standard of identity for bottled water, which was submitted by the permit holder.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for bottled water that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), FDA issued a temporary permit to Iceberg Industries Corp., 16 Forest Rd., suite 300, St. John's, Newfoundland, Canada, A1C 2B9, to market test products identified as ''iceberg water'' a name that is not permitted under the U.S. standard of identity for bottled water in § 165.110 (21 CFR 165.110) (65 FR 54283, September 7, 2000). The agency issued the permit to facilitate market testing of products whose labeling differs from the requirements of the standard of identity for bottled water issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate market testing of products that deviate from the standard for bottled water in § 165.110 in that they are identified as ''iceberg water'' rather than as ''bottled water'' or one of the other names specified in § 165.110(a)(2). The test product meets all the requirements of the standard with the exception of this deviation.

On September 28, 2001, Iceberg Industries Corp. requested that its temporary permit be extended to allow for additional time for the market testing of its products under the permit in order to gain additional information in support of its petition. The petitioner requests FDA to amend the standard of identity for bottled water to provide for a new kind of bottled water, ''iceberg water,'' and to require icebergs in a marine environment as its source.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified as iceberg water to gain information on consumer expectations and acceptance. FDA is inviting interested persons to participate in the market test under the conditions that apply to Iceberg Industries Corp. (e.g., the composition of the test product), except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must include a description of the test products to be distributed, justification for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101.

Therefore, under the provisions of § 130.17(i), FDA is extending the temporary permit granted to Iceberg Industries Corp., 16 Forest Rd., suite 300, St. John's, Newfoundland, Canada, A1C 2B9 to provide for continued market testing on an annual basis of 150,000 cases of the 24 x 350 milliliters (mL), 150,000 cases of the 12 x 1 liters (L), and another 100,000 cases of the 24 x 500 mL giving 400,000 cases in total. The total fluid weight of the test product will be 1,124,024 gallons or 4,260,000 L. The test products will bear the name ''Borealis Iceberg Water.'' FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule amending the standard of identity for bottled water that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be. All other conditions and terms of this permit remain the same.

Dated: June 18, 2002.

Christine Taylor,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–16291 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Assuring Radiation Protection; Availability of a Cooperative Agreement; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is announcing the availability of approximately $500,000 in total fiscal year (FY) 2002 funds. These funds will be used to support one cooperative agreement for the coordination of Federal and State actions to assure radiation protection of the American public.

DATES: Submit applications by July 29, 2002.

ADDRESSES: Completed applications should be submitted to: Maura C. Stephanos, Grants Management Specialist, Grants Management Staff (HFS–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7101, e-mail: *mstepha1@oc.fda.gov*. Application forms are available either from Maura C. Stephanos or on the Internet at *http://grants.nih.gov/grants/funding/pjs398/phs398.html/*. Note: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice, contact Maura C. Stephanos (*see* **ADDRESSES**).

Regarding the programmatic aspects of this notice, contact Penny R. Boyce, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3650, FAX 301–594–3306; e-mail: *pzb@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA is announcing its intention to accept and consider applications for a cooperative agreement in support of coordination of Federal and State action to protect the American public from exposure to radiation. The cooperative agreement covered by this notice will be in furtherance of FDA's responsibilities under section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii) to establish and carry out a comprehensive radiation control program. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9 by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at http://health.gov/healthypeople. Internet viewers should proceed to ''Publications.''

I. Background

Since 1968, FDA has taken the lead in working with the Nuclear Regulatory Commission (NRC) and its predecessor organizations, the Environmental Protection Agency (EPA), the Federal Emergency Management Agency (FEMA), and the Department of Energy (DOE), to provide financial support for a forum established to foster the exchange of ideas and information among the States and the Federal Government concerning radiation control. This forum has made it possible for State and Federal agencies to work together to study existing and potential radiological health problems of mutual interest and to apply their increasingly limited resources with maximum efficiency in seeking ways to address these problems.

Three major mechanisms traditionally have been used to achieve this coordination between State and Federal agencies:

1. When certain radiation control issues warrant specific consideration, committees and other working groups comprised of representatives of State radiation control programs and liaison members from the concerned Federal agencies have been formed to evaluate these issues and recommend ways to address them. The recommendations of the committees are evaluated by a central management board and final recommended actions are relayed to the appropriate Federal and State agencies.

2. Annual meetings of Federal and State officials are convened to present and discuss the results of the studies conducted. The annual meetings also include workshops to more carefully define new problems and areas of mutual concern in radiation control, and clinics to demonstrate mutually beneficial radiological health techniques, procedures, and systems. The annual meeting lasts approximately 4 days, with an average attendance of 350 participants.

3. Additional educational activities have been provided for the benefit of members of State programs having radiation control responsibilities and the general public to acquaint them with radiation exposure problems and the proposed solutions. Methods used have included videotapes, publications, and training courses.

II. Goals and Objectives

The objective of this cooperative agreement will be to coordinate Federal and State activities to achieve effective solutions to present and future radiation control problems. The recipient of this cooperative agreement award will be expected to obtain the States' cooperation and participation on committees and working groups established to deal with individual problems. The recipient will also plan and facilitate an annual meeting, and develop and offer educational activities to demonstrate mutually beneficial techniques, procedures, and systems relevant to the mission of assuring radiation protection.

The recipient will establish committees to address, evaluate, and offer solutions for a wide range of radiation health and protection issues. Examples of relevant areas already identified to be of interest include, but are not limited to: (1) The application of x-rays to the healing arts; (2) the application of medical/nonmedical ionizing radiation; (3) the development of a system for managing the disposition of unwanted radioactive materials (orphan sources); and (4) the control and mitigation of radiation exposure from all sources. These areas are explained more fully in the following paragraphs.

A. Areas of Interest

1. Application of X-Rays to the Healing Arts

The recipient's activities related to x-rays in the healing arts should include issues related to general diagnostic radiology and mammography.

a. General Diagnostic Radiology

Issues related to radiography, fluoroscopy, and computed tomography should be considered in terms of practice guidelines, quality assurance procedures, and patient exposure evaluation. In the area of patient exposure, the recipient will be responsible for conducting an annual survey of a representative sample of medical x-ray facilities conducting one specific diagnostic x-ray procedure (from a set of predefined procedures that will be the subject of the survey over time).

b. Mammography

The recipient will be responsible for providing advice and recommendations to FDA on issues related to the implementation of the Mammography Quality Standards Act (MQSA). Consideration should be given to issues related to: The training of those conducting MQSA inspections; the results of the ongoing FDA Inspection Demonstration Program under MQSA; and informing mammography facilities about the results of MQSA inspections nationwide and steps that they can take to improve their performance under MQSA.

2. Application of Medical/Nonmedical Ionizing Radiation

The recipient will also address issues in the nonmedical applications of ionizing radiation as well as the medical and nonmedical applications of nonionizing radiation, particularly ultraviolet radiation.

3. Managing the Disposition of Unwanted Radioactive Materials (Orphan Sources)

The recipient will develop, implement, and manage a national program to identify, handle, and dispose of unwanted radioactive materials (orphan sources). The responsibilities for this task include: (1) Clarifying the State and Federal jurisdictional and regulatory responsibilities; (2) establishing agreements with interested NRC Agreement and non-Agreement States to identify and dispose of discrete orphan sources; (3) establishing cost guidelines for disposal of discrete orphan sources; and (4) reimbursing States for recovery, recycling, arrangements for reuse, and disposal costs of these sources. Additionally, the recipient will study, evaluate, and develop actions on issues related to radioactive waste disposal, radioactive contamination, contaminated sites, and international radiation protection as recommended by working groups and subcommittees established by the recipient.

4. Control and Mitigation of Radiation Exposure

The recipient will be responsible for developing criteria relevant to the control and mitigation of radiation exposure from all sources. Specific areas to be addressed include: Responding to radiation accidents or incidents; evaluating the adequacy of State radiation control programs, controlling residual radioactivity levels from decontamination and decommissioning of nuclear facilities, determining the propriety of delegating implementation authority for Federal standards for control of radionuclides as hazardous air pollutants, and implementing the Indoor Radon Abatement Act. The recipient will also be required to review and provide comments on issues related to radiological emergency preparedness.

B. Suggested State Regulations for the Control of Radiation (SSRCR)

Updating and maintaining the SSRCR will be an integral aspect of this cooperative agreement. These regulations will be disseminated to the States for the purpose of promoting uniformity between the States. The regulations will address issues relevant to controlling radiation exposure from all sources such as low-level waste, radioactive contamination, radioactive materials, radon, and x-rays in the healing arts.

C. Committee Oversight and Management

The recipient should anticipate oversight and management responsibilities for approximately 45 committees. In some instances, the recipient will be required to provide representatives to certain Federal radiation committees, such as the Federal Radiological Preparedness Coordinating Committee (FRPCC) and its subcommittees (overseen by FEMA).

Federal representatives will be appointed to these committees and other working groups dealing with problems related to the agency mission. These representatives will participate in the discussions leading to any recommendations developed by the committees and working groups. They will be primarily responsible for assuring that such recommendations are in accordance with Federal policy and regulations. The Federal representatives will also act as investigators, collaborators, or resource personnel, as appropriate.

D. Special Projects

The recipient will also occasionally implement special projects as determined by the participating State and Federal agencies. Areas for which groups may be needed include, but are not limited to, radioactive materials and radiation exposure problems in the environment, in the healing arts, in industry, and in, or related to, consumer products.

E. Annual Meeting

The recipient will be required to plan, conduct, and handle all administrative functions for an annual meeting. This meeting will offer an opportunity for member States and other interested parties to convene to exchange concerns and ideas for problem solving. The recipient should consult with stakeholders to determine priority agenda items and topics of interest. General sessions of this annual meeting should include workshops to define new problems, and discussions and lectures on mutually beneficial radiological health techniques, procedures, and systems. Identified areas of mutual concern in radiation control should be considered for assignment to a task force or committee comprised of experts. The recipient will be expected to publish the meeting proceedings in hardcopy and on the recipient's web site for limited dissemination to member States and relevant Federal personnel.

In conjunction with the annual meeting, the recipient will be required to hold training sessions. These sessions should demonstrate mutually beneficial techniques, procedures, and systems that have been developed by the sponsoring agencies or the recipient. The recipient may also be requested by FDA to provide instructors for Federal training courses with a radiological component held outside of the annual meeting.

Additionally, the recipient of this cooperative agreement award will be expected to provide the leadership to refresh and update previously-developed consensus guidance documents and SSRCR to provide States with up-to-date assistance in effective management of radiological hazards.

A Web site will be maintained by the recipient for the benefit of the States and other interested parties; the FDA Project Officer and other designated Federal personnel will be given complete and full access to all information posted on the site that is relevant to the work supported by FDA and other supporting agencies. The information and materials posted on the site should be reviewed and updated at regular intervals. Expertise in Web site maintenance and security is required to fulfill this task.

III. Reporting Requirements

An annual program progress report, a report detailing progress made under the National Orphan Source Program, and an annual Financial Status Report (FSR) (SF–269) are required. An original and two copies of these reports shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file these reports in a timely fashion may be grounds to withhold continued support of the cooperative agreement and/or suspend or terminate the agreement. The recipient will be advised of the suggested format for the annual Program Progress Report and the National Orphan Source Program report at the time an award is made.

A final program progress report and FSR will be due within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Reports generated by the task forces, committees, and workshops should include recommendations for the resolution of problem areas as well as cost/benefit evaluations. These reports will be reviewed by the recipient's governing body before final dissemination to Federal and/or State officials. Any publications supported by Federal funds must include a statement acknowledging Federal support, as well as a disclaimer that the information presented is not necessarily the view of the supporting agency.

Program monitoring of the recipient will be conducted by FDA on an ongoing basis through telephone conversations between the FDA Project Officer and/or the FDA Grants Management Specialist and the principal investigator. Periodic site visits with appropriate officials of the recipient organization may also be conducted. The results of these communications and visits will be recorded in the official cooperative agreement file and may be available to the recipient upon request consistent with FDA disclosure regulations.

The recipient will also provide a periodic newsletter that will be made available to member States and relevant Federal personnel on the Web site. The newsletter should include updates on projects and programs relevant to the mission of, and supported by, the contributing Federal agencies. The FDA Project Officer and liaisons from other agencies supporting this Agreement will be provided access to secured information on the Web site via passwords.

The recipient will maintain a database of personnel responsible for radiological

health programs in the member States and Federal agencies. This database will be updated annually and published for distribution by the recipient. Two paper copies of the directory and a noncopyright electronic version will be provided to all contributing Federal agencies.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a cooperative agreement award. This award will be subject to all policies and requirements that govern the research grant programs of PHS, 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's (NIH) modular grant program does not apply to this FDA program.

B. Eligibility

This cooperative agreement is available to any domestic private or public nonprofit organization (including State and local units of government) and to any domestic for-profit organization. For-profit organizations must exclude fees or profit from their requested support. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

C. Length of Support

The length of support will be for up to 5 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Acceptable programmatic performance during the preceding year, and (2) the availability of Federal fiscal year funds.

D. Funding Plan

Federal funds are currently available from FDA for this program. However, an award is subject to the condition that, in addition to FDA funds, augmenting funds are transferred to FDA from other Federal agencies to fully support this program. As the lead Federal agency, FDA intends to collect funds from all other contributing Federal agencies through Interagency Agreements (IAGs) and fund one award for up to $500,000 in total costs (including both direct and indirect costs). Support of this cooperative agreement may be for up to 5 years in duration with the total budget amount not to exceed $500,000 (direct plus indirect costs) per year or a total of $2,500,000 for a 5-year award. Funds obligated through IAGs will be immediately transferred to FDA for use in support of this agreement.

Any application received that exceeds $500,000 (direct plus indirect costs) per year will not be considered responsive and will be returned to the applicant without being reviewed. After the first year, additional years of noncompetitive support are predicated upon acceptable performance during the preceding year and the availability of Federal funds.

V. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have a substantive involvement in the programmatic activities of the project funded by the cooperative agreement.

Substantive involvement includes, but is not limited to, the following:

(1) Priorities on issues to be addressed will be jointly agreed to by the recipient and FDA in coordination with the Federal liaisons of agencies providing funding to FDA under an Interagency Agreement. The FDA Project Officer will be invited to all planning meetings of the central management board or committee of the recipient of the award. These meetings must be held on normal business days during normal business hours. The Project Officer will participate in the making of decisions with respect to the annual meeting (including the topics to be discussed and meeting site selection), committee organization and mission, and other activities under this award.

(2) Senior Federal liaisons from all contributing Federal agencies will also be named and will regularly attend the planning meetings of the central management board or committee, and will communicate with the other liaisons from their agency who are members of the task forces and related committees. These Senior Federal Liaisons will also regularly attend the annual meeting. Through the FDA Project Officer, the recipient will communicate with agencies on major policy and regulatory issues relevant to the work of FDA and the supporting agencies.

(3) FDA will collaborate with the recipient on data analysis, interpretation of findings, and, where appropriate, coauthor publications.

VI. Review Procedures and Criteria

A. Review Procedures

FDA's grants management and program staff will review all applications submitted in response to this notice for responsiveness. To be responsive, an application must: (1) Be received by the specified due date; (2) be submitted in accordance with sections IV.B. ''Eligibility,'' VII. ''Submission Requirements,'' and VIII.A. ''Submission Instructions'' of this notice; (3) not exceed the recommended funding amount stated in section IV.D of this document; (4) address the specific requirements of the project stated in section II. ''Goals and Objectives'' of this document; and (5) bear the original signatures of both the Principal Investigator and the Institution's/Organization's Authorized Official. If applications are found to be nonresponsive, they will be returned to the applicants without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts. This review will be competitive. The final funding decision will be made by the Commissioner of Food and Drugs.

B. Review Criteria

The application will be reviewed and evaluated according to the following criteria that are of equal value:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding the coordination of Federal and State activities to assure radiation protection of the American public.

2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.

3. The application establishes the applicant's ability to perform the responsibilities under the cooperative agreement, including the availability of appropriate staff and the ability to carry out the stated goals and objectives of the cooperative agreement within the established funding constraints stated in this notice.

4. The application specifies the manner in which interactions with FDA will be maintained throughout the lifetime of the project.

5. The application specifies how the recipient will monitor the progress of the work required under the cooperative agreement, and how the progress will be reported to FDA.

6. The application shall include a detailed and fully-justified budget that includes anticipated costs for personnel, travel, equipment, and supplies.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (see **ADDRESSES**). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is July 29, 2002. No supplemental or addendum material will be accepted 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 CDRH–02–1.''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible dated 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.) Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to NIH, and is then forwarded to FDA and not received in time for orderly processing will be deemed not responsive and returned to the applicant. Applications must be submitted via mail or hand delivered as stated above. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or on either form PHS 398 or PHS 5161–1 (Rev. 7/00) for State and local government applicants. 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.

The face page of the application should reflect the request for applications number, RFA–FDA–CDRH–02–1. Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information. Will be given confidential treatment to the extent permitted by 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 PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

Dated: June 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16293 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 02D–0260]

Draft Guidance for Industry on Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.'' The draft guidance provides information for free clinics that receive donated prescription drug samples from licensed practitioners or other charitable institutions. The draft guidance discusses concerns that have been expressed by certain individuals regarding regulatory requirements of FDA's regulations for drug sample donations. The draft guidance announces that FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with the requirements in the regulations, while the agency studies the potential impact of its regulations on free clinics.

DATES: Submit written or electronic comments on the draft guidance by September 25, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Office of Regulatory Policy (HFD–7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.'' Section 203.39 (21 CFR 203.39) of the agency's regulations sets forth requirements for donation of prescription drug samples to charitable institutions. ''Charitable institution or charitable organization'' is defined in § 203.3(f) (21 CFR 203.3(f)) as ''a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.'' Under § 203.39, a charitable institution may receive drug samples donated by a licensed practitioner or another charitable institution for dispensing to its patients, or may donate a drug sample to another charitable institution for dispensing to its patients, provided certain requirements are met. These requirements include, among other things, that a drug sample donated to a charitable institution must be inspected by a licensed practitioner or registered pharmacist, and that drug sample receipt and distribution records be maintained by the institution and retained for a minimum of 3 years.