

At no time did Ms. Delong or anyone else employed by PGL register their MMS manufacturing facilities with FDA as required under section 510 of the FD&C Act (21 U.S.C. 360). In addition, bottled MMS that PGL shipped to consumers did not bear labeling that bore the full place of business of the manufacturer.

On or about November 1, 2010, November 12, 2010, November 16, 2010, and June 30, 2011, Ms. Delong or another person involved with PGL, delivered for introduction into interstate commerce a number of packages containing bottled MMS. These packages contained MMS that Ms. Delong knew was primarily intended as a treatment for disease.

As a result of these convictions, FDA sent Ms. Delong by certified mail on October 12, 2016, a notice proposing to debar her for 12 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 Ms. Delong was convicted of misdemeanors under Federal law for conduct 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.

The proposal offered Ms. Delong an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Delong received the proposal on October 20, 2016. Ms. Delong did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her 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 the Director (Staff Manual Guide 1410.35), finds that Karis Copper Delong has been convicted of four misdemeanor counts under federal law for conduct 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.

Based on consideration of the factors under section 306(c)(3) of the FD&C Act,

FDA finds that each offense be accorded a debarment period of 3 years. Under section 306(c)(2)(A) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 3-year period of debarment for each of the four offenses of conviction need to be served consecutively, resulting in a total debarment period of 12 years.

As a result of the foregoing finding, Karis Copper Delong is debarred for a period of 12 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)(3), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(3), 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 Karis Copper Delong, in any capacity during Ms. Delong's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Delong provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she 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 Karis Copper Delong during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Ms. Delong for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-1677 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 will be placed in the docket, and will be viewable at <https://www.regulations.gov> or at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2017.

**Armando Zamora,**

*Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.*

[FR Doc. 2017-03172 Filed 2-16-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Advisory Committee on Minority Health

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Minority Health.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meetings and/or participate in the public comment session should email [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov).

**DATES:** The meeting will be held on Thursday, March 23, 2017, from 9:00 a.m. to 5:00 p.m. and Friday, March 24, 2017, from 9:00 a.m. to 1:00 p.m.

**ADDRESSES:** The meeting will be held at the 5600 Fishers Lane Building, Room 05N76, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Dr. Minh Wendt, Designated Federal Officer, ACMH; Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-8222, Fax: 240-453-8223; [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health in improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the Office of Minority Health.

Topics to be discussed during this meeting will include strategies to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities, as well as other related issues.

Public attendance at this meeting is 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 designated contact person at least fourteen (14) business days prior to the meeting. Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to three minutes per speaker. Individuals who would like to submit written statements should mail or fax their comments to the Office of Minority Health at least seven (7) business days prior to the meeting. Any members of the public who wish to have printed material distributed to ACMH committee members should submit their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on Thursday, March 16, 2017.

Dated: February 14, 2017.

**Minh Wendt,**

*Designated Federal Officer, ACMH, Office of Minority Health, U.S. Department of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Presidential Advisory Council on HIV/AIDS

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding a meeting to continue discussions and possibly develop recommendations regarding People Living with HIV/AIDS. The meeting will be open to the public.

**DATES:** The Council meeting is scheduled to be held on March 13, 2017, from 9:00 a.m. to approximately 5:00 p.m. (ET) and March 14, 2017, from 9:00 a.m. to approximately 12:00 p.m. (ET). The meeting will be open to the public.

**ADDRESSES:** 330 Independence Avenue SW., Washington, DC 20201 in the Snow Room (Conference Room 5051).

**FOR FURTHER INFORMATION CONTACT:** Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/

AIDS, 330 C Street SW., Room L106B, Washington, DC 20024; (202) 795-7622 or *Caroline.Talev@hhs.gov*. More detailed information about PACHA can be obtained by accessing the Council's page on the *AIDS.gov* Web site at *www.aids.gov/pacha*.

**SUPPLEMENTARY INFORMATION:** PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. In a memorandum, dated July 13, 2010, and under Executive Order 13703, dated July 30, 2015, the President gave certain authorities to the PACHA for implementation of the National HIV/AIDS Strategy for the United States (Strategy). PACHA is currently operating under the authority given in Executive Order 13708, dated September 30, 2015.

PACHA provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention, and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed, to promote effective HIV prevention and treatment and quality services to persons living with HIV disease and AIDS.

Substantial progress has been made in addressing the domestic HIV epidemic since the Strategy was released in July 2010. Under Executive Order 13703, the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) was released. PACHA shall contribute to the federal effort to improve HIV prevention and care.

The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda for the upcoming meeting will be posted on the *AIDS.gov* Web site at *www.aids.gov/pacha*.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at *Caroline.Talev@hhs.gov*. Due to space constraints, pre-registration for

public attendance is advisable and can be accomplished by contacting Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on Monday, March 6, 2017. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to two minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on Monday, March 6, 2017; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Public comment will be limited to two minutes per speaker. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business on Monday, March 6, 2017.

Dated: February 9, 2017.

**B. Kaye Hayes,**

*Executive Director, Presidential Advisory Council on HIV/AIDS.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; Notice of Closed 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 following 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 Center for Advancing Translational Sciences Special Emphasis Panel Review of RFA-TR-16-021: Coordination Center for the CTSA Program (U24).

*Date:* March 14, 2017.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.