ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Respondent/data collection activity	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OAA or APS Grantee	Corrective Action Plan (CAP)	75	1	8	600
Total Estimated Burden					2,056

Dated: May 21, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–11602 Filed 5–24–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0201]

Jessica Palacio; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Andrew S. Feldman, on behalf of Jessica Palacio (Palacio), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Palacio 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 Palacio was 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. FDA provided notice to Palacio of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Palacio submitted a request for hearing but failed to file with the Agency information and analyses sufficient to create a basis for a hearing.

DATES: The order is applicable May 28, 2024.

ADDRESSES: Any application for termination of debarment by Palacio under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–0201. An application will be placed in the docket and, unless 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, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4232, Silver Spring, MD 20993, 301–796–9603.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act mandates permanent debarment 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. On January 12, 2023, following a jury trial, the U.S. District Court for the Southern District of Florida entered

a judgment against Palacio for one count of false statements in violation of 18 U.S.C. 1001(a)(2).

A grand jury returned a two-count indictment on May 12, 2021, against Palacio, the study coordinator, for clinical trials from about 2013 to 2015 at Unlimited Medical Research, LLC (Unlimited). The indictment charged Palacio with conspiring to commit wire fraud, in violation of 18 U.S.C. 1349 and making a false statement to FDA, in violation of 18 U.S.C. 1001(a)(2). On September 13, 2022, the jury found Palacio guilty of both charges. However, on September 15, 2022, the court granted Palacio's motion for acquittal with respect to the conspiracy. On January 12, 2023, the court entered a criminal judgment against Palacio for false statements in violation of 18 U.S.C. 1001(a)(2) and sentenced Palacio to 36 months imprisonment.

By letter dated August 18, 2023, FDA's Office of Regulatory Affairs (ORA) notified Palacio of a proposal to issue an order of permanent debarment (Notice). As explained in the Notice, Palacio's conviction stemmed, in part, from a statement made in a signed affidavit to FDA investigators during the Agency's investigation into allegations of irregularities in data submitted by Unlimited. Unlimited previously contracted with Parexel International, a contract research organization that the sponsor company, GlaxoSmithKline (GSK), a global biopharma company, hired to conduct a clinical trial, known as the Vestri Study, to study certain asthma drugs in pediatric subjects aged 4 to 11 years. GSK reported allegations of irregular data to FDA related to certain records created by Unlimited that documented the participation of certain pediatric subjects. As study coordinator at Unlimited, Palacio would have, among other responsibilities, helped to ensure the study protocol was followed. Therefore, as part of the investigation, FDA questioned Palacio regarding the irregularities. Specifically, inspectors inquired about the screening visit of a specific subject called D.H., including records indicating Palacio performed a screening visit and records indicating the subject had been in school at the time of the purported screening. Palacio then signed an affidavit, on April 25, 2017, stating, ''I can confirm that the Screening/Visit 1 was performed by myself and Dr. Villaman-Bencosme.'' As explained in the Notice, this statement was false in that Palacio knew at that time that D.H. had not participated in the clinical trial; therefore, she had not screened D.H. for the Vestri study. The signed affidavit was part of the evidence offered at trial leading to Palacio's conviction for making false statements to FDA in violation of 18 U.S.C. 1001(a)(2).

The Notice explained that the proposed permanent debarment of Palacio is based on her Federal felony conviction for making false statements to FDA and that the conduct serving as the basis for that conviction relates to the development or approval, including the process for development or approval, of any drug product. The Notice also informed Palacio of an opportunity for her to request a hearing under section 306(i) of the FD&C Act and part 12 (21 CFR part 12).

In response to the Notice, Palacio submitted a timely request for a hearing, which included a notice of appearance and request for an extension to submit materials in support of the hearing request. Following two extensions to submit supporting materials, which were both granted, on December 4, 2023, Palacio submitted a response entitled ''Memorandum in Support of a Request for a Hearing (Memorandum).'' Palacio's Memorandum included several claims and multiple documents challenging whether she is subject to permanent debarment. Specifically, Palacio challenges whether her conviction relates to the development or approval, including the process for development or approval, of any drug product.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director, Office of Scientific Integrity (OSI Director) has considered Palacio's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that justifies 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 § 12.24(b) (21 CFR 12.24(b))).[1]

II. Argument in Support of a Hearing

Under section 306(a)(2)(A) of the FD&C Act, an individual convicted of a Federal felony for conduct relating to the development or approval, including the process for development or approval, of any drug product is subject to permanent debarment. The relevant factual issues are whether Palacio was, in fact, convicted of a Federal felony and whether the basis of that conviction relates to the development or approval, including the process for development or approval, of any drug product.

Palacio does not dispute that a court convicted her of a Federal felony under 18 U.S.C. 1001(a)(2). In fact, in her Memorandum, Palacio concedes that her conviction is a fact not in dispute. However, Palacio challenges whether the conduct underlying her conviction relates to the development and approval, including the process for development and approval, of a drug. In her Memorandum, Palacio offers two central claims to support her argument: (1) material facts exist, which would determine whether she qualifies for permanent debarment under section 306(a)(2)(A) of the FD&C Act; and (2) nine prior permanent debarments are factually distinguishable from her proposed debarment, as they relate to false statements made ''while a clinical trial or similar study was ongoing.''

Section 306(a)(2)(A) of the FD&C Act specifically provides for permanent and mandatory debarment of individuals convicted of a felony under Federal law for conduct related to the development or approval, including the process for development or approval, of any drug product. If the language of the statute is clear, there is no need to look outside the statute to its legislative history in order to ascertain the statute's meaning (*Chamber of Commerce of the United States* v. *Whiting,* 563 U.S. 582, 599 (2011)). Likewise, the Supreme Court has repeatedly held that the language in the FD&C Act should be construed in a manner consistent with its overall public health purpose. The FD&C Act is given ''liberal construction consistent with the Act's overriding purpose to protect public health . . .'' (*United States* v. *Article of Drug Bacto-Unidisk,* 394 U.S. 784, 798 (1969)). The Supreme Court has addressed the definition of ''relating to'' in the context of other statutory authorities. Specifically, the Supreme Court stated that ''relating to'' expressed a broad legislative purpose and defined it as ''. . . to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.'' (*Morales* v. *Trans World Airlines, Inc.,* 504 U.S. 374, 383 (1992) (citing Black's Law Dictionary 1158 (5th ed. 1979))). When applying this definition to ''reasonably related'' in the context of FDA-regulated drug patents, the Supreme Court declined to read the requirement

[1] Palacio's Memorandum references her request for a hearing pursuant to the standard identified in 21 CFR part 16 as opposed to the standard outlined in § 12.24. In the Notice, ORA explained that her proposed debarment and the request for a hearing are addressed under the regulations outlined in part 12. Consequently, FDA applies the standard described in § 12.24 to Palacio's hearing request.

narrowly. Rather, an activity that is ''appropriate to include in a submission to the FDA . . . is 'reasonably related' to the 'development and submission of information under . . . Federal law'' (*Merck KGaA* v. *Integra Lifesciences I, Ltd.,* 545 U.S. 193, 207 (2005)).

In a previous action requiring mandatory debarment under section 306(a)(2)(A) of the FD&C Act for conduct relating to the development or approval, including the process for development or approval, of any drug product, FDA stated that ''the statutory language 'relating to the development or approval' . . . by definition, encompasses all things that are logically connected with the development or approval of a drug product.'' (Atul Shah; Denial of Hearing; Final Debarment Order, (59 FR 62399, December 5, 1994), (citing Webster's Collegiate Dictionary, Merriam-Webster Inc., Springfield, MA, 1990, ''relate''); *see also* Ray Nathan; Denial of Hearing; Final Debarment Order, (76 FR 48869 at 48870, August 9, 2011), (affirming the Shah definition of ''relates to,'' and going further to define ''develop'' . . . ''to explore the possibilities of'' and ''to make suitable for commercial * * * purposes.'' (see ''Merriam-Webster's Collegiate Dictionary,'' 10th Edition (2002))).[2]

Palacio's felony conviction is related to the development and approval, including the process for development and approval, of a drug. The trial established that Palacio held the role of clinical trial coordinator at the clinical trial site, Unlimited, which contracted to conduct a clinical trial to study certain asthma drugs in pediatric subjects between the ages of 4 and 11 years. As ORA explained in the Notice, drug sponsors, like GSK, submit clinical trial data in support of drug product applications for review and approval by FDA, and the Agency relies upon the integrity of the data and information in the applications to determine whether a drug meets required safety and effectiveness standards. The basis for Palacio's Federal felony conviction for false statements in a signed affidavit is regarding conduct in her role as clinical trial coordinator. Specifically, in her signed affidavit Palacio ''represented . . . that she had performed a screening visit for D.H. in the Study, when in truth and in fact, and as [Palacio] then and there well knew, she had not performed a screening for D.H. . .'' Palacio's false statements about her role in the conduct of a clinical trial related to the development or approval, including the process for development or approval, of any drug product. Palacio's role and statements regarding her role pertaining to the Vestri Study, a clinical study meant to inform GSK's submission to FDA, are logically connected to the development or approval of a drug product. Palacio's Memorandum does not provide any material facts capable of overcoming the clear language in section 306(a)(2)(A) of the FD&C Act and the logical connection of her conduct to the development or approval, including the process for development or approval, of any drug product. Therefore, Palacio has failed to raise a genuine and substantial issue of fact warranting a hearing to determine whether she is subject to permanent debarment. Accordingly, the OSI Director need not address Palacio's other arguments, including her efforts to distinguish her own conduct from that of other debarred individuals.

III. Findings and Order

Therefore, the OSI Director, under section 306(a)(2)(A) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that Palacio 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.

As a result of the foregoing findings, Palacio is permanently debarred 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 May 28, 2024 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Palacio, in any capacity during her period of 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 Palacio, 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 Palacio during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: May 21, 2024.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2024–11546 Filed 5–24–24; 8:45 am]

BILLING CODE 4164–01–P

[2] See also, The Drug Development Process | FDA. (*https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2222]

Authorization of Emergency Use of a Drug Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use during the COVID–19 pandemic. FDA has issued an Authorization for the drug product PEMGARDA (pemivibart) as requested by Invivyd, Inc. (Invivyd). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of March 22, 2024.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to