section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to section 10(d) of Public Law 92–463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341–3724, telephone (770) 488–1430.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 20, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–6349 Filed 4–26–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006F–0059]

Danisco USA, Inc.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Danisco USA, Inc., to indicate that the petition proposes to amend the food additive regulations at 21 CFR 172.841 by incorporating by reference the specifications for polydextrose in the 5th edition of the Food Chemicals Codex (FCC), 2003.

ADDRESSES: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1302.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 15, 2006 (71 FR 7975), FDA announced that a food additive petition (FAP 6A4763) had been filed by Danisco USA, Inc., 440 Saw Mill River Rd., Ardsley, NY 10502–2605. The petition proposed to amend the food additive regulations in § 172.841 Polydextrose (21 CFR 172.841) to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry. After publication of the filing notice, FDA learned that the petition also proposed to update § 172.841 by incorporating by reference the specifications for polydextrose in the FCC, 5th ed., 2003. Currently, § 172.841 incorporates by reference the specifications of FCC, 4th ed., 1996.

The agency compared specifications in the monograph for polydextrose in the 4th and 5th editions of the FCC and found that the 5th edition retains the lead limit of 0.5 milligram(mg)/kilogram(kg), but no longer lists a specification limit of 5 mg/kg for heavy metals as lead. The 5th edition of the FCC eliminated the heavy metals as lead test from most monographs in favor of including individual specifications for relevant heavy metals. In addition, the 5th edition added a nickel specification of 2 mg/kg for hydrogenated polydextrose, as well as modified the pH specification of a 10 percent solution of untreated polydextrose from ''not less than 2.5'' (4th edition) to ''between 2.5 and 7.0'' (5th edition). The name of the specification for 5–Hydroxymethylfurfural has also changed from ''5–Hydroxymethylfurfural'' (4th edition) to ''5–Hydroxymethylfurfural and Related Compounds'' (5th edition), although the test and equation used to determine the level have remained the same. The agency has placed copies of the polydextrose monograph in the 4th and 5th editions of the FCC on public display at the Division of Dockets Management (see **ADDRESSES**) for public review.

Dated: March 30, 2006.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E6–6370 Filed 4–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0202]

Guidance for Industry on Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Bar Code Label Requirements—Questions and Answers.'' FDA regulations require certain human drug and biological products to have on their labels a linear bar code that identifies the drug's National Drug Code (NDC) number. We have received several inquiries about how the requirements apply to specific products or circumstances. The purpose of the guidance is to respond to the questions.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *For products regulated by the Center for Drug Evaluation and Research*: Valerie L. Whipp, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8963. *For products regulated by the Center for Biologics Evaluation and Research*: Elizabeth Callaghan, Center for Biologics Evaluation and Research (HFM–370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–8963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Bar Code Label Requirements—Questions and Answers.'' In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a final rule that requires certain human drug and biological product

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