

recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to [www.standards@cdrh.fda.gov](http://www.standards@cdrh.fda.gov). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

#### VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 036" will be available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. You may access the CDRH home page at <http://www.fda.gov/MedicalDevices>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

#### VII. Submission of Comments and Effective Date

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>. FDA will consider any comments received in determining

whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 036. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: July 2, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0899]

#### **Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative and Request for Nominations for Nonvoting Industry Representatives on the Cellular, Tissue, and Gene Therapies 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 Cellular, Tissue, and Gene Therapies Advisory Committee for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the Cellular, Tissue, and Gene Therapies 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 or upcoming 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 FDA by August 8, 2014, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by *August 8, 2014*.

**ADDRESSES:** All letters of interest from industry organizations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**). All nominations should be submitted by

logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTSRPortal/FACTRS/index.cfm>

**FOR FURTHER INFORMATION CONTACT:** Gail Dapolito, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 6124, Silver Spring, MD 20993-0002, 240-402-8046; [gail.dapolito@fda.hhs.gov](mailto:gail.dapolito@fda.hhs.gov).

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

#### **I. Cellular, Tissue, and Gene Therapies Advisory Committee**

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

#### **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 of this document (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 provided within 30 days of publication of this document (see **DATES**) by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. 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 has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the cell, tissue, and gene transfer products manufacturing industry.

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: July 3, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-16038 Filed 7-8-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Evaluation of the NIH Academic Research Enhancement Award (NIH OD)**

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995,

for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michelle M. Timmerman, Ph.D., Director, AREA Program, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Bethesda, Maryland 20892; or call non-toll-free number 301-402-0672; or email your request, including your address to [michelle.timmerman@mail.nih.gov](mailto:michelle.timmerman@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection:* Evaluation of the NIH Academic Research Enhancement Award, 0925-New, Office of the Director (OD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The Academic Research Enhancement Award (AREA) Program is

a grant mechanism spanning most of the Institutes and Centers (ICs) of the National Institutes of Health (NIH). The AREA program was established by Congress in 1985 to provide support to scientists at public and private colleges and universities that receive relatively small amounts of NIH funding. The purpose of the program is to support meritorious research, expose undergraduate and graduate students to research, and strengthen the research environment of the institutions receiving the grants. In the past three years alone, the federal government has awarded approximately 78 million dollars annually in AREA grants. The evaluation will allow the NIH and Congress to assess the extent to which the AREA program is meeting its goals and make recommendations so that this significant investment of public funds may be used as effectively as possible.

The evaluation will utilize the NIH's archived data on grants, institutions, Principal Investigators (PIs), and students funded with AREA monies. The evaluation will collect new data about (1) the quantity and quality of student participation in AREA projects, (2) records of PIs' subsequent funding histories, (3) applicants' experiences with the application process, (4) PIs' experiences implementing AREA Program objectives, and (5) the impact of AREA Program research participation on student career paths and outcomes.

The results of the evaluation will indicate the extent to which the AREA Program is meeting its goals of supporting meritorious research, strengthening the research environment at institutions of higher education that are not research intensive, and recruiting and training subsequent generations of the United States' biomedical scientist workforce. Intended audiences include the United States Congress, staff at NIH ICs that make AREA awards, and staff of the NIHOD.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 629.

**ESTIMATES OF ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Principal Investigator Survey .....	480	1	45/60	360
Awardee Semi-Structured Interview .....	50	1	45/60	38
Student Survey .....	301	1	30/60	151