

## I. CBER Vaccines and Related Biological Products Advisory Committee

The CBER Vaccines and Related Biological Products Advisory Committee (the Committee) reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

## II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

## III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as

nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 5, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-11258 Filed 5-8-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-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 June 11, 2015, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. 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>.

*Contact Person:* Kristina Toliver, 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](mailto: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 biologics license application (BLA) 125526, for mepolizumab for injection, submitted by GlaxoSmithKline for the proposed indication of add-on maintenance treatment in patients 12 years and older with severe eosinophilic asthma identified by blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment or blood eosinophils greater than or equal to 300 cells/microliter in the past 12 months.

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 May 28, 2015. 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 May 19, 2015. 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 May 20, 2015.

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 Kristina Toliver 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: May 5, 2015.

**Jill Hartzler Warner**,  
Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-11257 Filed 5-8-15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request National Institute of Health Neurobiobank Tissue Access Request**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National

Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 13, 2015, page 8723 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), 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.

**Direct Comments To OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov*. Formal requests for additional plans and

instruments must be requested in writing.

**Proposed Collection:** National Institute of Health Neurobiobank Tissue Access Request—Existing without OMB Clearance—National Institute of Mental Health (NIMH), National Institute of Health (NIH).

**Need and Use of Information Collection:** NIMH is seeking OMB approval for two Neurobiobank data collections: (1) Pre-Mortem Donor Recruitment Form, and (2) Tissue Access Request Form. The pre-mortem donor form will collect information from potential donors to ensure and enable appropriate research use of the tissues and biospecimens. Knowledge about the health history surrounding a particular tissue or biospecimen is essential to ethical scientific research conducted upon it. The tissue access request form will collect information from researchers who wish to gain access to the tissue stored throughout the Neurobiobank network. The NIH Neurobiobank Tissue Access Request form is necessary to verify that the researcher "Recipient" Principal Investigators and their organization or corporations applying to use the tissue is qualified to conduct human tissue research and have approved assurance from the DHHS Office of Human Research Protections to access tissue or biospecimens from the National Neurobiobank for research purposes. The primary use of this information is to document, track, monitor, and evaluate the appropriate use of the Neurobiobank tissue and biospecimen resources, as well as to notify interested recipients of updates, corrections, or other changes to the system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 38.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form	Number of respondents	Frequency of response	Average burden per response (in hours)	Total annual burden hours
Neurobiobank Tissue Access Request .....	50	1	30/60	25
Pre-Mortem Donor Recruitment Form .....	50	1	15/60	13
Total .....	100	.....	.....	38

Dated: May 5, 2015.

**Keisha L. Shropshire**,  
NIMH Project Clearance Officer, NIMH, NIH.

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