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Karl Koerper,

Reports Clearance Officer.

[FR Doc. 2015–03924 Filed 2–25–15; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–20115–N–0456]

Pediatric Stakeholder Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics (OPT), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are announcing a public meeting seeking input from patient groups, consumer groups, regulated industry, academia and other interested parties to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatrics, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (see the **SUPPLEMENTARY INFORMATION** section for additional background information).

DATES: The public meeting will be held on March 25, 2015, from 9 a.m. to 5 p.m. Registration to attend the meeting should be received by March 20, 2015 (see the **SUPPLEMENTARY INFORMATION** section for instructions).

ADDRESSES: The meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (1503–B & C), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.*

Submit either electronic or written comments by April 24, 2015. Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: *http://wwww.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm433552.htm.*

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *terrie.crescenzi@fda.hhs.gov* or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Section 508 of FDASIA directs the Secretary of HHS to submit a report to Congress on the implementation of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA). The first report must be submitted to Congress by July 9, 2016, and every 5 years thereafter. FDASIA also requires FDA to obtain, at least 180 days prior to submission of the report, stakeholder input from patient groups, consumer groups, regulated industry, academia, and any other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

The basic content of the report will include: An assessment of the effectiveness of BPCA (section 505A) and PREA (section 505B) in improving information about pediatric uses for approved drugs and biological products, including the number and type of labeling changes made since the enactment of FDASIA and the importance of such uses in the improvement of the health of children; various statistics related to both PREA and BPCA, including the Written Request referral process with the National Institutes of Health; an assessment of the timeliness and effectiveness of pediatric study plans; an assessment of studying biologics; efforts made to increase the number of studies conducted in the neonatal population; the number and importance of drugs and biologics studied in children with cancer and any recommendations for modification to the programs that would improve pediatric drug research and increase labeling of drugs and biologics; an assessment of the successes of and limitations to studying drugs for rare diseases; an assessment of the efforts to address the suggestions and options described in any prior report issued by the Comptroller General, Institute of Medicine, or the Secretary, and any stakeholder recommendations or modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

The specific topics to be discussed at the meeting will include, but not be limited to, pediatric labeling changes, waivers and deferrals, Written Requests, pediatric study plans, programmatic activities with the NIH Written Request referral process, activities concerning neonates, pediatric cancers and rare diseases, and transparency.

II. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://stakeholderinput.eventbrite.com.* Please register by March 20, 2015. Those who are unable to attend the meeting in person can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations due to a disability, please contact Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Persons interested in presenting comments at the meeting will be asked to indicate this in their registration. FDA will try to accommodate all participant requests to speak, however the duration of comments may be limited by time constraints.

Comments: Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket (see **ADDRESSES**) by April 24, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m.,

Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, FDA will post it at *http://wwww.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm433552.htm.*

Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03974 Filed 2–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Organ Transplantation (ACOT).

Date and Time: March 12, from 8:30 a.m. to 4:30 p.m. Eastern Standard Time. March 13, from 8:30 a.m. to 12:30 p.m. Eastern Standard Time.

Place: Health Resources and Services Administration, 5600 Fishers Lane, Room 05W11, Rockville, MD 20857.

Status: The meeting will be open to the public.

Purpose: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, thereby increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members including the Chair. Members serve as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine, and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

Agenda: The Committee will hear presentations, including those on the following topics: Kidney Paired Donation; Vascularized Composite Allografts; Donor Management Research; Living Donation; and the Affordable Care Act and Transplantation. Agenda items are subject to change as priorities indicate.

After Committee discussions, members of the public will have an opportunity to comment. Because of the Committee's full agenda and timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be posted on the Department's organ donation Web site at *http://www.organdonor.gov/legislation/advisory.html#meetings.*

The draft meeting agenda will be posted on *www.blsmeetings.net/ACOT.* Those participating on this meeting should pre-register by visiting *www.blsmeetings.net/ACOT.* The deadline to pre-register for this meeting is Wednesday, March 11, 2015. Registration will be confirmed on site. For all logistical questions and concerns, please contact Anita Allen, Seamon Corporation at 301–658–3442 or send an email to *aallen@seamoncorporation.com.*

Public Comment: It is preferred that persons interested in providing an oral presentation email a written request, along with a copy of their presentation, to Patricia Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, at *pstroup@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative.

The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may request it during the public comment period. Public participation and ability to comment will be limited to time as it permits. **FOR FURTHER INFORMATION CONTACT:** Patricia Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 17W65, Rockville, MD 20857; telephone (301) 443–1127.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–03929 Filed 2–25–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Emergency Clearance Request Human Influenza Surveillance of Health Care Centers in the United States and Taiwan

SUMMARY: In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for emergency review and processing of this information collection by March 7, 2015. NIAID is requesting emergency processing of this information collection, pursuant to 5 CFR 1320.13, because NIAID cannot reasonably comply with the normal clearance procedures which would cause a delay and likely prevent or substantially disrupt the collection of information. A delay in starting the information collection would hinder the agency in accomplishing its mission to the detriment of the public good. Public harm could result through the loss of critically needed information to understand the causes of severity of influenza and associated morbidity and mortality during the Northern hemisphere 2014–15 influenza season. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number. Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the