

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]

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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>.

htm. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before Friday, September 16, 2011. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m on Friday, September 23, 2011. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before Friday, September 2, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by Tuesday, September 6, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: July 28, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011-19481 Filed 8-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Eligibility Criteria for Sites Recruiting National Health Service Corps Scholars

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the eligibility criteria, including their Health Professional Shortage Area (HPSA) scores, for entities that are seeking to recruit National Health Service Corps (NHSC) scholarship recipients (Corps Personnel, Corps members) during the period July 1, 2011, through June 30, 2012. A searchable database that specifies all currently approved NHSC service sites is posted on the NHSC Web site at <http://datawarehouse.hrsa.gov/HGDW/Reports/OneClickRptFilter.aspx?rptName=NHSCAppSiteList&rptFormat=HTML3.2>. This database can be searched by State and can be utilized to determine which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program based on the threshold HPSA score set forth below. Please note that entities on this list may or may not have current job opportunities for NHSC scholars. Further, not all vacancies associated with sites on the list described below will be for Corps members, but could be for NHSC Scholarship Program participants serving their obligation through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA status of "designated" by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP); (3) enter into an agreement with the State agency that administers Medicaid and CHIP, accept assignment under Medicare, see all patients regardless of their ability to pay and post such policy, and use and post a discounted fee plan; and (4) be determined by the Secretary to have (a) A need and demand for health manpower in the area; (b)

appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development, and training opportunities for Corps members. Priority in approving applications for assignment of Corps members goes to sites that (1) Provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps members is not assigned to the entity.

Entities that receive assignment of Corps personnel must assure that (1) The position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in the requisite amount of clinical practice, as defined below, to meet his or her service obligation:

Full-Time Clinical Practice

"Full-time clinical practice" is defined as a minimum of 40 hours per week for at least 45 weeks per service year. The 40 hours per week may be compressed into no less than 4 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the full-time service obligation.

For all health professionals, except as noted below, at least 32 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s) during normally scheduled office hours. The remaining 8 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching activities at the approved service site shall not exceed 8 hours of the minimum 40 hours per week, unless the