the nurses providing care, such as level of education and psychological factors (e.g., nurse satisfaction with work). What nurses actually do (clinical vs administrative vs other duties), how nursing care is provided (staffing models used in each unit), and organizational characteristics (such as management or leadership style) are also important considerations.

Quality of Nursing Care

The concept of health care quality is extremely complex and usually includes a consideration of the structure and process as well as the outcomes of care. Research focusing on nurse staffing and quality of care in hospitals may, therefore, be expected to include an evaluation of the organization and delivery of nursing care in the hospital setting.

Proposed Research Agenda

Based on the expert discussions, the IOM Report, and a review of the published literature, the overarching questions to be addressed by research related to nurse staffing and quality of care in hospitals are: What is the contribution of nursing to the quality of care in hospitals, and what are the cost implications of this contribution? Within this area, a high research priority

[1] Wunderlich, Gooloo S. & Davis, Carolyne K. (1996). Nursing Staff in Hospitals and Nursing Homes—Is It Adequate? Washington, D.C.: National Academy Press.

continues to be identifying patient outcomes that are sensitive to nursing care.

The primary areas proposed for future research focusing on the impact of nurse staffing on the quality of care in hospitals include:

- What is the relationship between the organization and delivery of nursing care and patient outcomes? What are the key organizational variables that influence staff performance and outcomes?
- What are the unique skills and the mix of registered nurses and other nursing and ancillary staff that impact on outcomes? This includes understanding what work needs to be done for patients to impact patient outcomes and who are the best people to do it.
- What specific organizational variables and delivery of care variables are related to specific patient outcomes? Specific questions within this category include: What is the relationship between nursing skill mix and achievement of outcomes such as appropriate self-care? What are the relative contributions of nurse, patient, other clinicians (e.g., M.D.), and organizational factors to specific patient outcomes?
- What is the impact of computer technology on patient outcomes? Included in this area are questions about the use of decision support that may extend off-site clinical expertise to hospital nursing staff. Also included are questions about the data elements about nursing and nurses that should be routinely collected.
- What is costworthy in an era when limited resources are available for hospital care? Although a nursing intervention may work for a clinical problem and even be more effective than other interventions, there may be other diseases or clinical problems that affect more people and also have cost-effective interventions.

At the AAN Conference, the following patient outcomes were identified for further refinement by research teams: achievement of appropriate self-care, demonstration of health-promoting behaviors, health-related quality of life, perception of being well cared for (broadened beyond patient satisfaction), symptom management, and adverse outcomes. Other outcomes of interest relate to the patient's family and community.

In line with the recommendations of the IOM Report the specific focus of this proposed research agenda is the relationship between nurse staffing and quality of care in hospitals. However, comments and suggestions about research pertaining to nurse staffing and quality in other types of delivery settings are welcome by AHCPR, NINR, and DN (HRSA).

Dated: November 6, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–28997 Filed 11–12–96; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 88P–0439]

Medical Devices; Reclassification of Suction Lipoplasty System for Aesthetic Body Contouring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the General and Plastic Surgery Devices Panel (the Panel) to reclassify the suction lipoplasty system for aesthetic body contouring from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by the American Society for Aesthetic Plastic Surgery (ASAPS) and other publicly available information. FDA is also issuing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the Federal Register.

DATES: Written comments by February 11, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFA–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION: On December 28, 1988, ASAPS submitted a petition under section 513(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e)), requesting that the suction lipoplasty system intended for surgical use in aesthetic body contouring, be reclassified from class III into class II. The major components of this system, the cannula (a manual surgical instrument for general use (21 CFR 878.4800)), and the suction pump (powered suction pump (21 CFR 878.4780)) when intended for certain uses other than suction lipoplasty procedures are classified in class I and class II, respectively. However, when these devices, individually labeled or combined into a system, are intended for use in aesthetic body contouring, they are automatically classified into class III under section 513(f)(1) of the act.

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the agency to reclassify the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the suction lipectomy system for use in aesthetic body contouring, it is necessary that the proposed new class has sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 310–394), (as amended by the Medical Device amendments of 1976 (the amendments) (Pub. L. 94–295), class II devices were defined as those devices for which there is insufficient information to show that general controls alone will ensure safety and effectiveness, but there is sufficient information to establish that performance standards would provide a reasonable assurance of safety and effectiveness of the device. In the time that has passed since the submission of the petition and the Panel meeting, the definition of class II devices has been amended by the Safe Medical Devices Act of 1990 (the SMDA). Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls alone will ensure safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the issuance of a performance standard, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(B) of the act).

It is the agency's position that is not necessary to obtain a new reclassification recommendation from a