very similar studies, FDA will support only the study with the best score.

VI. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of the PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Robert L. Robins (address above). State and local governments may choose to use the PHS 398 application form in place of the PHS 5161. Application receipt dates are October 15, 1996, and March 15, 1997. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. No supplemental or addendum material will be accepted after the receipt date. Evidence of final IRB approval will be accepted for the file after the receipt date.

The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA OP–97–1''

If an application for the same study was submitted in response to the previous RFA, a submission in response to this RFA will be considered a request to withdraw the previous application. Applications originally submitted for the October closing date will also be administratively withdrawn, if resubmitted the following March. Resubmissions are treated as new applications; therefore, the applicant may wish to include previous summary statements from past reviews.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt dates.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the Division of Research Grants, NIH. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect RFA–FDA–OP–97–1. The title of the proposed study should include the name of the product and the disease/disorder to be studied along with the IND/IDE number.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: May 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–14234 Filed 6–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0162]

Review of the Calcium and Related Nutrient Needs of the U.S. Population; Announcement of Open Meetings and Request for Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the National Academy of Sciences (NAS), Institute of Medicine (IOM), and Food and Nutrition Board (FNB) will begin a review of data on calcium intakes in the U.S. population and data on calcium metabolism in humans throughout their lives. This review will also include the metabolism of related nutrients (such as vitamin D, magnesium, phosphorus, and fluoride) and of nonnutrient components of foods (such as phytosterols and fiber) as they relate to bioavailability of calcium. Reviews will also be conducted to determine upper safe levels of intake that will diminish the potential risk of adverse effects. This review by NAS/IOM/FNB was requested by the Government, and it is intended to provide FDA and the National Institutes of Health (NIH), and the National Heart, Lung, and Blood Institute (NHLBI) with an up-to-date review of the needs of the American public for calcium and related nutrients. To assist in the preparation of its scientific report, NAS/IOM/FNB is inviting the submission of scientific data and information on this topic. In addition, FDA is announcing that NAS/IOM/FNB will provide an opportunity for oral presentations at two open meetings on the review of calcium and related nutrient needs of the U.S. population.

DATES: The first meeting will be held on July 9 and 10, 1996, 8:30 a.m. to 5:30 p.m. Submit an abstract with references to the FNB by June 17, 1996, to be considered for a 3-minute presentation to the panel. The second meeting will be held on July 15 and 16, 1996, 8:30 a.m to 5:30 p.m. Submit an abstract with references to the FNB by June 24, 1996, to be considered for a 3-minute presentation to the panel.

ADDRESSES: The meetings will be held at the National Academy of Sciences Bldg., Auditorium, 2101 Constitution Ave. NW., Washington, DC 20418. Submit written requests to make oral presentations of scientific data, information, and views at the open meetings to Sandra A. Schlicker, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences Bldg., 2101 Constitution Ave. NW., rm. 3046, Washington, DC 20418, 202–334–1383, and to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of the scientific data, information, and views should be submitted to each office.

FOR FURTHER INFORMATION CONTACT: James T. Tanner, Center for Food Safety

and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C St. SW., rm. 2804, Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: FDA has a contract with NHLBI to provide partial support of the NAS project entitled ''Calcium and Related Nutrients: Needs of Americans.'' Recent research and data have suggested that calcium intakes may be inadequate to meet the needs of many population groups in the United States, particularly with regard to the calcium intake during adolescence and young adulthood. However, controversy exists regarding what the optimal intake should be for calcium and related nutrients (such as vitamin D, magnesium, phosphorus, and fluoride) in order to prevent deficiency states (such as osteomalacia and rickets) while at the same time reducing the risk of degenerative diseases (such as osteoporosis) and also taking into account the potential effects of chronic ingestion of lower levels of intake during some life stages.

In response to recent suggestions that calcium requirements of healthy Americans are greater than previous estimates, the NAS/IOM is undertaking a study to review both the scientific literature on calcium metabolism in humans throughout their lives and also available data on calcium intakes by the U.S. population. The analysis also will include a review of the requirements for the related nutrients, vitamin D, magnesium, phosphorus, and fluoride. The impact of these nutrients and of other nonnutrient components of foods (such as phytosterols, fiber) on bioavailability of calcium will also be evaluated.

The study also will review existing data and will develop estimates of dietary intake levels that are compatible with good nutrition throughout the life cycle, which may result in decreasing risk of chronic disease. In addition, reviews will be conducted to determine upper safe levels of intake that will diminish the potential risk of adverse effects.

On July 9 and 10, 1996, a meeting to solicit scientific opinion on the functional indicators of calcium, phosphorus, magnesium, fluoride, and vitamin D status for each stage of the life span will be held. This meeting will be held by the panel on calcium and related nutrients, a subunit of the standing committee on the Scientific Evaluation of Dietary Reference Intakes, a committee of the FNB of the IOM. Speakers have been invited to present their views on appropriate measures to ensure adequate intake of these nutrients. In addition, interested individuals and organizations may present their perspectives regarding the determination of dietary reference intakes during the open forum session of the meeting. In order to be considered for a 3-minute presentation to the panel, an abstract with references must be submitted to the FNB by June 24, 1996. Interested parties should contact Sandra A. Schlicker (address above) for further information.

On July 15 and 16, 1996, a meeting to solicit scientific opinion on criteria to evaluate risk assessment data in developing a model for establishing maximum levels of nutrient intake compatible with low risk of adverse effects will be held. This meeting will be held by the Subcommittee on Upper Reference Levels of Nutrients, a subunit of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, a committee of the FNB of the IOM. Speakers have been invited to present their views on appropriate measures of adequacy for these nutrients. In addition, interested individuals and organizations may present their perspectives regarding the determination of dietary reference intakes during the open forum session of the meeting. In order to be considered for a 3-minute presentation to the panel, an abstract with references must be submitted to the FNB by June 17, 1996. Interested parties should contact Sandra A. Schlicker (address above) for further information. This study will provide guidance useful in the development of recommendations for requirements and upper safe limits of the topic nutrients.

Dated: May 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–14137 Filed 6–5–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[2728, R–142]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form No.:* HCFA–2728; *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. *Frequency:* Annually; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 60,000; *Total Annual Hours Requested:* 25,000.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Information Collection Requirements Contained in BPD–393, Examination and Treatment for Emergency Medical Conditions and Women in Labor; *Form No.:* HCFA–R–142; *Use:* BPD–393 contains information collection requirements for hospitals that would seek to prevent them from inappropriately transferring individuals with emergency medical conditions, as mandated by Congress. HCFA will use this information to help assure compliance with this mandate. This information is not contained elsewhere in regulations. *Frequency:* On occasion; *Affected Public:* Individuals or households, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 8,818,577.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to