labels to have a bar code containing the drug's NDC number. Bar codes will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This guidance is intended to explain certain bar code labeling requirements and their application to human drug and biological products.

In the **Federal Register** of June 7, 2005 (70 FR 33182), FDA announced the availability of a draft version of this guidance. FDA received comments in response to the draft guidance. The agency has considered those comments carefully and has revised the answer to Question 7 (which has been renumbered to Question 9) regarding the application of the 2-year implementation date. In response to recent inquiries from a trade association, the agency has also added Questions 3 and 4 regarding the application of the bar code labeling requirements to over-the-counter drug products. In addition, the agency has made minor editorial changes to the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on certain questions and answers on bar code labeling requirements. 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 requirements of the applicable statutes and regulations.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6312 Filed 4–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0108]

Draft ''Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs,'' dated April 2006. The draft guidance document further explains the requirements on informed consent as they relate to plasmapheresis and immunization programs. The draft guidance document is designed to assist blood establishments planning to apply for licensure or those revising their existing informed consent forms in determining whether the documents include all the appropriate information. This draft guidance, when finalized, will supersede the draft guidance document entitled ''Draft Reviewer's Guide: Informed Consent for Plasmapheresis/Immunization,'' dated October 1995.

DATES: Submit written or electronic comments on the draft guidance by July 26, 2006 to ensure their adequate consideration in the preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the draft guidance 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: Joseph L. Okrasinski Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs,'' dated April 2006. The draft guidance further explains the requirements under part 640 (21 CFR part 640) in 21 CFR 640.61 for the informed consent forms for the donors as they relate to plasmapheresis and immunization programs. The information in the draft guidance will assist those establishments applying for licensure as well as those establishments that are revising their existing informed consent forms. The draft guidance discusses information that is recommended for the informed consent forms. This information includes, but is not limited to, the following: Clarity of the language in the informed consent form, length and frequency of the procedures, possible adverse reactions, side affects that may occur, opportunities to ask questions, and discussion concerning Acquired Immunodeficiency Syndrome (AIDS). Also discussed in the draft guidance is the use of a separate informed consent form for a donor who is participating in an immunization program including one which involves an Investigational New Drug (IND), and its recommended informational content, such as the discussion of the general risks and precautions involved, and suggestions for the health and welfare of the participants. This draft guidance when finalized will supersede the draft guidance document entitled, ''Draft Reviewer's Guide: Informed Consent for Plasmapheresis/Immunization,'' dated October 1995.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will

represent the agency's current thinking on this topic. 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information under §§ 640.61 and 640.66 was approved under OMB control number 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 19, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6314 Filed 4–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

C.W. Bill Young Cell Transplantation Program: National Cord Blood Inventory; Recognition of Cord Blood Bank Accreditation Program(s)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of opportunity for public comment through conference calls.

SUMMARY: Public Law 109–129 requires the Secretary of Health and Human Services to recognize one or more cord blood accreditation entities for the accreditation of cord blood banks participating in the collection and maintenance of umbilical cord blood units for the National Cord Blood Inventory. These cord blood units will be made available for unrelated donor blood stem cell transplants through the C.W. Bill Young Cell Transplantation Program. The HRSA, Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) is in the process of information-gathering to assist in the determination of which cord blood bank accreditation program(s) to recognize on an interim basis for the initial cycle of funding for the National Cord Blood Inventory. The purpose of this solicitation is to receive public input on the following: (1) Approaches to accreditation required to ensure quality cord blood bank operations (including collection sites); (2) Utilization of accreditation programs to ensure product quality and best practices; (3) Degree to which accreditation standards are evidence based and supported by published literature; (4) Extent to which accreditation standards allow for variations in cord blood bank practices; (5) Criteria for the Secretary to consider in recognizing cord blood bank accrediting programs for the National Cord Blood Inventory, C.W. Bill Young Cell Transplantation Program.

The HRSA intends for this interim process to be followed by a formal, more comprehensive recognition process that will include input from both the Advisory Council, once it is established, and the interested public as required in the legislation. The purpose of this Notice is to invite interested parties to register for and participate in either of two conference calls, described below, that HRSA is scheduling to obtain comment on factors relevant to determining which accrediting organization(s) to recognize for the initial cycle of funding under the National Cord Blood Inventory.

DATES: The conference calls will be held on May 9, 2006, at 2 to 4 p.m. e.s.t. and May 15, 2006, at 2 p.m. to 4 p.m. e.s.t. Participants are asked to register for the conference by contacting Anita Wabeke at (301) 443–4747 or e-mail *awabeke@hrsa.gov.* The registration deadline is May 3, 2006 for both conferences. Registration is not guaranteed; it is on a first come basis. Since the topics listed above will be discussed on both calls, and to facilitate hearing all points of view, HRSA requests that organizations and individuals wishing to participate do so in only one of the calls. Due to the limited number of lines available for the calls, organizations with multiple participants are encouraged to register for one line to allow maximum participation from all interested parties. Parties wishing to submit written comments should ensure that the comments are postmarked or E-mailed no later than May 17, 2006 for consideration.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, DoT, HSB, HRSA, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, DoT, HSB, HRSA, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 20, 2005, the Stem Cell Therapeutic Act of 2005 was enacted as Public Law 109–129. The Act authorizes the establishment of the National Cord Blood Inventory and the C.W. Bill Young Cell Transplantation Program as the successor to the National Bone Marrow Donor Registry. The National Cord Blood Inventory is to be a high quality, genetically diverse inventory of cord blood units for patients who need a blood stem cell transplant and who lack an available related donor. The cord blood units in the National Cord Blood Inventory will be made available for transplantation through the C.W. Bill Young Cell Transplantation Program. Cord blood banks collecting and maintaining units for the National Cord Blood Inventory must meet the statutory definition of a qualified cord blood bank, which includes a requirement that cord blood banks be accredited by an