

FDA acknowledges that according to the CLIA (Clinical Laboratory Improvement Amendments) program at CMS (August 2014), there are approximately 11,000 CLIA-certified high complexity labs that have the appropriate certifications to manufacture LDTs. However, FDA is not aware of information describing the exact number of certified high complexity laboratories currently offering LDTs. Therefore, FDA has relied upon the information provided by New York State when creating these estimates. FDA acknowledges that, without firm data on the number of labs offering LDTs or the number of tests offered per lab, the estimate of the number of respondents is necessarily uncertain.

After the initial notification, respondents will only notify FDA of new tests or modifications that affect performance or intended use. We estimate the number of tests in subsequent years to be approximately 5 percent of the estimated number of initial notifications.

FDA bases its estimate of the average burden per response on Agency creation of a mock notification. We would expect labs to take up to an hour for their first notification and only 30 minutes for subsequent notifications, due to familiarity with the system.

Therefore, we estimate the total reporting burden to respondents to be 5,850 hours for the first year and 325 hours for subsequent years.

This draft guidance also refers to previously approved collections of information found in FDA regulations.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 21 CFR part 803 (medical device reporting) have been approved under OMB control numbers 0910–0291 and 0910–0437; the collections of information in 21 CFR part 806 (reports of corrections and removals) have been approved under OMB control number 0910–0359; and the collections of information in 21 CFR part 807, subparts B and C (registration and listing) have been approved under OMB control number 0910–0625.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Comments will also be accepted at a public meeting, which will be held prior to finalizing this draft guidance. A 2-day meeting is tentatively scheduled for early January 2015 and will be announced separately in the **Federal Register**.

Dated: September 29, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–23586 Filed 9–30–14; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pulmonary-Allergy Drugs 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: Pulmonary-Allergy Drugs 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 October 21, 2014, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email:

PADAC@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.

Agenda: The committee will discuss supplemental new drug application (sNDA) 203188, ivacaftor oral tablets, submitted by Vertex Pharmaceuticals Inc., for the treatment of cystic fibrosis in patients with an R117H mutation in the cystic fibrosis transmembrane conductance regulator gene.

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: 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 14, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 6, 2014. 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 7, 2014.

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 contact Cindy Hong 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: September 26, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-23548 Filed 10-2-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2014-N-0001]

Anesthetic and Analgesic Drug Products 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: Anesthetic and Analgesic Drug Products 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 November 24, 2014, from 8 a.m. to 5 p.m. and November 25, 2014, from 8 a.m. to 12 noon.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: AADPAC@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.

Agenda: The committee will discuss the risk of serious neurologic adverse reactions associated with epidural steroid injections (ESI) administered to reduce inflammation for pain management. The committee will also consider the efficacy of ESI and the overall risk benefit balance of injecting steroids in the epidural space to treat pain. These considerations will assist the Agency in our discussions of possible regulatory options, including but not limited to changes to the product labeling.

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: 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 November 7, 2014.

Oral presentations from the public will be scheduled between approximately 2 p.m. and 3:30 p.m. on November 24, 2014. 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 30, 2014. 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 31, 2014.

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 contact Stephanie L. Begansky 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: September 26, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-23549 Filed 10-2-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2014-0414]

Cook Inlet Regional Citizens' Advisory Council (CIRCAC) Charter Renewal

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.