

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22568 Filed 10–16–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1018]

Isachi Gil; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Isachi Gil's (Gil's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Gil for 6 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Gil was convicted of 12 felonies under Federal Law involving fraud or falsification and that Gil has demonstrated a pattern of conduct sufficient to find that there is reason to believe she may violate requirements under the FD&C Act relating to drug products. In determining the appropriateness and period of Gil's debarment, FDA considered the relevant factors listed in the FD&C Act. Gil failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable October 17, 2018.

ADDRESSES: Any application for termination of debarment by Gil 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–2013–N–1018. 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 V. 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)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual: (1) Has been convicted of a felony that 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, has demonstrated a pattern of conduct sufficient to find that there is reason to believe that the person may violate requirements under the FD&C Act relating to drug products.

On May 24, 2011, a jury found Gil guilty of 12 felonies. On September 28, 2011, the U.S. District Court for the Southern District of Florida entered judgment against her for five counts of felony healthcare fraud, in violation of 18 U.S.C. 1347, and seven counts of felony false statements related to healthcare matters, in violation of 18 U.S.C. 1035(a)(2). The court sentenced Gil to 43 months in prison, with 3 years of supervised release.

Gil's convictions stemmed from her work as a registered nurse in the home health field. From around March 14, 2007, through about July 15, 2009, Gil worked as a registered nurse, employed by a nursing staffing company and local home health agencies. During this time, Gil knowingly and willfully submitted and caused the submission of false and fraudulent claims to Medicare, seeking reimbursement for various home health services she had not provided. Specifically, Gil falsified and caused

Medicare beneficiaries to falsify weekly visit/time record sheets indicating that she provided skilled nursing services twice a day, 7 days a week, when she did not provide those services with such frequency. Gil falsified daily blood sugar/insulin log sheets stating that she administered insulin injections and provided other medical services to Medicare beneficiaries when she did not provide those services. Lastly, Gil created false weekly visit/time records claiming that she provided skilled nursing services to two separate Medicare beneficiaries at the same time and she caused local home health agencies to submit false and fraudulent claims that falsely represented that she provided home health services to eligible Medicare beneficiaries.

By letter dated March 18, 2014, FDA's Office of Regulatory Affairs (ORA) notified Gil of a proposal to debar her for 6 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal explained that the proposed debarment period was based on her 12 felony convictions. The proposal stated that maximum debarment period for each offense is 5 years and that FDA may determine whether debarment periods for multiple offenses should run concurrently or consecutively.

The proposal outlined findings regarding the four applicable factors ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of the offense, (2) the nature and extent of management participation in any offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other acts involving matters within FDA's jurisdiction. ORA found that the nature and seriousness of the offenses and her failure to take voluntary steps to mitigate the impact of her offenses were unfavorable factors for Gil. ORA found that her lack of prior convictions was a favorable factor for Gil. Finally, ORA found that the management participation factor was not applicable based on the information in the record. ORA concluded that "the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate." ORA proposed that each felony offense should have a 3-year debarment period. ORA further proposed that the 3-year debarment period for each healthcare fraud conviction should run concurrently and that the 3-year debarment period for each false

statement conviction should run concurrently, for a total debarment period of 6 years.

The proposal offered Gil the opportunity to request a hearing, providing her 30 days from the date of receipt of the letter to file the request and 60 days from the date of receipt of the letter to support her request with information sufficient to justify a hearing. In a letter dated May 9, 2014, through counsel, Gil filed a request for hearing and indicated that she had not received the proposal until April 10, 2014. She also stated that the information justifying the hearing request would be forthcoming. More than 60 days have passed from the date Gil represents she received FDA's letter, and she has not filed any information, or any legal or policy arguments, to support her request.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Acting Director of the Office of Scientific Integrity (OSI) has considered Gil's request for a hearing. 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 21 CFR 21.24(b)).

Inasmuch as Gil has not presented any information to support her hearing request, OSI concludes that Gil has failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, OSI denies Gil's request for a hearing. Further, Gil has not presented any arguments concerning whether debarment is appropriate for each of her felony convictions or whether the proposed debarment periods are appropriate. Based on the factual findings in the proposal to debar, OSI finds that a 3-year debarment period for each felony offense is appropriate and that the 3-year debarment period for each healthcare fraud conviction should run concurrently and that the 3-year debarment period for each false statement conviction should run concurrently, for a resulting total debarment of 6 years.

II. 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) Gil was convicted of a felony that 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, Gil demonstrated a pattern of conduct giving reason to believe that she 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 6-year debarment is appropriate.

As a result of the foregoing findings, Isachi Gil is debarred for 6 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 application who knowingly uses the services of Gil, in any capacity during her 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 Gil, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she 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 Gil during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: October 10, 2018.

George M. Warren,

Director, Office of Scientific Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of