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.

[FR Doc. 2018–22581 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

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

certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the guidance for industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.''

DATES: Submit either electronic or written comments on the collection of information by December 17, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2011–D–0125 for the guidance for industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number 0910–0775—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law.

The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 201(rr) of the FD&C Act (21 U.S.C.321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 910 of the FD&C Act (21 U.S.C. 387j) sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976).

FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A grandfathered tobacco product may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: Dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act sections or action	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the grandfathered status of a tobacco product under the guidance is not required and also on the number of grandfathered submissions received from 2011 to June 2018. We estimate submissions have increased due to the effective date of the deeming rule. FDA has stated that, for deemed combustible products that were on the market as of August 8, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2021. FDA has also stated that, for deemed noncombustible products that were on the market as of August 2, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2022. When these compliance periods end, FDA expects a drop in the number of grandfathered submissions. The number of hours to gather the evidence is FDA's estimate of how long it might take one to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it should take approximately 5,000 hours annually to respond to this collection of information.

Our estimated burden for the information collection reflects an overall increase of 4,235 hours. We attribute this adjustment to an updated number of submissions received through this approval and the number of submissions expected in the next 3 years.

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22578 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3163]

Agency Information Collection Activities; Proposed Collection; Comment Request; Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of