address, at a minimum, options, best practices, and identified standards to prevent instances of balance billing; steps that can be taken by State legislatures, State insurance regulators, State attorneys general, and other State officials as appropriate, consistent with current legal authorities regarding consumer protection; and legislative options for Congress to prevent balance billing.

The GAPB Advisory Committee must submit this report no later than 180 days after the date of its first meeting.

A copy of the charter for the Advisory Committee may be obtained by submitting a written request to the address specified in the **ADDRESSES** section of this notice.

B. Composition of the Advisory Committee on Ground Ambulance and Patient Billing

The GAPB Advisory Committee shall consist of the following:

(i) The Secretary of Labor, or the Secretary's designee;

(ii) the Secretary of Health and Human Services, or the Secretary's designee;

(iii) the Secretary of the Treasury, or the Secretary's designee;

(iv) One representative, to be appointed jointly by the Secretaries, for each of the following:

(I) Each relevant Federal agency, as determined by the Secretaries;

(II) State insurance regulators;

(III) Health insurance providers;

(IV) Patient advocacy groups;

(V) Consumer advocacy groups;

(VI) State and local governments;

(VII) Physician specializing in emergency, trauma, cardiac, or stroke;

(VIII) State Emergency Medical Services Officials; and

(IX) Emergency medical technicians, paramedics, and other emergency medical services personnel.

(v) Three representatives, to be appointed jointly by the Secretaries, to represent the various segments of the ground ambulance industry.

(vi) Up to an additional 2 representatives otherwise not described in paragraphs (i) through (v), as determined necessary and appropriate by Secretaries.

III. Submissions of Nominations

The Secretaries are requesting nominations for membership on the GAPB Advisory Committee. The Secretaries are also requesting nominations for a member to serve as the chairperson of the GAPB Advisory Committee. The Secretaries will consider qualified individuals who are self-nominated or are nominated by organizations representing affected stakeholders when selecting those representatives. The Secretaries will make every effort to appoint members to serve on the GAPB Advisory Committee from among those candidates determined to have the technical expertise required to meet specific statutory categories and Departmental needs, and in a manner to ensure an appropriate balance of membership. Selection of committee membership will be consistent with achieving the greatest impact, scope, and credibility among diverse stakeholders. The diversity in such membership includes, but is not limited to, race, gender, disability, sexual orientation, and gender identity.

The Secretaries reserve discretion to appoint members who were not nominated in response to this notice to serve on the GAPB Advisory Committee if necessary to meet specific statutory categories and Departmental needs in a manner to ensure an appropriate balance of membership.

Any interested person may nominate one or more qualified individuals (self-nominations will also be accepted). Each nomination must include the following information:

1. A letter of nomination that contains contact information for both the nominator and nominee (if not the same).

2. A statement from the nominee that he or she is willing to serve on the GAPB Advisory Committee for its duration and an explanation of interest in serving on the GAPB Advisory Committee. The nominee should also indicate which category or categories he or she is willing to represent. (For self-nominations, this information may be included in the nomination letter.)

3. A curriculum vitae that indicates the nominee's educational experience, as well as relevant professional experience.

4. Two letters of reference that support the nominee's qualifications for participation on the GAPB Advisory Committee. (For nominations other than self-nominations, a nomination letter that includes information supporting the nominee's qualifications may be counted as one of the letters of reference.)

To ensure that a nomination is considered, the Departments must receive all of the nomination information specified in section III of this notice by December 13, 2021. Nominations should be emailed or mailed to the appropriate address specified in the **ADDRESSES** section of this notice.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–25560 Filed 11–19–21; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0405]

Maytee Lledo: Final 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 (FD&C Act) permanently debarring Maytee Lledo from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Lledo was convicted of a felony under Federal law for conduct that relates to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Ms. Lledo was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why she should not be debarred within the timeframe prescribed by regulation. Ms. Lledo has not responded to the notice. Ms. Lledo's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable November 23, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. On April 16, 2021, in the U.S. District Court for the Southern District of Florida, Miami Division, a judgment of conviction was entered against Ms. Maytee Lledo, after her plea of guilty to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349, a felony offense under Federal law.

The factual basis for this conviction is as follows: As contained in the Information, entered into the docket on August 31, 2020, and the Factual Proffer in Support of Ms. Lledo's guilty plea, entered into the docket on February 5, 2021, both from her case, Ms. Lledo was a receptionist at Sacred Heart Medical Office P.A., a private medical practice, in Florida. That medical practice primarily served a pediatric population. From about September 2013 through June 2016, Ms. Lledo and others conspired to unlawfully enrich themselves by making materially false representations about clinical trials, fabricating data and the participation of subjects in those clinical trials, concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been fabricated, and inducing sponsors and contract research organizations to pay money for Ms. Lledo and her co-conspirators' own benefit. Specifically, one of Ms. Lledo's co-conspirators entered into a contract with a Contract Research Organization (CRO) retained by a drug manufacturer (Sponsor) to hire clinical investigators and to manage clinical trials. Ms. Lledo's co-conspirator entered into a contract with the CRO to conduct a study at Unlimited Medical Research site in return for payment. The study was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years. Her co-conspirators were responsible for complying with the study protocol, including administering study drug to subjects in the study and preparing written records, known as case histories, which documented the participation of subjects in the study.

Ms. Lledo participated in a scheme to defraud the Sponsor by fabricating the data and participation of subjects in the clinical trial in a variety of ways. Ms. Lledo and her co-conspirators falsified medical records to portray persons as legitimate study subjects when they were not. In addition, her co-conspirators made it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research when they had not; made it appear as though subjects had taken the study drug as required when they had not; and made it appear that the study subjects had received checks as payment when they had not. In addition, study subjects were required to make daily phone calls to an ''e-diary'' system and report their daily drug usage and experience with the study drug. As part of the conspiracy, Ms. Lledo placed thousands of telephone calls to the e-diary system, using falsely obtained PIN numbers to access the system, for purposes of reporting fabricated data on behalf of purportedly legitimate study subjects. Ms. Lledo entered this fabricated information in the e-diary system for at least 11 study subjects.

Based on this conviction, FDA sent Ms. Lledo by certified mail on July 27, 2021, a notice proposing to permanently debar her 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(a)(2)(A) of the FD&C Act, that Ms. Lledo was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product under the FD&C Act. The proposal also offered Ms. Lledo an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Lledo received the proposal on August 2, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Lledo has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Lledo is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Ms. Lledo 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. Lledo 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 application from Ms. Lledo during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 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) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Ms. Lledo for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0405 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: November 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25589 Filed 11–22–21; 8:45 am]

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