FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document.

Dated: February 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3444 Filed 2–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0193]

Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated February 2007. The guidance document assists establishments with making eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products. The guidance announced in this document finalizes the draft guidance, ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated May 2004. This guidance also finalizes the draft guidance, ''Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated June 2002 (Docket No. 2002D–0266).

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

ADDRESSES: Submit written requests for single copies of the 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, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER 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 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: Paul E. Levine, 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 document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated February 2007. The guidance announced in this document assists HCT/P establishments with complying with the requirements under part 1271 (21 CFR part 1271), subpart C. These regulations require HCT/P establishments to perform an eligibility determination for most cell and tissue donors, based on donor testing and screening for relevant communicable disease agents and diseases. This guidance applies only to cells and tissues procured on or after the effective date of the regulations contained in part 1271, subpart C (effective date May 25, 2005). This guidance does not replace the guidance on 21 CFR part 1270, ''Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation,'' dated July 29, 1997, which continues to apply to certain tissues recovered before May 25, 2005.

In the **Federal Register** of June 25, 2002 (67 FR 42789), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated June 2002. The draft guidance provides information intended to assist manufacturers of HCT/Ps in minimizing the risk of transmission of CJD and vCJD by HCT/P donors that have been possibly exposed to the agents of CJD and vCJD.

In the **Federal Register** of May 25, 2004 (69 FR 29835), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated Ma 2004. The draft guidance provided to HCT/P establishments recommendations for the appropriate screening and testing of cell and tissue donors for relevant communicable disease agents and diseases, and recommendations for complying with the regulations for eligibility determination for donors of HCT/Ps.

FDA issued these two draft guidances to assist manufacturers in minimizing the risk of communicable disease transmission by donors of HCT/Ps. FDA received numerous comments on the two draft guidances and those comments were considered as the guidance was finalized. Based on these comments and additional data, FDA has identified West Nile Virus, Sepsis, and Vaccinia as relevant communicable disease agents or diseases (RCDAD). On the other hand, FDA has not included severe acute respiratory syndrome (SARS-CoV) as an RCDAD in this guidance because there has been no laboratory-confirmed person-to-person transmission of SARS-CoV worldwide since July 2003. In addition, the guidance recommends nucleic acid amplification testing (NAT) for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) for both living and cadaveric donors. The guidance also modifies and/or clarifies the following:

- Recommendations for risk factors for vCJD;
- Physical examination of a living HCT/P donor;
- Exceptions to the requirement for determining donor eligibility and appropriate labeling;
- Screening criteria for HIV–1 group O, viral hepatitis, syphilis, *Chlamydia trachomatis* and *Neisseria gonorrhea*;
- Deferral criteria for receipt of human-derived clotting factors;
- Procedures for communicable disease testing laboratories;
- FDA's approach to identifying new RCDADs; and
- Use of gestational carriers or surrogates.

The guidance announced in this document finalizes the previously described draft guidances dated June 2002 and May 2004. The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 of 1995

This 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 collections of information in part 1271, subpart C have been approved under OMB Control No. 0910–0543. The collections of information in part 1271, subpart D have been approved under OMB Control No. 0910–0559.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance announced in 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 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: February 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3445 Filed 2–27–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0021]

Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members; 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 ''Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members.'' This guidance is intended to provide information to industry sponsors, applicants, and petitioners on the development, preparation, or submission of briefing materials that will be given to advisory committee members as background information prior to open FDA advisory committee meetings. The guidance will help sponsors develop, organize, and submit advisory committee briefing materials for public release and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public.

DATES: Submit written or electronic comments on the draft guidance document by April 30, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *poppy.kendall@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members.'' This guidance will help sponsors develop, prepare, and submit advisory committee briefing materials and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public. The term ''briefing materials'' is used to describe the package of information that we provide to advisory committee members before a meeting, and that usually contains information prepared by us and/or the sponsor (if the meeting involves an application or particular product). In addition, the Appendices to the draft guidance provide timelines for preparing and submitting briefing materials to FDA.

For open advisory committee meetings for which the briefing materials may contain information that under certain circumstances could be considered to be exempt from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552), we intend to post the publicly available version of the briefing materials on our Web site at least 2 full business days before the advisory committee meeting is scheduled to occur. With respect to meetings for which the briefing materials do not contain information that could be considered exempt from disclosure under FOIA, we will probably make the briefing materials available on our Web site more than 2 full business days before the advisory committee meeting is schedule to occur. In the latter case, we anticipate that meetings subject to this timeline will normally address general matters such as guidance documents and policy issues related to FDA-regulated products.

This draft guidance, which will harmonize the preparation and public availability of information given to advisory committee members for all products regulated by FDA, replaces three previously issued draft guidances: (1) ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000;'' (2) ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research;'' and (3) ''Availability of Information Given to Advisory Committee Members in Connection With the Center for Devices and Radiological Health Open Public Panel Meetings.'' An important goal of this guidance is to help ensure that briefing materials are made available to the public as provided under section 10(b) of the Federal