

applicants (both treatment and control) through baseline data collection; and (3) individual enrolled program participants' activities and outcomes.

The universe of information collection proposed for HPOG Next Gen includes the HPOG Next Gen Participant Accomplishment and Grant Evaluation System (PAGES). PAGES is a performance management system that will collect information from all grantees on their programs and

participants on a semi-annual basis over the grant period of performance and intake information on eligible applicants (both treatment and control) through baseline data collection. The data system will meet the performance data needs of the HPOG Next Gen grantees and of the ACF Office of Family Assistance to monitor the performance of the grants and prepare the report to Congress on the grants, as well as support an impact study, a

coordinated Tribal evaluation, and other future research and evaluation efforts sponsored by ACF.

*Respondents:* Grantee- and participant-level data to be collected by program staff in the approximately 40 grantee organizations (higher education institutions, workforce investment boards, private training institutions, nonprofit organizations, and tribal entities). Applicants at the 40 grantee organizations.

ANNUAL BURDEN ESTIMATES

| Instrument   | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| PAGES Grantee—and Participant-Level Data Collection (all grantees) .....   | 120                         | 40                           | 2                                  | 31.75                             | 2,540               |
| PAGES Participant-Level Baseline Data Collection (participants at non-Tribal grantees participating in impact study) ..... | 31,500                      | 10,500                       | 1                                  | .5                                | 5,250               |
| PAGES Participant-Level Baseline Data Collection (participants at Tribal grantees) .....                                   | 1,200                       | 400                          | 1                                  | .25                               | 100                 |
| Estimated Total Annual Burden Hours: .....   | .....                       | .....                        | .....                              | .....                             | 7,890               |

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Karl Koerper,**

*OPRE Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-0001]

**Request for Nominations on the Vaccines and Related Biological Products Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Vaccines and Related Biological Products Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by June 10, 2015, (see sections

I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by June 10, 2015.

**ADDRESSES:** All statements of interest from interested industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Sujata Vijh (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSportal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Sujata Vijh, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993-0002, 240-402-7107, FAX: 301-595-1307, email: [Sujata.vijh@fda.hhs.gov](mailto:Sujata.vijh@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

## 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.*

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## 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