occur again. Yet, again, McCoy has not provided any specific allegations or evidence to challenge ORA's determination that this consideration does not apply to him. FDA need only address the considerations in section 306(c)(3) of the FD&C Act ''where applicable.'' The considerations in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. The consideration at issue does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming *arguendo* that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, McCoy's unsubstantiated contention that there are disputed issues of fact with respect to that consideration fails to create a genuine and substantial issue of fact that warrants a hearing.

Based on the factual findings in the proposal to debar and on the record, OSI finds that a 4-year debarment is appropriate. Although McCoy has no previous criminal convictions related to matters within the jurisdiction of FDA, this sole positive factor does not counterbalance the nature and seriousness of his offense and lack of voluntary steps taken to mitigate the effect on the public. As noted in the proposal to debar, McCoy's actions occurred on a repeated basis, and ''[his] conduct created a risk of injury to [his] patients . . ., undermined the Agency's oversight of an approved drug product, and seriously undermined the integrity of the Agency's regulation of drug products.''

III. Findings and Order

Therefore, the Director of OSI, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds that: (1) McCoy has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) the conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 4 years is appropriate.

As a result of the foregoing findings, McCoy is debarred for 4 years from providing services in any capacity to a person with an approved or pending drug product application under section 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**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of McCoy, in any capacity during his period of 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 McCoy, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he 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 McCoy during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: September 25, 2018.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2018–21211 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3424]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on November 8, 2018, from 11 a.m. to 2:45 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/vrbpac1118/*.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 8, 2018, the Center for Biologics Evaluation and Research's (CBER) VRBPAC committee will meet in open session to hear an overview of the research program in the Laboratory of DNA Viruses (LDV), Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR), CBER, FDA. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On November 8, 2018, from 11 a.m. to 1:50 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact

person on or before November 1, 2018. Oral presentations from the public will be scheduled between approximately 12:45 p.m. to 1:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 24, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 25, 2018.

Closed Committee Deliberations: On November 8, 2018, from 1:50 p.m. to 2:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists.

We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21137 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3569]

GlaxoSmithKline, LLC, et al.; Withdrawal of Approval of 24 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 24 abbreviated new drug applications (ANDAs) 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 October 29, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

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 described 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
ANDA 061336	Bactocill (oxacillin sodium) Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base.	GlaxoSmithKline, LLC, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
ANDA 061773	Kefzol (cefazolin) for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 10 g base/vial, and EQ 20 g base/vial.	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Rte. 17 North, Paramus, NJ 07652.
ANDA 062615	Nystatin Vaginal Inserts USP, 100,000 units	Odyssey Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 063304	Clindamycin Phosphate Topical Solution USP, EQ 1% base	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 065001	Cefuroxime for Injection USP, EQ 750mg base/vial and EQ 1.5 g base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065002	Cefuroxime for Injection USP, EQ 7.5 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 070736	Ibuprofen Tablets USP, 300 mg, 400 mg, and 600 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 071202	Sensorcaine—MPF Spinal (bupivacaine hydrochloride (HCl)) in Dextrose Injection 8.25% USP, 0.75%.	Fresenius Kabi USA, LLC.
ANDA 071846	Nitroglycerin in Dextrose 5% Injection, 10 mg/100 milliliter (mL).	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 071847	Nitroglycerin in Dextrose 5% Injection, 20 mg/100 mL	Do.
ANDA 071848	Nitroglycerin in Dextrose 5% Injection, 40 mg/100 mL	Do.
ANDA 072629	Albuterol Tablets USP, EQ 2 mg base	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074991	Loperamide HCl Oral Solution, 1 mg/5 mL	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.