4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0333]

Richard M. Fleming; Denial of Hearing on Application for Termination of Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying Dr. Richard M. Fleming's (Dr. Fleming's) request for a hearing and denying his application for termination of debarment under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Dr. Fleming has failed to file information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may be submit comments 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

- 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-2013-N-0333 for "Richard M. Fleming; Denial of Hearing on Application for Termination of Debarment." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500. 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

On April 24, 2009, Dr. Fleming, the president of, and sole physician at, Fleming Heart and Health Institute, P.C. (FHHI), pled guilty to one felony count of healthcare fraud, in violation of 18 U.S.C. 1347 and 2, and one felony count of mail fraud, in violation of 18 U.S.C. 1341 and 2. On August 20, 2009, the U.S. District Court for the District of Nebraska entered a judgment of conviction against Dr. Fleming on these counts and sentenced Dr. Fleming to 5 years of probation. In pleading guilty to those offenses, Dr. Fleming admitted that his convictions stemmed from two separate actions. Dr. Fleming, through his practice at FHHI, performed various imaging studies and submitted reimbursement claims to Medicare and Medicaid. Dr. Fleming's felony healthcare fraud related to the submission of a reimbursement claim. Dr. Fleming admitted to knowingly executing and attempting to execute a scheme to

defraud Medicare and Medicaid healthcare benefit programs in connection with the delivery of and payment for healthcare benefits, items, and services, namely by submitting payment claims for tomographic myocardial perfusion imaging studies that he did not actually perform. Dr. Fleming's felony mail fraud violation related to money paid to him to conduct a clinical study of a soy chip food product for the purpose of evaluating health benefits. As Dr. Fleming admitted during his guilty plea, he received approximately $35,000 for conducting a clinical trial, but he fabricated data for certain subjects.

By letter dated November 18, 2013, pursuant to section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)), FDA's Office of Regulatory Affairs (ORA) notified Dr. Fleming of its proposal to debar him for 10 years based on those convictions. On September 28, 2018, FDA debarred Dr. Fleming for 10 years from providing services in any capacity to a person with an approved or pending drug product application. Following that debarment, Dr. Fleming made various submissions from September 2018 to October 2018, which FDA construed as a petition for reconsideration and denied on November 28, 2018.

On March 15, 2022, Dr. Fleming applied for termination of debarment pursuant to section 306(d)(1) of the FD&C Act. Absent a conviction reversal, FDA may grant an application to terminate debarment pursuant to section 306(b)(2)(B) only when "termination serves the interests of justice and adequately protects the integrity of the drug approval process" (see section 306(d)(3)(B)).

By letter dated July 12, 2022, ORA offered Dr. Fleming an opportunity for a hearing under 21 CFR part 12 on a proposal to deny his application for termination of debarment. In the letter, ORA stated that, considering all the favorable and unfavorable information in light of the remedial public health purposes underlying debarment, terminating Dr. Fleming's debarment would not best serve the interests of justice and would not adequately protect the integrity of the drug approval process.

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Dr. Fleming'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))).

The Chief Scientist has considered Dr. Fleming's arguments, as well as the proposal to deny Dr. Fleming's application for termination of debarment and concludes that there is no genuine and substantial issue of fact requiring a hearing. Further, the Chief Scientist finds that Dr. Fleming's application does not satisfy the grounds for terminating debarment.

II. Arguments

In his response to ORA's proposal to deny his request for termination, Dr. Fleming concedes that the convictions underlying his debarment pursuant to section 306(b)(2)(B)(ii)(I) of the FD&C Act have not been reversed. FDA could therefore only terminate his debarment under section 306(d)(3)(B) if the Agency determined that such termination would serve the interests of justice and adequately protect the integrity of the drug approval process. In the application to terminate his debarment, Dr. Fleming presented three reasons for terminating his debarment: (1) that he was effectively debarred in the period between when he was convicted of the two felony offenses on which his debarment was based and when FDA finalized his debarment; (2) that he has taken training courses related to billing and ethics; and (3) that he has taken steps to prevent future mistakes in billing and collecting data.

In proposing to deny Dr. Fleming's application to terminate his debarment, ORA weighed the seriousness and nature of the offenses that led to his debarment, including his culpability, against his statements regarding other mitigating factors. After accounting for his assertions that he had effectively been debarred since his original convictions, ORA found that Dr. Fleming had not established that terminating his debarment would serve the interests of

justice or adequately protect the integrity of the drug approval process. In his request for a hearing on ORA's proposal, Dr. Fleming repeats some of the arguments from his application for termination of debarment and provides some additional context related to his own views on drug regulation, the criminal justice system, and other ethical considerations. He further clarifies some of the corrective actions he has implemented with respect to patient billing.

As a preliminary matter, the Chief Scientist notes Dr. Fleming's request in his application for termination of debarment that FDA consider the time starting from when he was convicted in 2009 as "time served." Dr. Fleming contended that, because he was convicted in 2009, "the effective period of debarment has been 12+ years." While Dr. Fleming does not renew this argument in his request for a hearing on ORA's proposal, the timing of when he was convicted, when ORA proposed his debarment, and when FDA finalized his debarment is not in dispute. Notwithstanding his arguments to the contrary, FDA did not debar Dr. Fleming until the Agency issued the final order debarring him in September 2018. Neither his convictions nor ORA's proposal to debar him started his debarment period pursuant to the Agency's authority under section 306(b)(2)(B)(ii)(I) of the FD&C Act. He thus cannot now argue that his ultimate debarment in September 2018 had any effect whatsoever on him before that time. The Chief Scientist therefore agrees with ORA that terminating his debarment on that basis would not serve the interests of justice or adequately protect the integrity of the drug approval process.

The Chief Scientist further agrees with ORA that Dr. Fleming has not shown that terminating his debarment would serve the interests of justice or adequately protect the drug approval process--even in light of the additional assertions and arguments proffered in support of his hearing request on ORA's proposal. Both offenses underlying his debarment are felony fraud convictions related to the regulation of drugs. As noted in ORA's proposal to deny Dr. Fleming's application for termination, the pattern of fraudulent conduct on which his convictions were based calls into question his ability to comply with the FD&C Act and indicates that he poses a threat to the drug approval process if he were allowed to participate in it. In light of the

conduct underlying the convictions on which Dr. Fleming's debarment was based, his assertions that he has taken some courses and adopted corrective measures relative to billing patients and collecting data do not come close to showing that terminating his debarment would serve the interests of justice and adequately protect the drug approval process in the sense contemplated by section 306(d)(3)(B)(ii). Dr. Fleming has thus presented no material factual dispute for a hearing on ORA's proposal to deny the application to terminate his debarment.

III. Conclusion

Therefore, the Chief Scientist, under authority delegated to her, denies Dr. Fleming's application for termination of debarment under section 306(d) of the FD&C Act. A hearing on this request is not necessary because there are no genuine and substantial issues of fact (see § 12.24(b)).

Any person with an approved or pending drug product application who knowingly uses the services of Dr. 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 Dr. Fleming 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 Dr. Fleming during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 22, 2023.

Namandjé N. Bumpus,

Chief Scientist.

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