suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise.

The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated should be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations will include complete curriculum vitae of each nominee, current business address and telephone number. Nominations will specify the advisory panel(s) or advisory committee(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee if selected, and appears to have no conflict of interest that would preclude membership. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 26, 2007.

Randall W. Lutter

Deputy Commissioner for Policy.

[FR Doc. E7–12799 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0359] (formerly 98N–0359)

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2008. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Submit written or electronic comments by September 4, 2007.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Tracy Summers, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20740, e-mail: *Tsummers@.fda.hhs.gov*, 301–827–1603.

SUPPLEMENTARY INFORMATION:

I. Background

On June 5, 2007, CFSAN released a document entitled ''FY 2007 Report to Stakeholders.'' The document, a copy of which is available on CFSAN's Web page (*http://www.cfsan.fda.gov/~dms/cfsan607.html*), includes the Center's priority workplan for fiscal year 2007, i.e., October 1, 2006, through September 30, 2007. The FY 2007 workplan is based on input we received from our stakeholders (see 71 FR 37083; June 29, 2006), as well as input generated internally. Throughout the priority-setting process, we focused on one central question: ''Where do we do the most good for consumers and the overall public health?''

The FY 2007 workplan is structured like the FY 2006 plan. It contains only those activities previously listed as ''A'' list items. Our goal is to fully complete at least 90 percent of the activities listed under sections 1 through 4 of the FY 2007 workplan by the end of the FY, September 30, 2007. The FY 2006 workplan also includes a fifth section entitled, ''Priority Ongoing Activities.'' Many of these activities are core functions that we perform on a regular basis and are among our very highest priorities.

II. 2008 CFSAN Program Priorities

FDA is requesting comments on what program priorities CFSAN should consider establishing for FY 2008. The input will be used to develop CFSAN's FY 2008 workplan. The workplan will set forth the Center's program priorities for the period of October 1, 2007, through September 30, 2008. FDA intends to make the FY 2008 workplan available on its Web site.

The format of the FY 2008 workplan will be similar to the FY 2007 workplan in that it will be divided into the following five sections:

(1) Food Defense
(2) Food Safety
(3) Nutrition and Labeling
(4) Dietary Supplements and Cosmetics
(5) Priority On-Going Activities

While there will likely be continuity and follow-through on many activities between the 2007 and 2008 work plans, the final FY 2008 Congressional

Appropriation will unquestionably affect what we will be able to commit to accomplish in FY 2008. Accordingly, FDA requests comments on broad program areas that should continue to be a priority as well as new program areas or activities that should be added as a high priority for FY 2008.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–12884 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications: RFA–FD08–001; Research Project Grants (R01); Catalog of Federal Domestic Assistance Number: 93.103

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal years (FY) 2009 and 2010. This announcement supersedes the previous announcement of this program, which was published in the **Federal Register** of December 19, 2005 (70 FR 75198).

1. Background

OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (that is, one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is fewer than 200,000 people a year. Additional information about OPD is available on FDA's Web site at *www.fda.gov/orphan*.

2. Program Research Goals

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the product will improve the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's ''Background and Significance'' section documentation to support the estimated prevalence of the orphan disease or condition and an explanation of how the proposed study will either help gain product approval or provide essential data needed for product development. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*), regulations issued under it, and applicable Department of Health and Human Services (HHS) statutes and regulations.

II. Award Information

Except for applications for studies of medical foods that do not need premarket approval, FDA will only award grants to support premarket clinical studies to determine safety and effectiveness for approval under section 505 or 515 of the act (21 U.S.C. 355 or 360e) or safety, purity, and potency for licensing under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance (CFDA), No. 93.103.

1. Award Instrument

Support will be in the form of a research project (R01) grant. All awards will be subject to all policies and requirements that govern the research grant programs of the PHS Act as incorporated in the HHS Grants Policy Statement, dated October 1, 2006, (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*), including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The National Institutes of Health (NIH) modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 360b), section 351 of the PHS Act, regulations issued under any of these sections, and other applicable HHS statutes and regulations regarding human subject protection.

2. Award Amount

Of the estimated FY 2009 funding ($14.2 million), approximately $10 million will fund noncompeting continuation awards, and approximately $4.2 million will fund 10 to 12 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2010 will be similar to FY 2009. Grants will be awarded up to $200,000 or up to $400,000 in total (direct plus indirect) costs per year for up to 4 years. Please note that the dollar limitation will apply to total costs, not direct costs, as in previous years. A fourth year of funding is available only for phase 2 or 3 clinical studies. Applications for the smaller grants ($200,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants ($400,000) must be for studies continuing in phase 2 or 3 of investigation.

Phase 1 studies include the initial introduction of an investigational new drug (IND) or device into humans, are usually conducted in healthy volunteer subjects, and are designed to determine the metabolic and pharmacological actions of the product in humans, the side effects including those associated with increasing drug doses. In some Phase 1 studies that include subjects with the rare disorder, it may also be possible to gain early evidence on effectiveness.

Phase 2 studies include early controlled clinical studies conducted to: (1) Evaluate the effectiveness of the product for a particular indication in patients with the disease or condition and (2) determine the common short-term side effects and risks associated with it.

Phase 3 studies gather more information about effectiveness and safety that is necessary to evaluate the overall risk-benefit ratio of the product and to provide an acceptable basis for product labeling. Budgets for each year of requested support may not exceed the $200,000 or $400,000 total cost limit, whichever is applicable.

3. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of