

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]

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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]

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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

appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via Web cast. The Web cast will be available at the following link: <https://collaboration.fda.gov/apac1016/>.

SUPPLEMENTARY INFORMATION: Agenda: On October 27, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Laboratory of Immunobiochemistry of the Division of Bacterial, Parasitic and Allergenic Products (DBPAP), Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

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 meeting link.

Procedure: On October 27, 2016, from 1 p.m. to 3:30 p.m., the meeting is open to the public. 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 October 13, 2016. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. 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 October 4, 2016. 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 October 5, 2016.

Closed Committee Deliberations: On October 27, 2016, the meeting will be closed from 3:35 p.m. to 4:20 p.m. to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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 disabilities. If you require accommodations due to a disability, please contact Janie Kim 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: August 9, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016-19338 Filed 8-12-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0217]

Premarket Notification Submissions for Electrosurgical Devices for General Surgery; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery." FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for electrosurgical devices intended for use in general surgery.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0217 for "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.