home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 027'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to sent two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 027. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: July 28, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19479 Filed 8–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0490]

Guidance for Industry and Food and Drug Administration Staff: Investigational New Drug Applications for 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 document 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,'' dated June 2011. The guidance document provides advice to potential sponsors to assist in the submission of an IND for certain minimally manipulated hematopoietic stem/progenitor cells from placental/umbilical cord blood, from an unrelated allogeneic cord blood donor and intended for hematopoietic reconstitution in patients with specified indications (HPC–Cs), when such HPC–Cs are not licensed and when a suitable human leukocyte antigen (HLA) matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition, and there is no satisfactory alternative treatment. If such HPC–Cs are made available for clinical use, they must be distributed under an IND. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2009.

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

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 document 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,'' dated June 2011. The guidance document provides advice to potential sponsors (*e.g.,* cord blood banks or registries, transplant centers, and individual physicians serving as sponsor-investigators) to assist in the submission of an IND for certain HPC–Cs, when such HPC–Cs are not licensed in accordance with 21 CFR Part 601, and when a suitable HLA matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition, and there is no satisfactory alternative treatment. The guidance document is applicable only to HPC–Cs intended for hematopoietic reconstitution in patients with the clinical indications listed in the guidance. If such HPC–Cs are made available for clinical use, they must be distributed under an IND meeting all of the applicable requirements in part 312 (21 CFR Part 312).

In the **Federal Register** of October 20, 2009 (74 FR 53751), FDA announced the availability of the draft guidance of the same title dated October 2009. FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. Changes incorporated in the final guidance include simplifying table A, which sets forth certain regulatory requirements and current best practices with respect to what should be included in an IND. In addition, organizational and editorial revisions were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2009.

In the October 20, 2009, notice announcing the availability of the draft

guidance, FDA also announced that it no longer intends to exercise enforcement discretion with respect to the IND and biologics license application (BLA) requirements, and the phase-in implementation period for IND and license application requirements will end as of October 20, 2011. FDA also encouraged sponsors to send in applications as soon as possible to allow sufficient time for review, comment, and resubmission as needed to complete all actions by the end of this 2-year period. FDA continues to encourage potential sponsors to submit new protocols as needed to their existing INDs, or new INDs if needed, or BLAs as soon as possible, so that FDA may work with them to ensure that the protocols are in effect or that the BLAs are approved, if appropriate, by the end of the phase-in implementation period.

We acknowledge that there will be cord blood banks that are not able to achieve licensure by October 20, 2011. Furthermore, we acknowledge that should we approve a bank's BLA, our approval may not include all the HPC–Cs in that bank's inventory. We note that if a bank is unable to obtain a BLA by October 20, 2011, or if its BLA does not include all the HPC–Cs in that bank's inventory, its unlicensed units may be released for use only under an IND.

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 312 have been approved under OMB control number 0910–0014; 21 CFR Part 56 have been approved under OMB control number 0910–0130; 21 CFR Part 1271 have been approved under OMB control number 0910–0543; and FDA Form 1571 has been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

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: July 26, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19483 Filed 8–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Thursday, September 22, 2011, from 2 p.m. to 6:30 p.m. and on Friday, September 23, 2011, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On Thursday, September 22, 2011, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155), for Fluarix (influenza virus vaccine), Afluria (influenza virus vaccine), and Abilify (aripiprazole). There will also be an update on a study jointly funded by the Agency for Healthcare Research and Quality (AHRQ) and FDA on antipsychotic use and metabolic effects in children.

On Friday, September 23, 2011, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for Akten (lidocaine hydrochloride), Famvir (famciclovir), Levaquin (levofloxacin), Navstel (balanced salt ophthalmic solution with hypromellose, dextrose, and glutathione), Retrovir (zidovudine), Topamax (topiramate), Triesence (triamcinolone acetonide injectable suspension), Videx EC (didanosine), Ziagen (abacavir sulfate), and Zomig Nasal Spray (zolmitriptan). There will be an informational update on Kaletra (lopinavir/ritonavir) oral solution and tablets.

As mandated by the Food and Drug Administration Amendments Act, Title III, Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110–85), the committee will discuss the safety of and profit-making waiver for the pediatric humanitarian device, Melody Transcatheter Pulmonary Valve and Ensemble Delivery System.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.*