

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-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://www.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://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm433552.htm>.

Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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