- 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.

Application No.	Drug	Applicant
NDA 007883	Antabuse (disulfiram) Tablets, 250 milligrams (mg) and 500 mg.	Teva Women's Health, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.
NDA 011324	Sinografin (diatrizoate meglumine and iodipadmide meglumine) Injection, 52.7%/26.8%.	Bracco Diagnostic Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831.
NDA 018932	ReVia (naltrexone hydrochloride) Tablets, 50 mg	Teva Women's Health, Inc.
NDA 019880	Paraplatin (carboplatin) Injection, 50 mg/vial, 150 mg/vial, and 450 mg/vial.	Corden Pharma Latina S.p.A., c/o Clinipace, Inc., 4840 Pearl East Circle, Suite 201E, Boulder, CO 80301.
NDA 020261	Lescol (fluvastatin sodium) Capsules, 20 mg and 40 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936–1080.
NDA 020452	Paraplatin (carboplatin) Injection in multiple dose vials, 50 mg/5 milliliters (mL), 150 mg/15 mL, 450 mg/45 mL, and 600 mg/60 mL.	Corden Pharma Latina S.p.A.
NDA 021431	Campral (acamprosate calcium) Delayed-Release Tablets, 333 mg.	Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940.
NDA 021551	Halflytely and Bisacodyl Tablet Bowel Prep Kit (polyethylene glycol 3350, potassium chloride, sodium bicarbonate, and sodium chloride powder for oral solution, 210 grams (g)/0.74 g/2.86 g/5.6 g; bisacodyl delayed-release tablet, 5 mg).	Braintree Laboratories, Inc., 60 Columbian St. West, P.O. Box 850929, Braintree, MA 02185.
NDA 021823	Actonel with Calcium (risedronate sodium tablets, 35 mg; calcium carbonate tablets USP, equivalent to 500 mg base).	Warner Chilcott Co., LLC., 100 Enterprise Dr., Rockaway, NJ 07866.
NDA 021905	Valtropine (somatropin) for Injection, 5 mg/vial	LG Chem, Ltd., c/o Parexel International, LLC., 4600 East-West Highway, Suite 350, Bethesda, MD 20814.
NDA 022396	Dyloject (diclofenac sodium) Injection, 37.5 mg/mL	Javelin Pharmaceuticals, Inc., c/o Hospira, Inc., 275 North Field Dr., Dept. 0389, HI–3S, Lake Forest, IL 60045.
NDA 050619	Mycostatin (nystatin) Pastilles, 200,000 Units	Delcor Asset Corp., c/o Mylan, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504–4310.
NDA 050739	Omnicef (cefdinir) Capsules, 300 mg	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 050749	Omnicef (cefdinir) Oral Suspension, 125 mg/5 mL and 250 mg/5 mL.	Do.
NDA 050757	PrevPAC (amoxicillin capsules USP, 500 mg; clarithromycin tablets USP, 500 mg; and lansoprazole delayed-release capsules, 30 mg).	Takeda Pharmaceuticals U.S.A., Inc., One Takeda Parkway, Deerfield, IL 60015.
NDA 202356	Docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL, 130 mg/13 mL, and 200 mg/20 mL.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 1, 2019. The drug product strengths listed in the table include all strengths FDA has identified as being previously approved under these NDAs. In each case, approval of the entire application is withdrawn, including any strengths inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 1, 2019 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06237 Filed 3–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Interdiciplinary, Community-Based Linkages

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Interdiciplinary, Community-Based Linkages (ACICBL or the Committee) has been rechartered. The effective date of the renewed charter is March 24, 2019.

FOR FURTHER INFORMATION CONTACT: Joan Weis, Ph.D., RN, CRNP, FAAN, Designated Federal Official, at 301–443–0430 or email at *jweiss@hrsa.gov.* A copy of the current committee membership, charter, and reports can be obtained at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html.*

SUPPLEMENTARY INFORMATION: ACICBL provides advice and recommendations on policy and program development to the Secretary of HHS (Secretary) concerning the activities under Title VII, Part D of the Public Health Service Act, and is responsible for submitting an annual report to the Secretary and Congress describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under Part D of Title VII. ACICBL develops, publishes, and implements performance measures and guidelines for longitudinal evaluations and recommends appropriation levels for programs under this part. The charter renewal for the ACICBL was approved on March 15, 2019 and the filing date is March 24, 2019. Renewal of the ACICBL charter gives authorization for the Committee to operate until March 24, 2021.

A copy of the ACICBL charter is available on the committee website at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html.* A copy of the charter can also be obtained by