regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), is the subject of NDA 215252, held by Exela Pharma Sciences, LLC, and initially approved on October 28, 2021. DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% is indicated for the following: (1) temporary control of rapid ventricular rate in atrial fibrillation or atrial flutter; and (2) rapid conversion of paroxysmal supraventricular tachycardias to sinus rhythm.

DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Fresenius Kabi USA, LLC submitted a citizen petition dated March 5, 2024 (Docket No. FDA–2024–P–1131), under 21 CFR 10.30, requesting that the Agency determine whether DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DILTIAZEM HYDROCHLORIDE IN DEXTROSE 5% (diltiazem HCl), 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19233 Filed 8–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3925]

Authorization of Emergency Use of a Freeze-Dried Plasma Product for Treatment of Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat; 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 of a freeze-dried plasma product, octaplasLG Powder, for emergent treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

DATES: The Authorization is effective as of August 8, 2024.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 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: Andrew C. Harvan, 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

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces. Among other actions, 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 and other agents that may cause, or are otherwise associated with, an imminently life-threatening

and specific risk to U.S. military forces 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 Department of Health and Human Services (HHS) Secretary 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, United States Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) 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 under 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 the internet website of FDA. 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 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

On June 7, 2018, the Deputy Secretary of Defense determined that ''there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces.'' The Deputy Secretary of Defense further stated that, ''[m]ore specifically, U.S. [f]orces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.'' On July 9, 2018, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of freeze-dried plasma for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary of HHS was published in the **Federal Register** on July 16, 2018 (83 FR 32884) and a correction was published in the **Federal Register** on July 31, 2018 (83 FR 36941).

On February 22, 2024, Octapharma Pharmazeutika Produktionsges.m.b.H. (Octapharma) submitted a complete EUA request for octaplasLG Powder. Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, on August 8, 2024, FDA issued an EUA for octaplasLG Powder, manufactured by Octapharma, subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the

[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.

Authorization are available on the internet at *https://www.regulations.gov.*

BILLING CODE 4164–01–P

August 8, 2024

Octapharma Pharmazeutika Produktionsges.m.b.H.
c/o Sergio Alegre
Octapharma USA Inc.
117 West Century Road
Paramus, NJ 07652

Dear Mr. Alegre,

This letter is in response to Octapharma Pharmazeutika Produktionsges.m.b.H.'s (Octapharma) request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of octaplasLG Powder (blood group types A and AB)[1] for U.S. military forces[2] for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On June 7, 2018, pursuant to section 564(b)(1)(B) of the Act (21 U.S.C. § 360bbb-3(b)(1)(B)), the Deputy Secretary of the Department of Defense (DoD) determined that there is "a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces."[3,4,5] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, on July 9, 2018, the Secretary of the Department of Health and Human Services (HHS) then declared that circumstances exist justifying the authorization of emergency use of freeze dried

[1] Hereafter octaplasLG Powder (blood group types A and AB) will be referred to as octaplasLG Powder.

[2] For purposes of this EUA, the term "U.S. military forces" may include troops, civilians, contractors, and allied military personnel operating with Department of Defense. Also, for purposes of this EUA, it is anticipated that U.S. military medical personnel trained in the use of octaplasLG Powder will administer the authorized octaplasLG Powder to U.S. military forces. However, in the event the operational environment prevents such administration, it is possible that other trained U.S. military forces may need to administer the authorized octaplasLG Powder during an emergency as set forth in this authorization.

[3] DoD. *Letter to the HHS Secretary issuing a determination of a military emergency, or significant potential for a military emergency, and requesting a declaration under section 564 of the Federal Food, Drug, and Cosmetic Act.* June 7, 2018.

[4] Under section 564(b)(1)(B) of the Act, the Secretary of Defense may make a determination that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with—**(i)** a biological, chemical, radiological, or nuclear agent or agents; or **(ii)** an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces.

[5] When the DoD Secretary makes such a determination, the Secretary of Health and Human Services (HHS) shall determine, within 45 calendar days of such determination, whether to make a declaration that circumstances exist to justify EUA issuance and, if appropriate, shall promptly make such a declaration.

plasma for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.[6]

Octapharma requested this EUA so that octaplasLG Powder, which is not FDA-approved, may be acquired, distributed, and held by DoD for preparedness purposes in advance of an actual threat of agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces, with the intent that it may be administered by U.S. military medical personnel or other Authorized Providers[7] during an event or post-event for the treatment of hemorrhage or coagulopathy caused by exposure to agents of military combat when plasma is not available for use or when the use of plasma is not practical. An EUA is needed to facilitate DoD pre-event planning and preparedness activities related to the acquisition and use of this non-FDA approved product to enable activities to support rapid administration of treatment during an actual emergency event involving the threat of agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces.

This EUA is important for supporting military emergency response because it enables rapid initiation of treatment with octaplasLG Powder during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces, without FDA or DoD having to take further action with respect to otherwise applicable requirements under federal law.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of octaplasLG Powder (as described in the Scope of Authorization section of this letter (Section II)) in the specified population for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces when plasma is not available for use or when the use of plasma is not practical, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of octaplasLG Powder for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces when plasma is not available for use or when the use of plasma is not practical in the specified population, when administered

[6] HHS. *Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)*. July 9, 2018.

[7] Authorized Providers are medical personnel trained in the use of octaplasLG Powder who may administer the authorized octaplasLG Powder to U.S. military forces. In the event the operational environment prevents such administration, other trained U.S. military forces may need to administer the authorized octaplasLG Powder as Authorized Providers during an emergency as set forth in this authorization.

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 I have concluded that:

1. Agents of military combat (e.g., firearms, projectiles, and explosive devices) can cause, or otherwise be associated with a serious or life-threatening disease or condition to humans exposed to these agents, specifically hemorrhage or coagulopathy during an emergency when plasma is not available for use or when the use of plasma is not practical;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that octaplasLG Powder, when used in accordance with the Scope of Authorization, may be effective for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, and that the known and potential benefits of octaplasLG Powder for this use outweigh the known and potential risks of such product;

3. There is no adequate, approved, and available alternative to the emergency use of octaplasLG Powder; and

4. The Deputy Secretary of Defense has requested emergency use of this product for treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.[8]

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:

- Octapharma will supply octaplasLG Powder, either directly or through authorized distributor(s) to DoD as directed by DoD, for use consistent with the terms and conditions of this EUA.
- octaplasLG Powder will be used for U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

Product Description

octaplasLG Powder is a biological product to be used for U.S. military forces for treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces when plasma is not available for use or when the use of plasma is not practical.

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

octaplasLG Powder is an unapproved lyophilized plasma product created from the FDA approved, pooled, solvent/detergent treated plasma product, Octaplas. Octaplas is manufactured from human plasma collected in US licensed plasma donation centers. All plasma donations are tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. octaplasLG Powder is presented as a powder for solution for intravenous infusion, filled into and freeze-dried in glass vials, with each product vial containing 9-14 g of A- or AB-blood group specific human plasma protein and is reconstituted with 190 ml of water for injections (WFI) solvent. Prior to reconstitution, octaplasLG Powder can be stored at +2°C to +25°C for 24 months.

octaplasLG Powder is authorized to be distributed with an FDA cleared or approved transfusion filter set.

octaplasLG Powder is authorized to be distributed as directed by DoD for storage, distribution, and administration, when packaged in the authorized packaging and with the authorized labeling (e.g., carton and container labels, fact sheets).

octaplasLG Powder is authorized to be administered without a prescription and by U.S. military medical professionals or other authorized providers under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

octaplasLG Powder is authorized for emergency use with the following information required to be made available to medical professionals or other authorized providers and recipients (to the extent practicable given the emergency circumstances) when plasma is not available for use or when the use of plasma is not practical.

- Fact Sheet for Health Care Professionals or Other Authorized Providers
- Fact Sheet for Recipients

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized octaplasLG Powder in the specified population, when used for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

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 the authorized octaplasLG Powder may be effective in the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized octaplasLG Powder, when used for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized octaplasLG Powder product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Deputy Secretary of Defense's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the octaplasLG Powder described above is authorized for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical in the specified population.

III. Conditions of Authorization

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

Octapharma

A. Octapharma will ensure that the authorized octaplasLG Powder will be distributed as directed by DoD, and the authorized Fact Sheet for Health Care Professionals or Other Authorized Providers, the authorized Fact Sheet for Recipients, and any other labeling that FDA may authorize, as well as any authorized amendments thereto will be made available to applicable DoD components.

B. Octapharma, in consultation with DoD, may request changes to this authorization, including the authorized Fact Sheet for Health Care Professionals or Other Authorized Providers and the authorized Fact Sheet for Recipients, the authorized labeling (e.g., carton and container labels, label on each packaged unit) and authorized packaging for the authorized octaplasLG Powder, or to the manufacturing, labeling, and packaging processes of Octapharma or its authorized agent(s) for the authorized product. Any request for changes to this EUA must be submitted to Office of Blood Research and Review (OBRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[9]

[9] 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. All changes to the authorization require review and concurrence from OBRR. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and

C. Octapharma will ensure that the terms of this EUA are made available to DoD. Octapharma will provide applicable DoD components a copy of this letter of authorization and communicate to applicable DoD components any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., Fact Sheets).

D. Octapharma will inform applicable DoD components about the need to have a process in place for performing adverse event monitoring designed to ensure that suspected adverse reactions and all medication errors associated with the use of the authorized octaplasLG Powder are reported to Octapharma. Octapharma will conduct any follow-up requested by FDA regarding adverse events, to the extent feasible given the emergency circumstances.

E. Octapharma will ensure that the authorized octaplasLG Powder is distributed within the expiry dating period.

F. Octapharma will ensure that the authorized octaplasLG Powder is distributed with an FDA cleared or approved transfusion filter set.

G. Octapharma will post on its website the following statement: "For information about the FDA-authorized emergency use of octaplasLG Powder please see: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization."

H. Octapharma will promptly notify FDA of any suspected or confirmed quality, manufacturing, distribution, and/or other issues with the authorized octaplasLG Powder of which it becomes aware.

I. Octapharma will establish a Collaborative Research and Development Agreement (CRADA) with DoD to collect data related to use of octaplasLG Powder under combat conditions. These data will be collected whenever octaplasLG Powder is transfused to patients to the extent practicable given the emergency circumstances. Collected data will include suspected adverse reactions, including serious and unexpected adverse reactions, and any medication errors associated with the use of the authorized octaplasLG Powder. Octapharma will report data to FDA on an annual basis.

J. Octapharma must submit to the Emergency Use Authorization submission file periodic safety reports annually, or at another appropriate interval determined by CBER, in accordance with a due date agreed upon with OBRR/CBER beginning after the first full calendar month after authorization. Each periodic safety report must contain descriptive information which includes:
   - A narrative summary and analysis of suspected adverse reactions submitted during the reporting interval, including interval and cumulative counts by age groups;

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concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER.

- A narrative summary and analysis of medication errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval;
- Actions taken since the last report because of adverse experiences;
- Cumulative doses distributed, and doses distributed during the reporting interval.

K. Octapharma will report to FDA, as soon as possible, any serious and unexpected suspected adverse reaction that is not described under 'Risks and Adverse Events' in the authorized Fact Sheet for Health Care Professionals or Other Authorized Providers and any suspected adverse reaction resulting in death. Octapharma will conduct any follow-up requested by FDA regarding adverse events, to the extent feasible given the emergency circumstances.

L. Upon request by FDA, Octapharma will make available any records maintained in connection with this letter.

DoD

M. DoD will distribute the authorized octaplasLG Powder under its direction to the extent such decisions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling (e.g., Fact Sheets).

N. Through a process of inventory control, DoD will maintain records regarding distribution under its direction of the authorized octaplasLG Powder (e.g., lot numbers, quantity, receiving site, receipt date).

O. DoD will ensure that the terms of this EUA are made available to applicable DoD components through applicable DoD communication channels and procedures.[10] DoD will provide applicable DoD components a copy of this letter of authorization and communicate to applicable DoD components any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., Fact Sheets).

P. DoD will inform applicable DoD components that the authorized octaplasLG Powder may be used only by U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

Q. DoD will be responsible for authorizing components acting as part of a DoD response to administer the authorized octaplasLG Powder in accordance with the terms of this EUA, including instructing such components about the terms of this EUA with regard to storage, distribution, and administration, and for instructing about the means through which they are to obtain and use the authorized octaplasLG Powder.

[10] For example, through pre-deployment training, hard copy, web posting, etc.

R. DoD will train applicable DoD components on the use of the authorized octaplasLG Powder in accordance with this EUA and any applicable DoD procedures or protocols.

S. DoD will make available to applicable DoD components through applicable DoD communication channels and procedures the authorized Fact Sheet for Health Care Professional or Other Authorized Providers, the authorized Fact Sheet for Recipients, and any other Fact Sheets that FDA may authorize, as well as any authorized amendments thereto.[11] U.S. military medical personnel or other authorized providers administering the authorized octaplasLG Powder will ensure that the authorized Fact Sheet for Recipients has been made available to U.S. military forces that receive octaplasLG Powder through appropriate means, to the extent feasible given the emergency circumstances. Under exigent circumstances, other appropriate means for disseminating these Fact Sheets may be used.[12]

T. DoD will inform applicable DoD components about the need to have a process in place for performing adverse event monitoring designed to ensure that suspected adverse reactions and all medication errors associated with the use of the authorized octaplasLG Powder are reported to Octapharma, to the extent practicable given emergency circumstances, in according with the conditions of the EUA. Submitted reports should state that octaplasLG Powder was used under an EUA.

U. DoD will have a process in place for recording and reporting of data, as outlined in a CRADA to be established between DoD and Octapharma. These data will be recorded whenever octaplasLG Powder is transfused to patients to the extent reasonable and practicable given the emergency circumstances. Collected data will include suspected adverse reactions and any medication errors associated with the use of the authorized octaplasLG Powder.

V. DoD will report to Octapharma, as soon as reasonably possible, any serious and unexpected suspected adverse reaction that is not described under 'Risks and Adverse Events' in the authorized Fact Sheet for Health Care Professionals or Other Authorized Providers and any suspected adverse reaction resulting in death.

W. DoD will ensure that the authorized octaplasLG Powder is distributed for use under its direction within the expiry dating on the manufacturer's labeling

X. Per the terms of the CRADA with Octapharma, DoD will work with Octapharma to ensure that any records associated with the use of this product under this EUA are maintained, to the extent practicable given the emergency circumstances, until notified by FDA. Upon request by FDA, DoD will make available these and any other records maintained in connection with this letter.

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[11] For example, through pre-deployment training, hard copy, web posting, etc.

[12] FDA recognizes that the complex environment in which octaplasLG Powder may be used may prevent dissemination of Fact Sheets at the time of use of the octaplasLG Powder. Therefore, "other appropriate means" may include activities such as DoD components sharing the Fact Sheet for Recipients with U.S. military forces in pre-deployment or other training.

Y. DoD will promptly notify FDA of any suspected or confirmed quality, manufacturing, distribution, and/or other issues with the OctaplasLG Powder of which it becomes aware.

Conditions Related to Descriptive Printed Material

Z. All descriptive printed matter relating to the use of the authorized octaplasLG Powder shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

AA. All descriptive printed matter relating to the use of the authorized octaplasLG Powder shall clearly and conspicuously state that:

- This product has not been FDA approved or licensed;
- This product has been authorized by FDA under an EUA for use by DoD;
- This product has been authorized only for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical; and
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of octaplasLG Powder for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No descriptive printed matter relating to the use of the authorized octaplasLG Powder may represent or suggest that this product is safe or effective for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of octaplasLG Powder for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Peter W. Marks -S

Digitally signed by Peter W. Marks -S
Date: 2024.08.08 10:34:14 -04'00'

Peter W. Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research

Enclosures

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18971 Filed 8–26–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: 0937–0191–30D]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 26, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937–0191–30D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Collection: Reinstatement, with no change.

OMB No.: 0937–0191.

Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Real Property Assistance Program is requesting OMB approval on a previously approved information collection, 0937–0191. 40 U.S.C. 550 (the ''Act''), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held exempt from taxation under Section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Type of Respondent: Responses are dependent on when Federal surplus real property is made available and is desired by a respondent/applicant for acquisition. Likely respondents include State, local, or tribal units of government or instrumentalities thereof, and not-for-profit organizations.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Applications for surplus Federal real property		10	1	200	2,000
Total		10	1	200	2,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–19250 Filed 8–26–24; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7082–N–07]

60-Day Notice of Proposed Information Collection: Disaster Recovery Grant Reporting System (DRGR), OMB Control No.: 2506–0165

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 28, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; email *PaperworkReductionActOffice@hud.gov*.

FOR FURTHER INFORMATION CONTACT: Tennille Smith Parker, Director, Disaster Recovery and Special Issues Division, email *Tennille.Parker@HUD.gov,* telephone (202) 402–4649 or Robert C. Peterson, Director of State and Small Cities, email *Robert.C.Peterson@hud.gov,* Office of Block Grant Assistance, telephone (202) 402–4211, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Pollard.