TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
610.40(c)(1)(ii)	2,361	1.52	3,600	0.08 (5 minutes)	288
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.20 (12 minutes)	96
610.40(h)(2)(vi)	2,361	7.62	18,000	0.08 (5 minutes)	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,945	5.40	10,500	0.17 (10 minutes)	1,785
610.46(a)(3)	1,945	5.40	10,500	0.17 (10 minutes)	1,785
610.46(b)(3)	4,961	0.35	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,945	12.03	23,400	0.17 (10 minutes)	3,978
610.47(a)(3)	1,945	12.03	23,400	0.17 (10 minutes)	3,978
610.47(b)(3)	4,961	0.41	2,050	1	2,050
630.6(a) [3]	648	668.72	433,333	0.08 (5 minutes)	34,667
630.6(a) [4]	84	53.57	4,500	1.5 (90 minutes)	6,750
630.6(d)(1)	63	35.71	2,250	1	2,250
Total					63,019

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,361 = 366).
[3] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

Dated: October 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24797 Filed 10–17–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0960]

Kelvin Soto: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Kelvin Soto from providing services in any capacity to a person that has an approved or pending drug product application for a period of 6 years. We base this order on a finding that Mr. Soto was convicted of four felony counts under Federal law for conduct involving health care fraud and conspiracy to commit health care fraud and that this pattern of conduct is sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. Mr. Soto was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Soto failed to request a hearing. Mr. Soto's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective October 20, 2014.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4144, Rockville, MD 20857, 301–796–4640.

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 debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct that involves bribery; payment of illegal gratuities; fraud; perjury; false statement; racketeering; blackmail; extortion; falsification or destruction of records; interference with, obstruction of an investigation into, or prosecution of any criminal offense; and FDA finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

On November 6, 2012, the U.S. District Court for the Southern District of Florida entered judgment against Mr. Soto after a jury found him guilty of four counts of health care fraud in violation of 18 U.S.C. 1347 and one count of conspiracy to commit health care fraud in violation of 18 U.S.C. 1349.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Mr. Soto was a registered nurse working for Ideal Home Health Inc. (Ideal), which was a business in Miami-Dade County, FL. Ideal purportedly provided skilled nursing services to Medicare beneficiaries who required home health services. As a registered nurse in the home health field, it was Mr. Soto's duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

Mr. Soto conspired with others to defraud Medicare. Mr. Soto and his coconspirators, among other things, submitted and caused the submission of false and fraudulent claims to Medicare and concealed the submission of these false and fraudulent claims.

Mr. Soto and his co-conspirators falsified and caused Medicare beneficiaries to falsify weekly visit/time record sheets, falsified skilled nursing progress notes representing that Mr. Soto had administered insulin injections and provided various other medical services to Medicare beneficiaries, and caused Ideal to submit false and fraudulent claims to Medicare for home health benefits by falsely representing that they had provided these home health services. As a result of these fraudulent claims, Mr. Soto caused Medicare to make payments

to Ideal, which amounted to approximately $58,400.

As a result of his conviction on April 9, 2014, FDA sent Mr. Soto a notice by certified mail proposing to debar him for 6 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding under section 306(b)(2)(B)(ii)(I) of the FD&C Act that Mr. Soto was convicted of felonies under Federal law for conduct which involved health care fraud, and the Agency found, on the basis of the conviction and other information, that Mr. Soto had demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. This conclusion was based on the fact that Mr. Soto had legal and professional obligations to ensure that he submitted accurate medical claims for services he provided, as well as ensure that he provided the appropriate drug products to his patients. Instead, Mr. Soto submitted and caused the submission of false weekly visit/time record sheets and false daily blood sugar/insulin log sheets. He engaged in this conduct repeatedly over a period of more than 2 years. His convictions indicate that he knowingly and willfully disregarded his legal and professional obligations to keep accurate medical records and to submit accurate claims for the services he provided. Having considered the conduct that forms the basis of his conviction and the fact that this conduct occurred in the course of his profession and showed a disregard for the obligations of his profession and the law, FDA found that Mr. Soto has demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if he were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. Therefore, FDA had reason to believe that, if Mr. Soto were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products.

The proposal offered Mr. Soto an opportunity to request a hearing, providing him with 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on April 14, 2014. Mr. Soto failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Kelvin Soto has been convicted of four counts of a felony and one count of conspiracy to commit a felony under Federal law for conduct involving health care fraud, and on the basis of the conviction and other information, finds that Mr. Soto has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products.

Based on the factors under section 306(c)(2)(A)(iii) of the FD&C Act (21 U.S.C. 335a(c)(2)(A)(iii)), FDA finds that each offense be accorded a debarment period of 3 years. In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. 335a(c)(2)(A)). FDA has concluded that the 3-year period of debarment for each of the five offenses of conviction need not be served consecutively. Rather, FDA has concluded that the 3-year periods of debarment for the four counts of health care fraud shall run concurrently. The 3-year period of debarment for the conspiracy conviction shall run consecutively to the periods of debarment for the health care fraud convictions, resulting in a total debarment period of 6 years.

As a result of the foregoing finding, Kelvin Soto is debarred for a period of 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 sections 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains Mr. Soto as a consultant or contractor, or otherwise uses the services of Kelvin Soto in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Kelvin Soto during his period of debarment (section 306(c)(l)(A) of the FD&C Act).

Any application by Mr. Soto for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2013–N–0960 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24814 Filed 10–17–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1492]

Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #227) entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections.'' The purpose of this document is to provide recommendations to sponsors submitting CMC data submissions. For review efficiency, the Center for Veterinary Medicine (CVM) prefers that CMC information be submitted in a single technical section. However, there may be instances when a two-phased technical submission process is more beneficial to improve the overall time to drug approval. Sponsors may submit the phased CMC technical section as a single technical section or a two-phased technical section. This guidance describes the use of the two-phased technical section submission process.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft