Administration, Office of Minority Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2382, Silver Spring, MD 20993, 301–796–8453, FAX: 301–847–8601, email: *Christine.merenda@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Office of Minority Health (OMH) was established in 2010, as mandated by the Patient Protection and Affordable Care Act (Pub. L. 111–148). OMH serves as the principal advisor to the Commissioner on minority health and health disparities. OMH provides leadership and direction in identifying Agency actions that can help reduce health disparities, including the coordination of efforts across the Agency.

OMH advances FDA's regulatory mission in addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all. To achieve this mission, OMH has committed to identifying gaps in existing knowledge to shape further research projects intended to lead to better understanding of medical product clinical outcomes in racial/ethnic demographic subgroups. A guiding principle for FDA in meeting the health needs of patients across the demographic spectrum is the importance of encouraging diversity in clinical trials. Thus, FDA is also interested in gaining input for improving clinical trials in therapeutic areas impacted by low rates of inclusion of racial/ethnic demographic subgroup populations, ranging from issues surrounding recruitment and participation in clinical trials to clinical outcome analysis of demographic subgroup populations. Of particular note in this regard is FDA's ''Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data'' at *http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf.*

Research in regulatory science is distinctive for developing new tools, standards, and approaches for assessing the safety, efficacy, quality, and performance of all FDA-regulated products. The results can help to transform the way medical products are developed, evaluated, and manufactured. Health disparities research with a regulatory focus seeks to expand and strengthen knowledge of, and the availability of data on, medical product clinical outcomes in racial/ethnic demographic subgroups, to inform healthcare decisions by providers and patients.

II. Request for Comments and Information

OMH seeks comments and information to identify specific areas of public health concern involving racial/ethnic demographic subgroups that can be addressed through regulatory science research, including new or emerging areas of concern. We encourage comments to include supporting information regarding the topic addressed, such as previously published peer-reviewed literature or new research findings. These comments and information will support OMH in its development of a research agenda that will inform funding decisions for the next fiscal year. (This notice is not a request for specific research or grant proposals from outside entities.) In addition to input on improving clinical trial inclusion and outcome analysis, requested comments and information identifying disease areas with outcome differences for further study may include, but are not limited to, the following:

- An area of study that could lead to a diagnostic or screening test based on the development and evaluation of biomarkers for a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- An area of study that could lead to changes in labeled indications, or dosages, for a single or class of drug(s) or biologic(s) used to treat a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- An area of study that could lead to changes in the design or use of a device to treat a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- Research to identify effective ways to communicate with patients and consumers from racial/ethnic subgroups, including those with low health literacy and limited English proficiency, so they are informed about FDA actions (new approvals, warnings, recalls, etc.) that impact their health.
- Research evaluating methods to accommodate cultural and language differences that can improve health communications to racial/ethnic subgroups, and assess the cost of these methods to the Government.
- Research evaluating the impact of different formats and amounts of numerical information in FDA communications for patients, health care providers, health educators, and informal caregivers.

III. 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.*

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03846 Filed 2–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Division of Cancer Epidemiology and Genetics (DCEG) Fellowship Program and Summer Student Applications (NCI)

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 April 9, 2014 (Vol. 79, P. 19632) 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 Cancer Institute (NCI), 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: Jackie Lavigne, Office of Education, Division of Cancer Epidemiology and Genetics, 9609 Medical Center Drive, MSC 9776, Bethesda, MD 20892–9776 or call non-toll-free number 240–376–7237 or Email your request, including your address to: *lavignej@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Division of Cancer Epidemiology and Genetics (DCEG) Fellowship Program and Summer Student Applications (NCI), Existing Collection in Use without OMB Control Number, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Division of Cancer Epidemiology and Genetics (DCEG) Office of Education (OE) administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the Intramural Research Program to facilitate their development into future biomedical scientists. DCEG trains post-doctoral, doctoral candidates, graduate and baccalaureate students, through full time fellowships, summer fellowships, and internships in preparation for research careers in cancer epidemiology and genetics. The proposed information collection involves brief online applications completed by applicants to the full time and the summer fellowship programs. Full-time fellowships include: Full-time Equivalents (FTE) and non-FTE fellowships for US citizens, permanent residents and international fellows. These applications are essential to the administration of these training programs as they enable OE to determine the eligibility and quality of potential awardees; to assess their potential as future scientists; to determine where mutual research interests exist; and to make decisions regarding which applicants will be proposed and approved for traineeship awards. In each case, completing the application is voluntary, but in order to receive due consideration, the prospective trainee is encouraged to complete all relevant fields. The information is for internal use to make decisions about prospective fellows and students that could benefit from the DCEG program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 175.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Fellowship Program Application	Full-time Fellows	150	1	30/60	75
Summer Program Application	Summer Students	300	1	20/60	100

Dated: February 19, 2015.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–03789 Filed 2–24–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Assessment of Oncology Nursing Education and Training in Low and Middle Income Countries (NCI)

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 July 8, 2014, Vol. 79, page 38542 and allowed 60-days for public comment. One public comment was received on July 9, 2014. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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: Annette Galassi, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., Rm. 3W250, Rockville, MD 20850 or call non-toll-free number 240–276–6632 or Email your request, including your address to: *agalassi@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Assessment of Oncology Nursing Education and Training in Low and Middle Income Countries, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is a request for OMB to approve the Assessment of Oncology Nursing Education and Training in Low and Middle Income Countries (LMICs). NCI-Designated Cancer Centers have a range of international activities, some of which are funded by NCI, but many of which are not. These international activities may include oncology nursing education and training in LMICs, but the extent of these activities across cancer centers is unknown. The proposed assessment requests information about oncology nursing education and training projects including: descriptions of projects, partner organizations, types of activities, cost, and impact. The information will be collected annually. NCI's Center for Global Health (CGH) is in the process of developing its strategic plan for oncology nursing education in LMICs.