a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–14213 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0965]

''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components.'' The guidance document describes a system for the uniform labeling of blood and blood components for transfusion, Source Plasma, and other components for use in further manufacturing. The guidance will assist manufacturers in complying with the labeling requirements under FDA's regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components'' to 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 the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For information about this notice: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

For technical information: Kenneth A. Zemann, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3543, or FAX 301–827–3534.

SUPPLEMENTARY INFORMATION:

I. Background

The International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA a draft document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*,'' Version 1.2.0 (draft Standard). The ICCBBA requested that ISBT 128 replace the current ''ABC Codabar'' system as an approved machine readable barcode for labeling blood and blood components. On November 21, 1998, FDA made the draft Standard available on its website for public comment. In the **Federal Register** of November 27, 1998 (63 FR 65600), FDA announced the availability of the draft Standard and requested public comment on both the use of ISBT 128 and timeframes for implementation. The ICCBBA revised the draft Standard in response to public comment and submitted to FDA the revised document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*,'' Version 1.2.0, dated November 1999 (the Version 1.2.0 Standard).

FDA has reviewed the draft Standard, the comments received, and the Version 1.2.0 Standard. FDA believes that conformance to the Version 1.2.0 Standard, prepared and revised by ICCBBA, will help facilitate the use of a uniform container label for blood and blood components. FDA is announcing the availability of a guidance entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components'' that recognizes as acceptable the Version 1.2.0 Standard prepared by ICCBBA, and the implementation of the ISBT 128 uniform labeling system, except where inconsistent with FDA's regulations under 21 CFR 606.121. Although FDA finds use of the Version 1.2.0 Standard acceptable, FDA has identified inconsistencies between the Version 1.2.0 Standard and Federal regulations. FDA intends to revise the regulations to remove these inconsistencies. The guidance provides recommendations to follow where discrepancies exist between the Version 1.2.0 Standard and the current regulations, pending completion of rulemaking to remove these discrepancies.

This guidance document represents the agency's current thinking with regard to use of the Version 1.2.0 Standard for use in labeling blood, blood components for transfusion, Source Plasma, and other components for further manufacturing use. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document at any time. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

The labeling regulations on which the guidance is based are reported under the Office of Management and Budget (OMB) control number 0910–0116. FDA tentatively concludes that this guidance contains no new collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document and the Version 1.2.0 Standard at http://www.fda.gov/cber/guidelines.htm.

Dated: May 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–14211 Filed 6–2–00; 11:16 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1277]

Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds.'' The purpose of this draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

DATES: Submit written comments by August 7, 2000.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds'' to Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN) (address below), or Randall A. Lovell, Center for Veterinary Medicine (CVM) (address below). Send one self-addressed adhesive label to assist that office in processing your request. The draft guidance, CFSAN's ''Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption,'' and CVM's ''Background Paper in Support of Fumonisin Levels in Animal Feed,'' may also be accessed at the CFSAN or CVM home page on the Internet at http://www.cfsan.fda.gov and http://www.fda.gov/cvm, respectively.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631, FAX 202–205–4422, or

Randall A. Lovell, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0176, FAX 301–827–1484.

SUPPLEMENTARY INFORMATION: FDA has developed a draft guidance document regarding the maximum recommended levels of fumonisins in corn used for production of human foods and animal feeds. Fumonisins are naturally occurring toxins produced by the molds *Fusarium moniliforme* (*F. verticillioides*), *F. proliferatum*, and other *Fusarium* species that are common contaminants of corn. Fumonisins have been linked to a variety of significant adverse health effects in livestock and experimental animals. Although human epidemiological studies are inconclusive at this time, based on a wide variety of significant adverse animal health effects, FDA believes that an association between fumonisins and human disease is possible.

The purpose of the draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. Based on information obtained from future national and international workshops on the risk from exposure to fumonisins, FDA will consider whether to establish tolerances, regulatory limits, or action levels, as appropriate, for fumonisins in human foods and animal feeds, respectively, under 21 CFR Part 109—Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material and under 21 CFR Part 509—Unavoidable Contaminants in Animal Food and Food-Packaging Material.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The draft guidance document entitled ''Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds'' is being issued as a level 1 draft guidance consistent with GGP's. This draft guidance represents the agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. 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 statute and regulations.

Interested persons may submit written comments to the Dockets Management Branch (address above) on the draft guidance by August 7, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance, CFSAN's ''Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption,'' CVM's ''Background Paper in Support of Fumonisin Levels in Animal Feed,'' and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–14106 Filed 6–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–2540–96]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.