part 314 have been approved under 0910–0001; and the collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24035 Filed 9–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0972]

Clinical Development Programs for Disease-Modifying Agents for Peripheral Neuropathy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a scientific public workshop to solicit information on a variety of issues related to the clinical development of disease-modifying agents for the treatment of peripheral neuropathy. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design. FDA intends to take this information into account in developing FDA guidance on clinical development programs for disease-modifying products for the management of peripheral neuropathy.

Date and Time: The public workshop will be held on February 11, 2013, from 8:30 a.m. to 5 p.m. and February 12, 2013, from 8:30 a.m. to 2 p.m.

Location: The public workshop will be held at FDA White Oak Campus, Building 31, The Great Room (Rm. 1503),White Oak Conference Center, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Entrance for the consultation meeting's participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*

Contacts:

Randi Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4287, *Randi.Clark@fda.hhs.gov,*

or

Allison Meyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1258, *Allison.Meyer@fda.hhs.gov.*

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: As part of the public workshop, an open public hearing will be held between 11 a.m. and 12 p.m. on February 11, 2013. If you wish to attend the public workshop or provide oral comments during the open public hearing, please email your registration to *CDER_Neuropathy_Workshop@fda.hhs.gov* by February 1, 2013. Those without email access may register by contacting one of the persons listed in the *Contacts* section of this document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing oral comments for the open public hearing, please also provide a short abstract of your remarks by February 1, 2013. We will try to accommodate all persons who wish to speak; however, the duration of each speaker's comments during this open public hearing may be limited by time constraints.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm310416.htm.*

If you need special accommodations because of a disability, please contact Randi Clark or Allison Meyer (see *Contacts*) at least 7 days in advance of the public workshop.

Comments: Submit either electronic or written comments by March 11, 2013. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing this public workshop to further the understanding of the development of disease-modifying agents for the treatment of painful peripheral neuropathies. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design.

FDA will explore the following topics during this public workshop:

1. Pharmacodynamic mechanisms and pharmacogenetic/pharmacogenomic targets of therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of disease for peripheral neuropathies.

2. Periperal neuropathy patient populations and study entry criteria for clinical trials designed to evaluate disease-modifying effects of therapeutic agents.

3. Clinically relevant endpoints for trials evaluating therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of these diseases.

4. Study duration, overall study design, and analysis of clinical trials needed to demonstrate a treatment effect on disease modification for peripheral neuropathy.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm310416.htm.*

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24037 Filed 9–28–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Single Source Program Expansion Supplement Award to Area Health Education Centers (AHEC) Program Grantee; Exception to Competition

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Exception to Competition—Single Source Program Expansion Supplement Award to Area Health Education Centers (AHEC) Program Grantee—University of Guam School of Nursing.

SUMMARY: The Health Resources and Services Administration (HRSA)'s Bureau of Health Professions is issuing a non-competitive single source program expansion supplement award to the University of Guam School of Nursing, an Area Health Education Center (AHEC) Program grantee, to coordinate the U.S. Affiliated Pacific Islands (USAPI) *Nursing Program Capacity Strengthening and Quality Improvement Initiative.* In fiscal year (FY) 2012, $203,703 will be available to fund this award. The Guam/Micronesia AHEC is uniquely qualified and has the capacity, capability, expertise, experience, and infrastructure to expeditiously, effectively, and efficiently implement the project within their existing educational programming. The University of Guam School of Nursing is the only nationally accredited baccalaureate nursing education program in the Pacific. Its focus is on health careers training and development, as well as improving the health careers pipeline in the region.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Guam/Micronesia AHEC—University of Guam School of Nursing.

Amount of Award: $203,703.

Authority: Section 751 of the Public Health Service Act (42 U.S.C. 294a), as amended by

Sec. 5403 of the Patient Protection and Affordable Care Act, Public Law 111–148.

CFDA Number: 93.824.

Project Period: September 1, 2012, through August 31, 2013.

Justification: The Guam/Micronesia AHEC—University of Guam School of Nursing is uniquely qualified to carry out the USAPI *Nursing Program Capacity Strengthening and Quality Improvement Initiative Project* because of their significant role in improving the public health capacity and infrastructure in the region.

The University of Guam School of Nursing is the only nationally accredited baccalaureate nursing education program in the Pacific. The Guam/Micronesia AHEC grantee is the University of Guam School of Nursing, whose focus is health career training and development, as well as improving the health careers pipeline in the region. The activities that will be carried out through this initiative will serve as building blocks in a more comprehensive strategic effort to strengthen nursing education, and, thus the nursing workforce in the USAPI jurisdictions. Funding this supplemental award in FY 2012 will enable the grantee to implement the activities identified in this initiative, targeted on nursing program director development, student assessment and preparation, program resource purchases, and faculty development.

FOR FURTHER INFORMATION CONTACT: Meseret Bezuneh, Project Officer, Health Resources and Services Administration, Division of Public Health and Interdisciplinary Education, 5600 Fishers Lane, Room 9C–05, Rockville, Maryland 20857, Phone: (301) 594–4149, Email: *mbezuneh@hrsa.gov.*

Dated: September 25, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–24102 Filed 9–28–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Single Source Program Expansion Supplement Award to Nurse Education, Practice, Quality and Retention (NEPQR) Program Grantee; Exception to Competition

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Exception to Competition—Single Source Program Expansion Supplement Award to Nurse Education, Practice, Quality and Retention (NEPQR) Program Grantee—Texas A&M University Corpus Christi (TAMUCC), College of Nursing and Health Science (CONHS).

SUMMARY: The Health Resources and Services Administration (HRSA)'s Bureau of Health Professions is issuing a non-competitive single source program expansion supplement award to the NEPQR Program grantee TAMUCC–CONHS to build upon their feasibility study, *Transitioning Enlisted Health Care Training into Academic Credit for Nursing Education Programs,* and undertake a dissemination program to advance the goal of aligning enlisted health care training with civilian nursing program requirements. In fiscal year (FY) 2012, $178,374 will be available to fund this award. TAMUCC–CONHS is uniquely qualified and has the capacity, capability, expertise, experience, and infrastructure to expeditiously, effectively, and efficiently implement the project within their existing educational programming. During the previous year, TAMUCC–CONHS has gained in-depth insight into the full range academic, financial, and socio-economic barriers that interfere with successful transition from military to civilian careers, and how these barriers are compounded by the burden of navigating the military-academic labyrinth. Thus they are well-positioned to bridge the gap between health care training command programs and academic programs in schools of nursing work.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Texas A&M University Corpus Christi