- Section 485.705(c)(2) through (c)(6), to ensure AAAASF's standards appropriately reference the CMS standards;
- Section 485.719(b)(3), to ensure AAAASF's standards appropriately reference the statutory requirements;
- Section 488.5(a)(4)(ii), to ensure that an appropriate number of medical records are fully reviewed during the survey process and that survey record totals are accurately reflected in the overall deficiency statement;
- Section 488.5(a)(4)(iv), to ensure all deficiencies found on survey are cited in AAAASF's final survey report;
- Section 488.5(a)(4)(vii), to ensure appropriate monitoring of non-compliance correction;
- Section 488.5(a)(11)(ii), to ensure accurate survey findings are reported to CMS;
- Section 488.5(a)(13)(ii), to ensure AAAASF notifies CMS regarding any decision to revoke, withdraw, or revise the accreditation status of a deemed status supplier;
- Section 488.26(b) and (c), to ensure deficiencies are cited at the appropriate level based on manner and degree of findings;
- Section 488.28(a), to ensure AAAASF's policies for an acceptable plan of correction meet the CMS requirements;
- Section 488.28(d), to ensure that AAAASF's policies for correction of deficiencies in OPTs is comparable to CMS requirements, requiring that deficiencies normally must be corrected within 60 days; and
- Section 489.13(b)(1), to ensure all enrollment requirements are met prior to AAAASF surveying an initial applicant.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAASF as a national accreditation organization for OPTs that request participation in the Medicare program, effective April 4, 2019 through April 4, 2025.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: March 15, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–06149 Filed 3–29–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. On July 13, 2018, FDA determined that TPOXX (tecovirimat), manufactured by SIGA Technologies, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8510.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act, FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA has determined that TPOXX (tecovirimat), manufactured by SIGA Technologies, Inc., meets the criteria for a priority review voucher. TPOXX (tecovirimat) is indicated to treat human smallpox disease in adults and pediatric patients weighing at least 13 kilograms.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm#prv.* For further information about TPOXX (tecovirimat), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06145 Filed 3–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0598]

Teva Women's Health, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 1, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.