whether a 510(k) is appropriate for review as a Special 510(k). In general, a change to an existing device may be appropriate for a Special 510(k) when: (1) The proposed change is made and submitted by the manufacturer authorized to market the existing device; (2) performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change; and (3) all performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format.

When finalized, this guidance will supersede the Special 510(k) policy in the 1998 guidance entitled ''The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.''

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''The Special 510(k) Program.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''The Special 510(k) Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18008 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21141 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–2011–N–0613]

John D. McCoy; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by John D. McCoy (McCoy) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring McCoy for 4 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that McCoy was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of McCoy's debarment, FDA has considered the relevant factors listed in the FD&C Act. McCoy has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable September 28, 2018.

ADDRESSES: Any application for termination of debarment by McCoy under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2011–N–0613. An application will be placed in the docket and, unless submitted as

''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that: (1) The individual 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 type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On April 20, 2009, in the U.S. District Court for the District of Arizona, McCoy pled guilty to a misdemeanor, namely adulterating a drug while held for sale after shipment in interstate commerce in violation of sections 301(k), 303(a)(1), and 501(d) of the FD&C Act (21 U.S.C. 331(k), 333(a)(1) and 351(d)). The conduct underlying the conviction involved the adulteration of BOTOX®/BOTOX® Cosmetic (BOTOX®). BOTOX® is a biological product derived from Botulinum Toxin Type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans. Toxin Research International was an Arizona corporation that marketed and sold TRI-Toxin, a Botulinum Toxin Type A product that was neither approved nor licensed by FDA. According to the records of the criminal proceedings, McCoy, while a physician at Skinovative Laser Center, mixed FDA-approved BOTOX® with TRI-toxin, while the BOTOX® was held for sale after shipment in interstate commerce, such that the BOTOX® was adulterated under section 501(d) of the FD&C Act.

By letter dated October 24, 2011, FDA's Office of Regulatory Affairs (ORA) notified McCoy of its proposal to debar him for 4 years from providing services in any capacity to a person having an approved or pending drug product application. The proposal outlined findings concerning three relevant factors ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act. ORA found that the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public were unfavorable factors for McCoy. The absence of prior convictions involving matters within FDA's jurisdiction was a favorable factor. ORA concluded, ''Weighing all the factors, particularly the nature and seriousness of the conduct underlying your conviction, the Agency has determined that the unfavorable factors outweigh the favorable factors, and therefore warrant the imposition of a four year permissible debarment in this case.''

In a letter dated November 23, 2011, through counsel, McCoy requested a hearing on the proposal. In his hearing request, McCoy argues that there are disputed issues of material fact that FDA must consider, under section 306(c)(3) of the FD&C Act, in determining the appropriateness and period of debarment. McCoy also indicated that additional information justifying the hearing would be forthcoming. More than 60 days have passed from the date McCoy received ORA's letter, and McCoy has not filed any additional information.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered McCoy's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see § 12.24(b) (21 CFR 12.24(b))).

OSI has considered McCoy's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In his hearing request, McCoy first contends that there are disputed issues of material fact with respect to whether he voluntarily acted to mitigate the impact of his offense on the public (see section 306(c)(3)(C) of the FD&C Act). ORA found no evidence that McCoy took any voluntary steps to mitigate the impact on the public. McCoy has not provided any specific allegations or evidence supporting his general assertion that the facts underlying ORA's findings are in dispute. Although McCoy indicated that he would submit additional information supporting his hearing request, he has not done so. Under § 12.24(b)(2), a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions. McCoy's bare assertion 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. Upon similar reasoning, McCoy's claim that the disputed issues of fact are not limited to those raised in his hearing request also falls far short of justifying a hearing.

Finally, McCoy contends that there are disputed issues of material fact with respect to whether, under section 306(c)(3)(D) of the FD&C Act, the extent to which changes in ownership, management, or operations has corrected the causes of any offense involved and provide reasonable assurances that the offense will not

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