conditions; (6) provides training in the epidemiology of these conditions for health professionals within and outside the United States; (7) translates scientific findings into intervention, prevention, and health promotion strategies; (8) conducts evaluations of programs to determine effectiveness; and (9) coordinates activities with other CDC organizations and federal and non-federal health agencies, as appropriate.

Delete in their entirety the title and mission statement for the *Division of Birth Defects and Developmental Disabilities (CN5), National Center for Environmental Health (CN).*

Section C–D, Delegations of Authority. All delegations and redelegations of authority to any officers or employees which were in effect immediately prior to this reorganization and which are consistent with this reorganization shall continue in effect pending further redelegation.

Dated: April 12, 2001.

Jeffrey P. Koplan,

Director.

[FR Doc. 01–9739 Filed 4–18–01; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0785]

Guidance on Medical Device Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Guidance on Medical Device Patient Labeling.'' This guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Guidance on Medical Device Patient Labeling'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important to help assure the safe and effective use of devices. This guidance document was published for public comment on March 3, 2000, as a draft proposal entitled ''Guidance on Medical Device Patient Labeling.''

Both the draft guidance document and the March 2000 notice provided an opportunity for public comment, which closed June 2, 2000. Based on the comments received, the following substantive changes have been incorporated into the final version of the guidance.

1. FDA inserted a paragraph in ''What is the purpose of this guidance?'' explaining that when translating the professional label into lay language, care should be taken to ensure that the lay language does not alter the intent of the indications, contraindications, warnings and precautions, or other parts of the labeling.

2. The sections ''When should you use medical device patient labeling?'' and ''Determining Sequence and Content'' were restructured and revised for clarity. Both sections were clarified to focus on the needs of the specific target population for the device rather than an inflexible formula.

3. The section entitled ''Alternatives to the device and treatment'' was deleted.

4. Changes were made to address the safe and proper methods of disposing of medical devices.

5. FDA has clarified that clinical studies information can be provided either as part of the patient labeling, or upon request.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device patient labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted the good guidance practices (GGP's) regulation, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Patient Labeling'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2 and then enter the document number (1128) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance on Medical Device Patient Labeling,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information.

The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Medical Device Patient Labeling'' will be available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the guidance at any time. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 2001.

Linda S. Kahan,

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

[FR Doc. 01–9652 Filed 4–18–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Chimpanzee Sanctuary Capability Statements

The purpose of this Notice is to determine the capabilities of any private nonprofit organizations interested in serving as a contractor to provide lifetime care for chimpanzees as required under the ''Chimpanzee Health Improvement, Maintenance, and Protection (CHIMP) Act,'' Public Law 106–551, which amended Section 481C of the Public Health Service Act on December 20, 2000.

To carry out the CHIMP Act, the National Institutes of Health (NIH), acting on behalf of the Secretary of Health and Human Services, will, among other things:

• Seek to award a contract to a private nonprofit organization that meets the detailed requirements set forth in the Act. A complete copy of the Act is available at *http://thomas.loc.gov/* or from the Contract Office listed below. Interested institutions should pay particular attention to the sections titled ''Chimpanzees Accepted Into System'' [Section 481C(d)(2)(A)–(K)], ''Requirements'' [Section 481C(e)(2)(A)–(H)], ''Board of Directors'' [Section 481C(e)(3)], and ''Requirement of Matching Funds'' [Section 481C(e)(4)]; and

• Identify the number of chimpanzees no longer needed for research that are available for placement in the sanctuary.

In order for NIH to assess those organizations capable of responding to a Request for Proposals, we are requesting that interested organizations submit capability statements. When responding to this notice, organizations are asked to review the requirements of the CHIMP Act and address the following 5 items:

1. *Nonhuman Primate Management Experience and Stability:* (a) Describe when your organization was established; (b) its management structure; (c) the staff that would be assigned to this project; (d) their experience in managing and caring for chimpanzees; (e) evidence of financial stability and resources that can be brought to the project;

2. *Matching Funds:* Provide evidence of your organization's ability to make non-Federal contributions in cash or in-kind, in an amount not less than 10% of the establishment costs (including construction costs), and 25% of the yearly operational expenses;

3. *Capacity to Hold Chimpanzees:* Due to cost effectiveness constraints aimed at achieving the savings foreseen by the Congressional Budget Office, potential offerors must demonstrate the capacity to house and care for at least 75 chimpanzees. Describe your facility's present or planned capacity to manage and operate a system holding at least 75 chimpanzees, with the future possibility of expansion at the original or additional sites;

4. *Working with Diverse Groups:* Describe your ability and willingness to work with members of the animal protection community, NIH, and a wide variety of other interested parties. In addition, describe your experience or plans for using a board of directors experienced in captive chimpanzee management, animal protection, behavioral primatology, business management, laboratory animal medicine, accreditation of animal facilities, and biohazard containment;

5. *Board of Directors:* Submit letters of commitment for possible members to serve on the board of directors of the sanctuary. Indicate the full name, credentials, expertise, and organizational affiliation(s) for each person.

If possible, please address the 5 items above in a capability statement of no more than 30 pages in length. The capability statement will neither bind nor obligate any organization at this time. If a Request for Proposals (RFP) is issued, the NIH will transmit a copy of it to all organizations whose capability statements have been received by the due date of May 15, 2001. An announcement of availability of the RFP will also be made in the Commerce Business Daily and in the NIH Guide for Grants and Contracts. Please send three copies of the capability statement with an accompanying signed transmittal letter so that they will be received at the following address by May 15, 2001: Mr. Robert Best, Contracting Officer, National Heart, Lung, and Blood Institute, DEA, Contracts Operations Branch, Two Rockledge Centre, Room 6100, 6701 Rockledge Drive, MSC 7902, Bethesda, MD 20892–7902.

Dated: April 12, 2001.

Ruth L. Kirschstein,

Acting Director, NIH.

[FR Doc. 01–9681 Filed 4–18–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Spore in Breast and Prostate Cancer.

Date: May 9–10, 2001.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Barcelo Hotel, 2121 P Street, NW, Washington, DC 20037.

Contact Person: Brian E. Wojcik, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8019, Bethesda, MD 20892, 301/402–2785.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when