still be subject to the general limitations on exemptions.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Stryker, 3800 East Centre Ave., Portage, MI 49002, for powered wheeled stretcher, classified under 21 CFR 890.3690. With this notice FDA is seeking comments on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19978 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3839]

Impax Laboratories, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Ursodiol Capsules USP, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of abbreviated new drug application (ANDA) 077895 for Ursodiol Capsules USP, 300 milligrams (mg), held by Impax Laboratories, LLC (Impax). Impax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: On July 27, 2006, FDA approved ANDA 077895 for Ursodiol Capsules USP, 300 mg, submitted by CorePharma, LLC (CorePharma). According to annual reports filed with the Agency, this product has not been commercially manufactured since February 2010.

In a letter dated August 9, 2011, FDA informed CorePharma that it had concerns about the validity of bioequivalence data submitted with ANDA 077895 from studies conducted by a certain contract research organization intended to establish bioequivalence of CorePharma's product to its reference listed drug (RLD), new drug application 019594, Actigall (Ursodiol) Capsules, 300 mg. In that letter, FDA directed CorePharma to supplement its ANDA with either: (1) New bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. In a letter dated January 26, 2012, CorePharma submitted a request for an extension of time to submit new bioequivalence data in response to the Agency's August 9, 2011, letter. On February 10, 2012, the Agency granted CorePharma's request for an extension to submit new bioequivalence data by October 30, 2012.

FDA subsequently sent another letter to CorePharma on August 19, 2016, requesting that CorePharma provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) (21 CFR 314.150(d)). In response to the August 19, 2016, correspondence, FDA received a letter from CorePharma dated September 7, 2016, stating that CorePharma did not wish to request the withdrawal of approval of ANDA 077895 for Ursodiol Capsules. In February 2017, the Agency was notified that the ownership of ANDA 077895 was transferred from CorePharma to Impax.

On April 24, 2017, FDA issued a letter to Impax, noting that as of the date of the April 24, 2017, letter, FDA had not received the requested bioequivalence data. In the April 24, 2017, correspondence, FDA strongly suggested to Impax that it voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) as a result of failing to provide data and information establishing bioequivalence to the RLD. In a letter dated February 25, 2019, Impax informed FDA that it would like to request the withdrawal of ANDA 077895 under § 314.150(d). Additionally, in a March 14, 2019, correspondence to FDA, Impax waived any opportunity for hearing provided under § 314.150(a).

In the **Federal Register** of February 5, 2019 (84 FR 1745), FDA erroneously included ANDA 077895 in a list of drug applications for which approval was being withdrawn under § 314.150(c). Elsewhere in this issue of the **Federal Register** FDA is publishing a correction to that notice to remove ANDA 077895 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and because of Impax's request, FDA is withdrawing approval of ANDA 077895, and all amendments and supplements thereto, under § 314.150(d). Distribution of Ursodiol Capsules USP, 300 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19908 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Siemens Healthcare Diagnostics, Inc. (Siemens), for the ADVIA Centaur Zika test. FDA revoked this Authorization on July 17, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), in consideration of the premarket notification submission submitted to FDA by Siemens for the ADVIA Centaur Zika test that was determined to be substantially equivalent to a legally marketed class II predicate device on July 17, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of July 17, 2019.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On September 18, 2017, FDA issued an EUA to Siemens, for the ADVIA Centaur Zika test, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on November 17, 2017 (82 FR 54361), as required by section 564(h)(1) of the FD&C Act. In response to requests from Siemens, the EUA was amended on November 16, 2017, and April 18, 2019. Subsequently, on May 23, 2019, FDA classified a de novo application for a generic Zika virus serological reagents device as Class II (special controls) under product code QFO (*https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf*). Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met.

II. EUA Criteria for Issuance No Longer Met

On July 17, 2019, FDA revoked the EUA for Siemens' ADVIA Centaur Zika test because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. FDA has determined that the criteria for issuance of such authorization under section 564(c)(3) of the FD&C Act are no longer met because Siemens' ADVIA Centaur Zika test was determined on July 17, 2019, to be substantially equivalent to a legally marketed class II predicate device with the generic name ''Zika virus serological reagents'' (*https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191578.pdf*). As such, FDA concluded that there is an adequate, approved, and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the FD&C Act and accordingly revoked the Authorization pursuant to section 564(g)(2)(B) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at *https://www.regulations.gov/*.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Siemens' ADVIA Centaur Zika test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

July 17, 2019

Matthew Gee, M.Sc.
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591

Dear Mr. Gee:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA170005) for emergency use of Siemens Healthcare Diagnostics Inc.'s ("Siemens") ADVIA Centaur Zika test, issued on September 18, 2017, and amended on November 16, 2017, and April 18, 2019.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. Siemens submitted a premarket submission to FDA for the ADVIA Centaur Zika test (K191578) that was determined to be substantially equivalent to a legally marketed Class II predicate device, classified under 21 CFR 866.3935, with the generic name "Zika virus serological reagents," on July 17, 2019. FDA has concluded "that this is an adequate, approved[1], and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the Act."

Accordingly, FDA revokes EUA170005 for emergency use of the ADVIA Centaur Zika test, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the ADVIA Centaur Zika test that was authorized by FDA for emergency use under EUA170005 is no longer authorized by FDA.

[1] In the context of section 564 of the Act, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

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