

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0157] (Formerly Docket No. 2006D-0514)

Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications; 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: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications," dated October 2009. In this guidance, we refer to these products for hematopoietic reconstitution for specified indications as hematopoietic progenitor cells, cord (HPC-C). This guidance (HPC-C licensure guidance) provides recommendations to manufacturers applying for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for specified indications. Elsewhere in this issue of the **Federal Register**, FDA is publishing a draft guidance entitled "Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications." FDA is also announcing the end of the phased-in implementation period for IND and biologics license application (BLA) requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products. The HPC-C licensure guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies," dated December 2006.

DATES: Submit electronic or written comments on agency guidances at any time. FDA no longer intends to exercise enforcement discretion with respect to IND and BLA requirements for minimally manipulated, unrelated

allogeneic hematopoietic stem/progenitor cell products and the phase in implementation period for IND and BLA requirements will end after October 20, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (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 electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Tami Belouin, 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 guidance document entitled "Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications," dated October 2009. This guidance provides recommendations to manufacturers applying for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for specified indications. Elsewhere in this issue of the **Federal Register**, FDA is publishing an IND draft guidance entitled "Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications." FDA is also announcing that it no longer intends to exercise enforcement discretion with respect to IND and BLA requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products and the phase-in implementation period for IND and license application requirements for

these products will end (see **DATES** for ending date). We encourage sponsors to send in applications as soon as possible to allow sufficient time for review, comment, and re-submission as needed to complete all actions by the end of this 2-year period.

In the **Federal Register** notice of January 20, 1998 (63 FR 2985), FDA requested submission of comments proposing establishment controls, process controls, and product standards designed to ensure the safety and effectiveness of minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products derived from peripheral and cord blood for hematopoietic reconstitution. Also, in the January 20, 1998, notice, FDA announced its intention to phase in implementation of IND and license application requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products to permit the development of licensing standards for those products where possible.

In the **Federal Register** notice of January 17, 2007 (72 FR 1999), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies," dated December 2006. FDA received comments on the December 2006 draft guidance and those comments were considered as the guidance was finalized. The HPC-C licensure guidance announced in this notice finalizes the December 2006 draft guidance. Some of the comments received by FDA expressed the importance of access and availability of HPC-C products that not do meet standards for licensure and therefore cannot be licensed. FDA recognizes the importance of these products and is publishing a draft IND guidance addressing IND submissions for such products.

This guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on these topics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches may be used if such approaches satisfy 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 21 CFR part 201 have been approved under OMB Control No. 0910–0572; 21 CFR part 211 have been approved under OMB Control No. 0910–0139; 21 CFR part 600 have been approved under OMB Control No. 0910–0308; 21 CFR parts 601, 610, and FDA Form 356(h) have been approved under OMB Control No. 0910–0338; 21 CFR part 1271 have been approved under OMB Control Nos. 0910–0559, 0910–0469, and 0910–0543; and FDA Form 3500A has been approved under OMB Control No. 0910–0291.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the 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 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/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 14, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0270]

Medical Device User Fee and Modernization Act; Notice to Public of Web Location of 2010 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

Web location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. WO66, rm. 4436, Silver Spring, MD 20993, 301–796–5739.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web location of the list of guidances on which CDRH is intending to work over the next fiscal year. We note that the agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown

that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the third annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a specific docket where comments about the fiscal year 2010 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each fiscal year from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in 2010, visit the FDA Web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm>.

II. Request for 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