Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On May 5, 2010, Mr. Foyle pleaded guilty to a misdemeanor offense of introducing and delivering for introduction into interstate commerce a misbranded drug in violation of 21 U.S.C. 352(o), 331(a), and 333(a)(1). On July 7, 2011, the U.S. District Court for the District of Nevada entered judgment against Mr. Foyle for the misdemeanor offense of misbranding.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: On July 23, 2008, Agents from Customs and Border Protection found two express mail packages at JFK International Mail Facility, each with a return address of Muhi Trading Corporation, Bahadur Manzil. A border search was conducted on both packages, which revealed 1,000 capsules labeled as the prescription drug omeprazole in each package. The pills were in blister packs on which was written ''Omega Biotech LTD.'' Mr. Foyle and his co-defendant, David Freeman, were the importers of record for the packages. At all relevant times, neither Muhi Trading Corporation nor Omega Biotech LTD. were registered to manufacture, prepare, propagate, compound, or process drugs.

On January 20, 2009, an Agent with the Office of Criminal Investigations at FDA (OCI) conducted an undercover purchase of omeprazole through a Web site Mr. Foyle and Mr. Freeman used to sell their misbranded drugs. Mr. Foyle and Mr. Freeman repackaged omeprazole in their apartment and mailed it to the undercover Agent. Laboratory testing of the tablets confirmed that the tablets contained omeprazole. On February 24, 2009, OCI Agents searched Mr. Foyle and Mr. Freeman's residence and found unapproved drugs. The omeprazole pills that Mr. Foyle and Mr. Freeman imported, repackaged, and sold had not been approved by or registered with FDA. At no time was Mr. Foyle and Mr. Freeman's apartment registered as a location where drugs could be manufactured, prepared, propagated, compounded, or processed.

As a result of his convictions, on October 31, 2012, FDA sent Mr. Foyle a notice by certified mail proposing to debar him for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act that Mr. Foyle was convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act, and the conduct that served as the basis for Mr. Foyle's conviction undermines the process for the regulation of drugs because the introduction of misbranded drugs into interstate commerce is prohibited by the FD&C Act. The proposal also offered Mr. Foyle an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Foyle failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Ashley Brandon Foyle has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Foyle is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Foyle, in any capacity during Mr. Foyle's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act). If Mr. Foyle provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Foyle during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Foyle for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0867 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–10313 Filed 4–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Administrative Supplement to West End Medical Center, Inc. for provision of services in Gwinnett County, Georgia.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive award of $250,000 under the Health Center Program (section 330 of the Public

Health Service Act.) that will be awarded to West End Medical Center, Inc. (WEMC), Atlanta, Georgia, during the budget period June 1, 2012, through May 31, 2013. This award will support the delivery of primary care services in Gwinnett County, Georgia, to prevent a disruption in services.

SUPPLEMENTARY INFORMATION:

Original Period of Grant Support: June 1, 2012, to May 31, 2013 (Budget Period).

Amount of Supplemental Award: $250,000.

Period of Supplemental Funding: June 1, 2012, to May 31, 2013.

Authority: Section 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.224.

Justification for the Exception to Competition: The former grantee, Gwinnett County Board of Health (GCBH), relinquished the grant and its responsibilities. WEMC has been a HRSA funded Health Center grantee since 2002 and is a well-established organization with sound fiscal and grants management operations.

As a means of providing continued services in the Gwinnett County service area (formerly served by the GCBH), WEMC has arranged for the provision of services via an agreement with an existing health care provider in this area until the competitive award is announced.

FOR FURTHER INFORMATION CONTACT: Darrin Bowden via phone at (301) 594–4420 or via email at *dbowden@hrsa.gov.*

Dated: April 25, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–10294 Filed 4–30–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

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

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide a one-time noncompetitive Ryan White HIV/AIDS Program Part C funds award to the Bartz-Altadonna Community Health Center (BACHC), Lancaster, California.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is $402,187.

Authority: Section 2651 of the Public Health Service (PHS) Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Project period: The period of support for this award is 15 months, explained below in further detail.

Justification for the Exception to Competition: The Catalyst Foundation, Lancaster, California (Grant Number: H76HA00784) announced the relinquishment of their Part C grant on February 14, 2013. To prevent a lapse in HIV medical care, grant funds of $402,187 are to be awarded to BACHC to provide interim HIV medical care. BACHC is a Federally Qualified Health Center under section 330 of the PHS Act (H80CS22686), and the sub-grantee to Catalyst that is already providing the clinical care for the Ryan White HIV/AIDS Program Part C clients. The Catalyst Foundation has identified BACHC as a successor for the Part C grant. The $402,187 represents a proportional share of the last award to the Catalyst Foundation to cover 15 months of HIV primary medical care services until the service area is competed by July 1, 2014.

FOR FURTHER INFORMATION CONTACT: John Fanning, Public Health Analyst, Division of Community Based Programs, HIV/AIDS Bureau, Health Resources and Services Administration, by email at *jfanning@hrsa.gov,* or by phone at (301) 443–0493.

Dated: April 25, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–10304 Filed 4–30–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as Amended (5 U.S.C. App.), Notice is Hereby Given of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: June 13, 2013.

Open: 8:30 a.m. to 2:00 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health, 45 Center Drive, Bethesda, MD 20892.

Closed: 2:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Lore Anne McNicol, Ph.D., Director, Division of Extramural Research, National Eye Institute, National Institutes of Health, 301–451–2020, *lam@nei.nih.gov.*

Any person interested may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov*, where an agenda and any additional information will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 25, 2013

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10201 Filed 4–30–13; 8:45 am]

BILLING CODE 4140–01–P