Resettlement, 901 D Street SW., Washington, DC 20447, Telephone (202) 401–4997. Email: *jallyn.sualog@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: Since the beginning of FY 2013, the Unaccompanied Alien Children (UAC) program has seen a dramatic increase in the number of DHS referrals. The influx of border crossers referred by DHS has grown beyond anticipated rates resulting in the need for a significant increase in the number of shelter beds and supportive services for the children.

The UAC program has specific requirements for the provision of services to unaccompanied alien children. The named organizations were chosen for the noncompetitive awards because they already have the infrastructure, licensing, and appropriate levels of trained staff to meet service requirements and the urgent need for expanded services in order to respond to the increased numbers of unaccompanied children. The immediate provision of services will alleviate the buildup of children held in border patrol stations while awaiting placement in shelter care.

Statutory Authority: Section 462 of the Homeland Security Act, (6 U.S.C. 279) and sections 235(c) and 235(d) of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, (8 U.S.C. 1232(c) and 1232(d)).

Eskinder Negash,

Director, Office of Refugee Resettlement.

[FR Doc. 2013–10311 Filed 4–30–13; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Inspection by Accredited Persons Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On January 31, 2013, the Agency submitted a proposed collection of information entitled ''Medical Devices; Inspection by Accredited Persons Program'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0510. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10248 Filed 4–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance: Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Emergency Use Authorization of Medical Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On January 8, 2013, the Agency submitted a proposed collection of information entitled ''Emergency Use Authorization of Medical Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0595. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10247 Filed 4–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0867]

Ashley Brandon Foyle: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Ashley Brandon Foyle for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Foyle was convicted of introducing and delivering for introduction into interstate commerce a misbranded drug, which relates 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. In addition, FDA determined that the type of conduct that served as the basis for Mr. Foyle's conviction undermines the process for the regulation of drugs. Mr. Foyle was given notice of the proposed debarment and an opportunity to request a hearing within the prescribed timeframe by regulation but failed to respond. Mr. Foyle's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective May 1, 2013.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory

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