

estimate it will take 5 hours to complete Form FDA 3542.

We estimate there will be 241 instances (based on an average of 114 NDAs filed and 127 NDA supplements filed per year) where an NDA holder would comply with the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 819 such declarations (241 × 3.4 declarations per instance = 819). Based upon informal communications with industry and our experience with the collection, we estimate it will take 20 hours to complete Form FDA 3542a.

Dated: August 5, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016-19385 Filed 8-12-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Facilitating Anti-Infective Drug Development for Neonates and Young Infants; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding anti-infective drug development for neonates and young infants. FDA is interested in discussing the scientific challenges pertaining to development of anti-infective products for neonates and young infants. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, public health organizations, academic experts, and industry on various aspects of drug development for new and currently marketed anti-infective drugs for neonates and young infants. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on September 15, 2016, from 8:30 a.m. to 4:30 p.m. See the

SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring,

MD 20910. The hotel's phone number is 301-589-0800.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding anti-infective drug development for neonates and young infants. Discussions will focus on challenges related to enrolling neonates and young infants in clinical trials, strategies to assess central nervous system (CNS) penetration of the drug, including nonclinical and in vitro data, potential development pathways, and the role of clinical trial networks in anti-infective drug development in the neonatal population.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to NeonatalAntibacterialWorkshop2016@fda.hhs.gov. Persons without access to the Internet can call 301-796-1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Agenda: The workshop draft Agenda will be made available at: <http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm> at least 2 days prior to the meeting. The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be available on the Internet at: <http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm> approximately 45 days after the workshop.

Dated: August 8, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

[FR Doc. 2016-19336 Filed 8-12-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on October 27, 2016, from 1 p.m. to 4:20 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-9016 or 240-402-8158, email: Janie.Kim@fda.hhs.gov or Denise.Royster@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the