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

assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Johanna McLatchy, 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, 301–796–3200 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS 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 biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

The Authorization follows the February 4, 2020, determination by the Secretary of 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. Notice of the Secretary's determination was provided in the **Federal Register** on February 7, 2020 (85 FR 7316) and notice of the Secretary's amended determination was provided in the **Federal Register** on March 20, 2023 (88 FR 16644). 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 section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on April 1, 2020

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

(85 FR 18250). Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, on March 22, 2024, FDA issued an EUA to Invivyd for the drug product PEMGARDA (pemivibart), subject to the terms of the Authorization. The initial Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorization can be found on FDA's web page at: *https://www.fda.gov/drugs/emergency-preparedness-drugs/emergency-use-authorizations-drugs-and-non-vaccine-biological-products.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 3, 2024

Invivyd, Inc.
Barry Sickels, PhD
Senior Vice President
Regulatory Affairs and Quality Assurance
1601 Trapelo Road, Suite 178
Waltham, MA 02451

RE: Emergency Use Authorization 122

Dear Dr. Sickels:

This letter is in response to Invivyd, Inc.'s (Invivyd) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of PEMGARDA (pemivibart) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in certain adults and adolescents, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, as amended on March 15, 2023, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020; U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).* March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020). *See* Amended Determination ("The declarations issued pursuant to section 564(b)(1) of the FD&C Act that circumstances exist justifying the authorization of emergency use of certain in vitro diagnostics, personal respiratory protective devices, other medical devices and drugs and biological products, as set forth in those declarations, and that are based on the February 4, 2020 determination, remain in effect until those declarations are terminated in accordance with section 564 of the FD&C Act.").

On March 22, 2024, FDA issued an EUA authorizing the emergency use of PEMGARDA for the pre-exposure prophylaxis of COVID-19 in certain adults and adolescents.

PEMGARDA is a recombinant human monoclonal IgG1λ antibody that targets the SARS-CoV-2 spike protein receptor binding domain, thereby inhibiting virus attachment to the human ACE2 receptor on host cells. PEMGARDA is not FDA-approved for any indication, including for use as pre-exposure prophylaxis of COVID-19.

On April 3, 2024, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the March 22, 2024 letter in its entirety, to revise a deadline in post-authorization requirement 7 of Condition P regarding the submission to FDA all genotypic an phenotypic resistance analysis data for subjects failing pemivibart prophylaxis in the CANOPY clinical trial.

Based on the totality of scientific evidence available to FDA, including data from CANOPY (NCT06039449), a Phase 3 clinical trial evaluating PEMGARDA for protection against COVID-19 based on an immunobridging approach, it is reasonable to believe that PEMGARDA may be effective for use as pre-exposure prophylaxis of COVID-19 in certain adults and adolescents, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of PEMGARDA outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of PEMGARDA for pre-exposure prophylaxis of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of PEMGARDA for pre-exposure prophylaxis of COVID-19, when administered as described in the Scope of Authorization (Section II), meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that PEMGARDA may be effective for use as pre-exposure prophylaxis of COVID-19 in certain adults and adolescents, as described in the Scope of Authorization (Section II), and that, when used under the conditions described in this authorization, the known and potential benefits of PEMGARDA outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of PEMGARDA for pre-exposure prophylaxis of COVID-19 as further described in the Scope of Authorization (section II).[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- PEMGARDA may only be used by healthcare providers for pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):
  - Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate immune response to COVID-19 vaccination.

  Limitations on Authorized Use

  - PEMGARDA is **not** authorized for the following uses:
    - For treatment of COVID-19, or
    - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

- Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.

- PEMGARDA should only be administered in settings in which healthcare providers have immediate access to medications to treat a severe hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

- PEMGARDA may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under State law to prescribe drugs.[4]

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[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] Under section 201(a)(1) of the Act, the term "State" is defined to mean "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico."

- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least two weeks after vaccination.

- The use of PEMGARDA covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

PEMGARDA injection is a sterile, preservative-free, clear to slightly opalescent, colorless to yellow solution supplied in a single-dose 6R vial intended for intravenous infusion only. PEMGARDA is supplied in a single-dose vial at a concentration of 125 mg/mL. Each PEMGARDA carton contains nine vials of PEMGARDA. Each vial contains an overfill to allow the withdrawal of 500 mg (4.0 mL) of PEMGARDA.

The authorized storage and handling information for PEMGARDA is included in the authorized Fact Sheet for Healthcare Providers.

PEMGARDA is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients, parents, and caregivers, respectively, through Invivyd's website at www.PEMGARDA.com (referred to as the "authorized labeling"):

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for PEMGARDA
- Fact Sheet for Patients, Parents, and Caregivers: Emergency Use Authorization (EUA) of PEMGARDA for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the known and potential benefits of PEMGARDA, when used for pre-exposure prophylaxis of COVID-19 in adults and adolescents and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks, pursuant to Section 564(c)(2)(B) of the Act.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that PEMGARDA may be effective when used for pre-exposure prophylaxis of COVID-19 in adults and adolescents and used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that PEMGARDA (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of PEMGARDA under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the

Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), PEMGARDA is authorized for use as pre-exposure prophylaxis of COVID-19 as described in this Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Invivyd and Authorized Distributors[5]

A. Invivyd and authorized distributor(s) will ensure that PEMGARDA is distributed and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

B. Invivyd and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Invivyd and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving PEMGARDA. Invivyd will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Invivyd may request changes to this authorization, including to the authorized Fact Sheets for PEMGARDA. Any request for changes to this EUA must be submitted to the Office of Infectious Disease/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[6]

E. Invivyd may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of PEMGARDA as described in this

[5] "Authorized Distributor(s)" are identified by Invivyd as an entity or entities allowed to distribute the authorized PEMGARDA.

[6] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for PEMGARDA are prohibited. If the Agency notifies Invivyd that any instructional and educational materials are inconsistent with the authorized labeling, Invivyd must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require Invivyd to issue corrective communication(s).

F. Invivyd will report to FDA all serious adverse events and medication errors potentially related to PEMGARDA use that are reported to Invivyd using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options must state: "PEMGARDA use for pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product used for EUA supply will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

H. Invivyd will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with drug product distributed under this EUA for PEMGARDA that includes the following:

- Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
- Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information must be submitted for all potentially impacted lots.

Invivyd will include in its notification to the Agency whether the batch, or batches, in question will be recalled. If FDA requests that these, or any other batches, at any time, be recalled, Invivyd must recall them.

If not included in its initial notification, Invivyd must submit information confirming that Invivyd has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. Invivyd must submit this information as soon as possible but no later than 45 calendar days from the initial notification.

I. Invivyd will manufacture PEMGARDA to meet all quality standards and per the manufacturing process and control strategy as detailed in Invivyd's EUA request. Invivyd will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under Condition D.

J. Invivyd will list PEMGARDA with a unique product NDC under the marketing category of Emergency Use Authorization. Further, the listing will include each establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.

K. Through a process of inventory control, Invivyd and authorized distributor(s) will maintain records regarding distribution of PEMGARDA (i.e., lot numbers, quantity, receiving site, receipt date).

L. Invivyd will establish a process for monitoring genomic database(s) for the emergence of global viral variants of SARS-CoV-2. A summary of Invivyd's process should be submitted to the Agency as soon as practicable, but no later than 30 calendar days of the issuance of this letter, and within 30 calendar days of any material changes to such process. Invivyd will provide reports to the Agency on a monthly basis summarizing any findings as a result of its monitoring activities and, as needed, any follow-up assessments planned or conducted.

M. FDA may require Invivyd to assess the activity of the authorized PEMGARDA against any global SARS-CoV-2 variant(s) of interest (e.g., variants that are prevalent or becoming prevalent that harbor substitutions in the target protein). Invivyd will perform the required assessment in a manner and timeframe agreed upon by Invivyd and the Agency. Invivyd will submit to FDA a preliminary summary report immediately upon completion of its assessment followed by a detailed study report within 30 calendar days of study completion. Invivyd will submit any relevant proposal(s) to revise the authorized labeling based on the results of its assessment, as may be necessary or appropriate based on the foregoing assessment.

N. Invivyd shall provide samples as requested of the authorized PEMGARDA to the HHS for evaluation of activity against emerging global viral variants of SARS-CoV-2, including specific amino acid substitution(s) of interest (e.g., variants that are highly prevalent or that harbor substitutions in the target protein) within 5 business days of any request made by HHS. Analyses performed with the supplied quantity of authorized pemivibart may include, but are not limited to, cell culture potency assays, protein

binding assays, cell culture variant assays (pseudotyped virus-like particles and/or authentic virus), and in vivo activity assays.

O. Invivyd must conduct additional studies selecting SARS-CoV-2 with reduced susceptibility to PEMGARDA in cell culture. Such studies must employ strategies as agreed upon between Invivyd and the Agency, and Invivyd must provide a protocol within 30 calendar days of the issuance of this letter.

P. Invivyd must provide the following information to the Agency:

1. Anti-drug antibody (ADA) assessments for all participants from the CANOPY clinical trial on Days 1 and 28 by May 31, 2024; Month 3 by June 30, 2024; and Month 6 by July 31, 2024.
2. A topline safety summary for all participants (Cohorts A and B) through Month 6 (last patient last visit) from the CANOPY clinical trial by June 30, 2024.
3. An interim clinical study report for the CANOPY clinical trial with PK, safety and efficacy data for all participants (Cohorts A and B) through Month 6 (last patient last visit) by October 31, 2024.
4. All pharmacokinetic data and the bioanalytical report for all participants through Month 12 from the CANOPY clinical trial by March 31, 2025.
5. The final clinical study report for the clinical trial CANOPY by March 31, 2025.
6. Bimonthly (every 2 months) aggregate of post-EUA reports of severe or serious hypersensitivity reactions, including anaphylaxis. Sampson's criteria should be used to appropriately classify reported hypersensitivity reactions as anaphylaxis. In the bimonthly aggregate reports, include the following information at minimum.
    - Specific symptoms (preferred terms)
    - Severity of symptoms (for descriptive purposes)
    - Onset of event in relation to the infusion
    - Total dosage of pemivibart infused
    - Interventions taken (medications, hospitalization, etc.)
    - Duration of event
    - Outcome of event
7. All genotypic and phenotypic resistance analysis data for subjects failing pemivibart prophylaxis in the CANOPY clinical trial by August 30, 2024 (first batch of phenotypic data), March 31, 2025 (complete whole-genome sequence analysis data for Cohorts A and B), and April 30, 2025 (complete viral phenotypic data for Cohorts A and B).
8. Invivyd must submit spike sequence data for each treatment failure identified in the CANOPY trial as soon as practicable, but no later than 6 weeks after failure determination. Phenotypic data for spike variants with substitutions in the PEMGARDA epitope at contact and adjacent residues should be obtained and submitted within 2 calendar days from receipt from the contractor.

Q. Invivyd and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom PEMGARDA Is Distributed and Healthcare Providers Administering PEMGARDA

R. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of PEMGARDA as described in the Scope of Authorization (Section II) under this EUA.

S. Healthcare facilities and healthcare providers receiving PEMGARDA will track all serious adverse events and medication errors that are considered to be potentially related to PEMGARDA use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports must state, "PEMGARDA use for pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 must also be provided to Invivyd per the instructions in the authorized labeling.

T. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

U. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of PEMGARDA for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

V. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Invivyd and/or FDA. Such records will be made available to Invivyd, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

W. All descriptive printed matter, advertising, and promotional materials relating to the use of PEMGARDA under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling", or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of PEMGARDA under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.

- Not take the form of reminder advertisements or reminder labeling, as those terms are described in 21 CFR 202.1(e)(2)(i) and 21 CFR 201.100(f), respectively, except that reminder advertisements and reminder labeling intended only to provide price information to consumers, as described in 21 CFR 200.200, are permissible so long as such materials meet all conditions described in 21 CFR 200.200(a)(1)-(a)(4).
- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 for consideration at least 14 calendar days prior to initial dissemination or first use.

X. Invivyd may disseminate descriptive printed matter, advertising, and promotional materials relating to the emergency use of PEMGARDA that provide accurate descriptions of safety results and efficacy results on a clinical endpoint(s) or surrogate endpoint(s) from the clinical trial(s) summarized in the authorized labeling. Such materials must include any limitations of the clinical trial data as described in the authorized labeling. Invivyd may not imply that PEMGARDA is FDA-approved for its authorized use by making statements such as "PEMGARDA is safe and effective for the pre-exposure prophylaxis of COVID-19."

Y. All descriptive printed matter, advertising, and promotional material, relating to the use of PEMGARDA under this authorization clearly and conspicuously shall state that:

- PEMGARDA has not been approved, but has been authorized for emergency use by FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg); and

- The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

If the Agency notifies Invivyd that any descriptive printed matter, advertising, or promotional materials do not meet the terms set forth in Conditions W through Y of this EUA, Invivyd must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Invivyd to issue corrective communication(s).

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IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2024.04.03 11:54:53 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11640 Filed 5–24–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2245]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product; PAXLOVID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets, approved on May 25, 2023, manufactured by Pfizer, Inc., meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a) FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets, manufactured by Pfizer, Inc., meets the criteria for a material threat MCM priority review voucher. PAXLOVID was approved on May 25, 2023, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID–19) in adults who are at high risk for progression to severe COVID–19, including hospitalization or death.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv.* For further information about PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11643 Filed 5–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2219]

Progynon Associates, et al.; Proposal to Withdraw Approval of Four New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of four new drug applications (NDAs) and is announcing an opportunity for the NDA holders to request a hearing on this proposal. The basis for the proposal is that the NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: The NDA holders may submit a request for a hearing by June 27, 2024. Submit all data, information, and analyses upon which the request for a hearing relies July 29, 2024. Submit electronic or written comments by July 29, 2024.

ADDRESSES: The request for a hearing may be submitted by the NDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including