registered nurse in the home health field, it was Ms. Fernandez's duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

From on or about August 17, 2007, through on or about March 19, 2009, Ms. Fernandez conspired with others to defraud Medicare.

Ms. Fernandez and her coconspirators submitted, and caused the submission of, false and fraudulent claims to Medicare, and concealed the submission of these false and fraudulent claims.

Ms. Fernandez and her coconspirators falsified and caused Medicare beneficiaries to falsify weekly visit/time record sheets, and falsified skilled nursing progress notes representing that she had administered insulin injections and provided other medical services to Medicare beneficiaries. She caused Ideal to submit false and fraudulent claims to Medicare for home health benefits by falsely representing that she had provided these health services. As a result of these fraudulent claims, she caused Medicare to make payments to Ideal of approximately $82,040. Ms. Fernandez engaged in this criminal conduct repeatedly over a period of approximately 19 months.

As a result of her convictions, on September 8, 2014, FDA sent Ms. Fernandez a notice by certified mail proposing 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 was based on the finding, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, that Ms. Fernandez was convicted of felonies under Federal law for conduct involving health care fraud and conspiracy to commit health care fraud, and the Agency found, on the basis of the conviction and other information, that Ms. Fernandez had 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. This conclusion was based on the fact that Ms. Fernandez had legal and professional obligations to ensure that she submitted accurate medical claims for services she provided. Instead, Ms. Fernandez submitted, and caused the submission of, false weekly visit/time records and false daily blood sugar/insulin log sheets. She engaged in this conduct repeatedly over a period of almost 2 years. Her convictions indicate that she knowingly and willfully disregarded her legal and professional obligations to keep accurate medical records and to submit accurate claims for the services she provided. Having considered the conduct that forms the basis of her conviction and the fact that this conduct occurred in the course of her profession and showed a disregard for the obligations of her profession and the law, FDA found that Ms. Fernandez has demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if she were to provide services to a person that has an approved or pending drug application, she may violate requirements under the FD&C Act relating to drug products. The proposal offered Ms. Fernandez an opportunity to request a hearing, providing her with 30 days from the date of receipt of the letter in which to file the request, and advised her 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 September 12, 2014. Ms. Fernandez failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her 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 Odalys Fernandez has been convicted of five 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 Ms. Fernandez 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.

Based on the factors under section 306(c)(2)(A)(iii) of the FD&C Act, 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 (section 306(c)(2)(A)). FDA has concluded that the 3-year periods of debarment for the five 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 health care fraud convictions, resulting in a total debarment period of 6 years.

As a result of the foregoing findings, Odalys Fernandez 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 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 as a consultant or contractor, or otherwise uses the services of Ms. Fernandez 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 Ms. Fernandez provides services in any capacity to a person with an approved or pending drug product application during her period of debarment 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 Odalys Fernandez during her period of debarment (section 306(c)(1)(A) of the FD&C Act).

Any application by Ms. Fernandez for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2014–N–0563 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.

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

Dated: March 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07267 Filed 3–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0500]

Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; requests for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a request for additional comments on the chemistry, manufacturing, and control (CMC) information that a sponsor of an investigational new drug application (IND) should provide in its IND in order to meet regulatory requirements when commercially available foods or dietary supplements containing live biotherapeutic products (LBPs) are used as investigational new drugs in early phase clinical trials. The request for additional comments on the CMC information is related to the guidance entitled, ''Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,'' dated February 2012 (February 2012 guidance).

DATES: Submit either electronic or written comments on the requested CMC information by May 29, 2015.

ADDRESSES: Submit written requests for single copies of the February 2012 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the requested CMC information 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: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a request for additional comments on the CMC information that a sponsor of an IND should provide in its IND in order to meet the requirements under § 312.23 (21 CFR 312.23), when commercially available foods or dietary supplements containing LBPs are subject to study as investigational new drugs in early phase clinical trials.

In the **Federal Register** of February 21, 2012 (77 FR 9947), FDA announced the publication of a final guidance entitled ''Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,'' dated February 2012. The guidance provides IND sponsors with recommendations regarding CMC information that should be included in IND submissions for early clinical trials with LBPs, including LBPs lawfully marketed as foods or dietary supplements in the United States and proposed for clinical uses regulated under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance also outlines the Drug Substance and Drug Product information that should be provided in the CMC section of an IND to meet the requirements under § 312.23 and to support proceeding to clinical evaluation of an LBP in human subjects.

II. CMC Information

FDA is considering modifying the February 2012 guidance to address the CMC information that should be provided in an IND, under certain conditions. Specifically, FDA is considering whether to revise the guidance to address when the label on the commercially available product(s) would be considered adequate to satisfy the requirement for CMC information under § 312.23. For example, we are considering whether the label would be adequate to satisfy the CMC information when the following conditions are met: (1) The LBP product that is proposed for investigational use is a commercially available food or dietary supplement; (2) the investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of risk) associated with the use of the food or dietary supplement; (3) the investigation is not intended to support a marketing application for a drug claim for the food or dietary supplement; and (4) the investigation is conducted in compliance with the requirements for INDs (part 312), the requirements for review by an institutional review board (21 CFR part 56), and with the requirements for informed consent (21 CFR part 50). FDA is seeking public comment on this issue.

III. Comments

Interested persons may submit either electronic comments regarding the requested CMC information 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the February 2012 guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07273 Filed 3–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1439]

Critical Path Innovation Meetings; 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 guidance for industry entitled ''Critical Path Innovation Meetings.'' This guidance describes a Critical Path Innovation Meeting (CPIM), a means by which FDA's Center for Drug Evaluation and Research (CDER) and investigators from industry, academia, government, and patient advocacy groups can communicate to improve efficiency and success in drug development. The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food