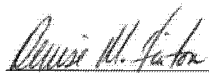


Page 2 – Mr. Gee, Siemens Healthcare Diagnostics Inc.

FDA does not have concerns with the use of any remaining inventory of the ADVIA Centaur Zika test that was distributed prior to revocation of the EUA, when such product is used in conjunction with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. FDA encourages the relabeling of any product already manufactured, but not distributed prior to the revocation of the EUA, with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. Importantly, the ADVIA Centaur Zika test product for which FDA had issued an EUA and the device cleared under K191578 are manufactured under the same quality system. Siemens should instruct customers who have remaining ADVIA Centaur Zika test EUA product inventory to either use their EUA product in combination with the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578, or to work with Siemens to replace the EUA product with the device cleared under K191578. FDA encourages Siemens to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,



RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-19982 Filed 9-13-19; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

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

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a telephone conference call. This call will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to participate in the call should email OMH-ACMH@hhs.gov by September 25, 2019. Information about the meeting is available from the designated contact person noted below and will be posted on the website for the Office of Minority

Health (OMH):

www.minorityhealth.hhs.gov.

Information about ACMH activities can be found on the OMH website under the heading *About OMH*.

DATES: The conference call will be held on Friday, September 27, 1:00 p.m. to 3:00 p.m. ET.

ADDRESSES: Instructions regarding participating in the conference call will be given at the time of preregistration.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-8222; fax: 240-453-8223; email 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 on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The topics to be discussed during this meeting will include strategies to address HIV-related health disparities

among racial and ethnic minority populations. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform OMH and the Office of Infectious Disease and HIV/AIDS Policy of efforts related to the federal *Ending the HIV Epidemic Initiative*. This call will be limited to 125 participants. Individuals who plan to participate and need special assistance, should contact BLH Technologies, Inc. at (240) 399-8735 and reference this conference call meeting at least five (5) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email OMH-ACMH@hhs.gov or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, for receipt prior to close of business on Friday, September 20, 2019.

Dated: September 11, 2019.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2019-19933 Filed 9-13-19; 8:45 am]

BILLING CODE 4150-29-P