II. Arguments

Fleming submitted multiple documents in support of his arguments that his guilty plea ''does not state a crime'' and that he is ''actually innocent.'' However, section 306(l) of the FD&C Act defines conviction as when a Federal or State court's judgment of conviction or when a Federal or State court's acceptance of a guilty plea. In Fleming's ''Petition to Enter a Plea of Guilty,'' he stated that he understood the charges against him and that he was voluntarily entering his guilty plea. The court entered a judgment of conviction after accepting Fleming's guilty plea. Federal court is the proper venue for any challenge to Fleming's guilty plea based on a claim of actual innocence, not this remedial proceeding. OSI carefully reviewed Fleming's submission in its entirety, and Fleming does not dispute that the court entered a judgment of conviction or that the court accepted his guilty plea; therefore, Fleming's arguments regarding his actual innocence fail to raise a genuine and substantial issue of fact warranting a hearing.

Under section 306(b)(2)(B)(ii)(I) of the FD&C Act, FDA has the authority to debar an individual convicted of certain Federal felonies, involving, among other things, fraud, if FDA finds that the individual has demonstrated a pattern of conduct giving reason to believe that he may violate requirements under the FD&C Act relating to drug products. The relevant factual issues are whether Fleming was, in fact, convicted of a felony involving fraud and whether there is reason to believe that he may violate requirements under the FD&C Act relating to drug products. Fleming does not dispute that he pled guilty to felony healthcare fraud and felony mail fraud or that, based on these convictions, there is reason to believe that he may violate requirements under the FD&C Act relating to drug products. Therefore, Fleming has failed to raise a genuine and substantial issue of fact warranting a hearing regarding whether he is subject to debarment.

Fleming's response included one argument that may be construed to be a challenge to ORA's proposed findings on the nature and seriousness of his offense. Fleming appears to claim that the imaging studies he performed on his patients were safer than the imaging studies he billed to Medicare and Medicaid. In the proposal to debar, in evaluating the nature and seriousness of the offenses, ORA noted that Fleming was convicted of two felonies, healthcare fraud and mail fraud. ORA considered that he billed Medicare and Medicaid for procedures other than those that he had performed, that he falsified clinical trial data, and that his actions ''have the potential for causing significant loss of public confidence in the healthcare system.'' Fleming's actions took place over a period of several months and demonstrated multiple instances of fraud. While Fleming contends that he performed safer imaging studies than those billed, FDA must weigh this claim against the serious nature of the fraud he committed. Construing Fleming's argument in a light most favorable to him, whether he performed safer imaging studies does not sufficiently counter the very serious nature of fraudulent conduct and is not enough to establish that a shorter debarment period would be appropriate.

Based on the factual findings in the proposal to debar and on the record, OSI finds that a 5-year debarment period for each felony offense is appropriate. The nature and seriousness of Fleming's offense, Fleming's managerial participation, and his lack of voluntary steps to mitigate the impact on the public weigh in favor of debarment. Although Fleming does not appear to have prior criminal convictions involving matters within FDA's jurisdiction, a debarment period of 5 years for each felony conviction is appropriate. As noted in the proposal to debar, the conduct underlying the offenses involved submitting claims for payment for procedures other than the procedures Fleming performed and falsifying clinical trial data, and ''[t]he conduct that form[ed] the basis of [his] conviction occurred in the course of [his] profession and showed disregard for the obligations of [his] profession and the law.'' Based on the pattern of fraudulent conduct, FDA has reason to believe that Fleming may violate the requirements under the FD&C Act relating to drug products. Furthermore, given that Fleming has offered no arguments challenging the proposed determination regarding the extent to which his debarment periods should run concurrently or consecutively, OSI further determines that the 5-year debarment period for each felony conviction should run consecutively, resulting in a total debarment of 10 years.

III. Findings and Order

Therefore, the Director of OSI, under section 306(b)(2)(B)(i)(I) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that: (1) Fleming has been convicted of a felony which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense and (2) based on the conviction and other information, Fleming has demonstrated a pattern of conduct giving reason to believe that he may violate requirements under the FD&C Act relating to drug products. FDA considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 10 years is appropriate.

As a result of the foregoing findings, Fleming is debarred for 10 years from providing services in any capacity to a person with an approved or pending drug product application under sections 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**) (see 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 Fleming, 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 Fleming, 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 Fleming 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. 2018–21210 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–D–3304]

The Special 510(k) Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft

guidance entitled ''The Special 510(k) Program.'' FDA established the Special 510(k) Program to facilitate the submission, review, and clearance of changes to a manufacturer's own legally marketed predicate device. This draft guidance, when finalized, will provide the framework that FDA will use when considering whether a premarket notification (510(k)) is appropriate for review as a Special 510(k). This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 27, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–3304 for ''The Special 510(k) Program.'' Received comments will be placed in the docket and, except for those 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''The Special 510(k) Program'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; Angela DeMarco, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–4471; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On March 20, 1998, FDA issued the guidance document entitled ''The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' which established the Special 510(k) Program. By establishing the Special 510(k) Program, FDA sought to streamline review of 510(k) submissions by leveraging design control requirements. The Special 510(k) Program allows manufacturers who are intending to change their own legally marketed device to utilize risk analysis and verification and validation activities to facilitate submission, review, and clearance of the change. While FDA intends to review Special 510(k)s within 30 days, the Special 510(k) Program does not alter any statutory or regulatory requirements related to the premarket notification process under sections 510 and 513 of the FD&C Act (21 U.S.C. 360 and 360c) and 21 CFR part 807, subpart E.

To improve the efficiency of 510(k) review, FDA believes that an update to the Special 510(k) Program both clarifies existing policy and expands on device changes appropriate for the Program. This draft guidance, when finalized, will explain the updated factors FDA intends to use when considering

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