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]

BILLING CODE 4164–01–P

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

guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 19, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather Longstaff, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0651, email: *heather.longstaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #227) entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections.'' It is intended to provide recommendations to industry regarding CMC data submitted to CVM to support approval of a new animal drug or abbreviated new animal drug. As specified in the Animal Drug User Fee Amendments of 2013 (ADUFA III) and Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II) respective goals letters, the Agency agreed to develop guidance for a two-phased CMC technical section submission and review process by the end of fiscal year 2014.

The two-phased process allows for two separate CMC submissions, each with its own review clock, and each including complete appropriate CMC information that is available for review at the time of submission. The draft guidance specifies the technical details of how the process works, the review clocks, the information that is appropriate for each technical section submission, and the possible review outcomes. The guidance also includes CVM's recommendations for meetings between the Division of Manufacturing Technologies and the sponsor during this process to ensure concurrence with the approach used for the CMC technical section.

II. Significance of Guidance

This level 1 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 Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 this guidance have been approved under 0910–0032 and 0910–0669.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24796 Filed 10–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than December 19, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys OMB No. 0915-xxxx–New

Abstract: The purpose of the public health system assessment surveys is to inform the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on the ability to add newborn screening for particular conditions within a state, including the feasibility, readiness, and overall capacity to screen for a new condition.

The Committee was established under the Public Health Service Act, 42 U.S.C. 217a: Advisory Councils or Committees. This Committee fulfills the functions previously undertaken by the former Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, established under Section 1111 of the Public Health Service Act (PHS), 42 U.S.C. 300b–10, as amended in the Newborn Screening Saves Lives Act of 2008. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), as