JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE

The Use of Dried Plasma in the Deployed Trauma System and Contingency Operations

This Clinical Practice Guideline (CPG) provides guidance and recommendations for the use of dried plasma in combat casualty care.

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INTRODUCTION

Damage control resuscitation is a bundle of care consisting of early transfusion with whole blood (WB) or balanced component therapy, early hemorrhage control, minimal use of crystalloid, administration of tranexamic acid (TXA), and rapid transport to forward surgical care.[1-5] Data indicates that if (1) blood products are transfused within 36 minutes from wounding[6] and (2) a casualty makes it to a surgical capability within 60 minutes, patient survival is improved (> 80% reduction in mortality risk).[7-9] Early transfusion saves lives. However, whole blood or balanced component therapy transfusion is not always available in prehospital or logistically constrained environments. [10]

Hemostatic resuscitation, using whole blood or balanced component therapy, is integral to an effective damage control resuscitation strategy.

While whole blood remains the preferred resuscitative fluid for bleeding patients; [11,12] in the absence of whole blood, a balanced component therapy ratio resuscitation (1:1:1) should be performed.[13] Plasma is an integral part of a balanced or 'hemostatic' resuscitation.[14,15] Dried plasma (DP), as opposed to liquid or fresh frozen plasma, has logistical advantages given that it is temperature stable and has a long shelf life, making it ideal for operational environments. Early administration of plasma has been demonstrated to decrease mortality.[16,17] **This guideline underscores that dried plasma is a complement to, not a replacement for, whole blood or balanced component resuscitation.** Whole blood remains the preferred resuscitative fluid for severe hemorrhage, but dried plasma provides a critical contingency option when WB or liquid plasma are not readily available.[18,19] Dried plasma has the potential to bridge the gap between injury and balanced resuscitation by restoring coagulation factors and volume support in the far-forward setting.[20,21] **Dried plasma is a universal product that can be administered to any patient regardless of blood group.**

The Military Health System has begun fielding dried plasma to U.S. Military forces under two separate Emergency Use Authorizations (EUAs).

It is important to note that dried plasma is not a novel therapy. Its use represents the reintroduction of a once proven but long-absent resuscitative product, updated with modern safety standards and manufacturing methods to minimize transfusion transmitted infection and adverse reactions.[22] This renewed development reflects the emphasis of early transfusion as well as operational demands of future combat casualty care within expeditionary environments where medical providers require flexible and reliable resuscitation strategies under conditions of constrained logistics.[20]

All types of dried plasma must be reconstituted with sterile water per the manufacturer's recommendations. Reconstitution effects utilizing other solutions remain unknown and may cause harm.

Dried plasma represents an important capability for austere and forward operational environments where conventional plasma is unavailable. Unlike liquid or fresh frozen plasma, dried plasma does not require cold chain support, is stored at room temperature for extended periods, and rapidly reconstitutes with sterile water at the point of care.

Dried plasma is intended to be used when whole blood or balanced component therapy is not readily unavailable. For planning considerations, it is not a replacement for whole blood or hemostatic resuscitation. Providers must document all dried plasma use so clinical outcomes are better understood to allow improvements in future care.

HISTORY & EVOLUTION OF DRIED PLASMA IN BATTLEFIELD MEDICINE

The use of dried plasma on the battlefield dates back to World War II. The U.S., Canada, and U.K. produced pooled freeze-dried plasma to treat combat casualties. These early preparations, while lifesaving, carried a high risk of transmitting hepatitis due to the pooling of plasma from multiple donors before the advent of modern viral testing. By the late 1950s, concerns over safety led the U.S. Military to discontinue its use of dried plasma, shifting instead to fresh frozen plasma (FFP) and later component therapy supported by an expanding cold chain infrastructure. [23-25]

Freeze dried plasma (FDP) at one point became the preferred treatment for hemorrhage secondary to its ease of use compared to WB, however, it was a lesson learned in World War II that WB is necessary for hemorrhaging casualties and that FDP is only a bridge to whole blood, but one that could potentially be a successful Golden Hour extender.

A Navy corpsman tends to a wounded Marine on Okinawa, Japan, May 1945. The corpsman is using the rifle as a plasma holder.

Service member being given plasma after he was wounded by shrapnel in Sicily on Aug. 9, 1943. Courtesy of Franklin D. Roosevelt Library

In contrast, other nations continued to refine and employ dried plasma. The German military introduced a freeze-dried plasma product, which saw widespread use in World War II and was further developed for Bundeswehr use in later decades by the German Red Cross. The French military adopted dried plasma in the 1940s and has maintained its use into the present day, deploying it in both combat and humanitarian missions.[26,27] Tens of thousands of units of French FDP have been administered safely, providing the most extensive modern clinical experience with this product type.

This historical record demonstrates that dried plasma is neither experimental nor untested. Rather, it has a long legacy of use on the battlefield, now being modernized for safety and integrated into contemporary trauma systems. By revisiting and updating its role in combat casualty care, dried plasma can once again fill a critical gap in forward resuscitation, particularly when cold chain logistics cannot support conventional plasma or WB delivery. Current dried plasma development complies with cGMP manufacturing, ensuring safety and traceability consistent with modern Food and Drug Administration (FDA) oversight. Modern processes such as solvent/detergent treatment, nanofiltration, and pathogen inactivation have been key to preventing the disease transmission concerns that halted its use in the United States after World War II.

Dried plasma is currently being fielded in the U.S. Military as a contingency product intended for forward deployed environments when WB or balanced component therapy is unavailable. It is not a replacement for whole blood or hemostatic resuscitation. Documentation of all dried plasma use is critical to inform future clinical recommendations and support a data-driven battlefield trauma system.

CONSIDERATIONS: USE OF DRIED PLASMA IN DEPLOYED ENVIRONMENTS

Currently, there are renewed clinical and operational needs that have driven NATO militaries, including Germany, Norway, and France, to prioritize dried plasma in their resuscitation strategies. The U.S. Department of War, Health and Human Services' Biomedical Advanced Research and Development Authority, and academic centers have reinitiated research and development programs to bring freeze-dried and spray-dried plasma products to licensure under FDA oversight. Multiple investigational products are currently in preclinical or clinical evaluation. As these products are fielded to operational environments, documentation of use and outcomes will be required for the medical record and if the product is under an EUA by the FDA.

While several manufacturers are developing innovative freeze-dried (lyophilized) and sprayed-dried formulations of dried plasma, as of the date of publication for this CPG, the U.S. Military has fielded two dried plasma products under an EUA from the FDA; (1) Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armees (further referred to as "French FDP or FLYP") and (2) octaplasLG Powder manufactured by Octapharma USA. Both of these formulations utilize pooled plasma and a freeze-drying process to produce a shelf stable powder in a glass bottle for reconstitution with sterile water at the point of care. There are no comparative efficacy studies that have evaluated clinical outcomes from use of the different types of dried plasma in bleeding patients. As the military fields more than one type of dried plasma, it is imperative that clinical documentation occurs to better understand the resuscitative efficacy of these products.

Multiple planning considerations should be accounted for when fielding dried plasma to the unit level. Both available formulations are manufactured in a glass bottle with risk of breakage if not adequately protected during transportation and storage in tactical environments. Additionally, the volume of sterile water for reconstitution is unique for each manufacturing process and must be adhered to. There are unique attributes of rigid glass bottle storage that require a vented administration line to allow flow of the reconstituted plasma. It is not possible to utilize pressure bags, pressure infusers or "squeezing the bag" to increase flow rates during administration; therefore, anticipate potentially slower administration times. The manufacturers of both French FDP and octaplasLG Powder recommend using filtered administration lines (included in the packaging) given the theoretical risk of infusing residual particulate matter that were not fully reconstituted. While both products are shelf stable for two years when stored between 2-25 degrees Celsius (35.6°F-77°F), degradation of coagulation factors and proteins should be expected if prolonged and extreme temperature excursions occur in storage or tactical employment.

The FDA has placed requirements for U.S. Military utilization of dried plasma products under their respective EUAs, to include specific training, documentation and reporting mandates. Providers must familiarize themselves with the product specific requirements as outlined further in this CPG. Additional training resources can be found at deployedmedicine.com or the Joint Trauma System website at https://jts.health.mil/

INDICATIONS FOR DRIED PLASMA USE

- Casualties with life-threatening hemorrhage/coagulopathy where whole blood or balanced component resuscitation is not immediately available (potential Golden Hour Extender).
- As part of a balanced component therapy resuscitation as substitution for liquid or frozen plasma if they are not readily available.
- May be used aboard ships when other products are not available.
- Dried plasma may be used prior to determining the recipient's blood group.

CONTRAINDICATIONS

- Prior severe transfusion reaction (rare in the acute combat setting).
- IgA deficiency
- Severe deficiency of Protein S

ADVANTAGES

- It is most valuable in Role 1 and Role 2 environments, during prolonged casualty care, and during long-range or constrained evacuation scenarios where cold chain support is limited or absent.
- Long shelf life at room temperature.
- Light, compact, and portable; suitable for austere or constrained logistics environments.
- Rapid reconstitution at point of care.
- Demonstrated efficacy in correcting trauma-induced coagulopathy.

LIMITATIONS

- For octaplasLG Powder, the documentation in the Case Report Form (CRF) must be filled out by providers and submitted.
- For French FDP, documentation of use will be provided to a site coordinator who will ensure completion of the CRF.
- The Serious Adverse Event (SAE) form is required in event of serious adverse events.
- Dried plasma provides coagulation factors for secondary hemostasis, but not red cell mass or platelets, and therefore must be integrated into a broader damage control resuscitation strategy that includes oxygen carrying capability and primary hemostasis.
- Factor V and VIII stability vary by product and may be lower compared to thawed plasma.
- General civilian use is not available, though an FDA Emergency Use Authorization has been granted for specific military applications.
- There are no comparative efficacy studies on the different types of dried plasma available.

OPERATIONAL ROLE

- Dried plasma complements whole blood and component therapy by extending coagulation support until definitive transfusion is available.
- Dried plasma has the potential to bridge the time gap until whole blood or balanced component therapy can be administered prior to surgical hemorrhage control.
- It should be integrated into damage control resuscitation framework and should not be seen as a standalone capability, but as part of a bundle of battlefield resuscitation to include ASBP-supplied whole blood, balanced component therapy, walking blood banks, TXA, early hemorrhage control and prompt evacuation to forward surgical care.

Dried plasma is not a substitute for whole blood or hemostatic resuscitation with balanced component therapy. There are no comparative effectiveness studies looking at clinical outcomes of the different dried plasma products. It is imperative that providers at all roles of care document the use of dried plasma. Without good documentation, the Joint Force will not know the clinical outcomes of dried plasma use on the battlefield.

DRIED PLASMA IMPLEMENTATION FOR EACH ROLE OF CARE

PREHOSPITAL / ROLE 1

Tactical Combat Casualty Care (TCCC) Guidelines were developed to address care delivered in a prehospital environment prior to surgical capability where unique clinical and operational constraints differ from other battlefield roles of care. The TCCC Guidelines recognize tactical requirements and logistical constraints to include a limited number of medical responders, ongoing operations, constraints on cube/weight for medical equipment, and challenges with ensuring cold-chain storage for blood products.

Accordingly, TCCC recommends the following resuscitation fluids of choice for casualties in hemorrhagic shock, listed from most to least preferred:

1. Cold stored low titer O whole blood
2. Pre-screened low titer O fresh whole blood
3. Plasma, red blood cells (RBCs) and platelets in a 1:1:1 ratio
4. Plasma and RBCs in a 1:1 ratio
5. Plasma or RBCs alone

Dried plasma can be used when:

1. First line FDA compliant cold-stored low titer O whole blood is not available
2. Collection or transfusion of prescreened low titer O whole blood from a walking blood bank is delayed AND time-critical resuscitation warrants prompt volume resuscitation to stabilize a patient until fresh whole blood is available. Examples may include:
    - Delayed donor response time following walking blood bank activation due to physical distance or enemy threat
3. Used as a liquid or fresh frozen plasma substitute in 1:1 resuscitation with RBCs, when conventional plasma products are not readily available
4. Neither whole blood nor traditional plasma components are readily available, to provide hemostatic support until able to perform a balanced resuscitation

ROLE 2 & ROLE 3: FORWARD SURGICAL CARE

At both Role 2 and Role 3 MTFs, dried plasma can be used as a critical adjunct to resuscitation strategies if whole blood is not immediately available. Dried plasma can also be treated as a regular plasma product within the damage control resuscitation framework. The use of dried plasma **must be documented** to include type of dried plasma product and the time of transfusion.

Dried plasma can be used when:

1. First line FDA approved cold-stored low titer O whole blood is not available
2. Collection or administration of second and/or third line products (fresh frozen or liquid plasma) is delayed AND time-critical resuscitation warrants prompt resuscitation to stabilize a patient until other products are available. Examples may include:
    - Fresh frozen plasma has not been thawed and ready for transfusion.
    - Delayed donor response time following walking blood bank activation due to physical distance or enemy threat.
    - Time to fill out prescreening donor questionnaire impacts resuscitation (if donor pool has not been prescreened).

- Required time for rapid lab or point of care testing of previously unscreened donors.
- Required time for lab testing of previously unscreened donors at a lab capable facility.

3. Dried plasma can be used as an FFP or liquid plasma substitute in 1:1 resuscitation with RBCs.

Other considerations: Plasma has shown efficacy in both burn resuscitation and severe Traumatic Brain Injury (TBI). Many burn centers use plasma instead of crystalloid to resuscitate burn patients. For TBI, there is strong preclinical evidence that plasma decreases the size of hemorrhagic injury. The 2026 TCCC Guidelines adopted plasma use for TBI.

Dried plasma can be used in place of liquid plasma or FFP for both burn and TBI resuscitation. All uses must be documented; this cannot be overstated. Documentation of combat casualty care is how the battlefield trauma system evolves and care is improved.

Ensure dried plasma utilization (transfused or destroyed) is documented and EUA/SAE forms from prior roles of care are scanned into the Theater Medical Data Store/Theater Blood Mobile or appropriate operational blood IT system.

OCTAPLASLG POWDER PRODUCT ADMINISTRATION

The EUA for octaplasLG Powder allows use 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."

octaplasLG® Reconstitution Guide

Reconstitution of octaplasLG® powder should be done at room temperature.

1. Remove the flip-off cap from the powder bottle (octaplasLG®) to expose the central portion of the rubber stopper.
2. Disinfect the rubber stopper with an alcohol swab and allow the rubber stopper to dry.

3. Remove the blister from the transfer set and
4. close the clamp on the transfer line.

5. Remove the outer packaging of the WFI bag.
6. Remove the blue protective cap from the bag outlet.
7. Do not touch the rubber stopper of the outlet to maintain sterility.

8. Connect the transfer set to the powder bottle by perforating the rubber stopper centrally with the spike.
9. Open the ventile next to the spike.

10. Connect the transfer set to the WFI bag by pushing the needle through the blue outlet.

11. Make sure that the transfer set is well connected, hold/hang the WFI bag vertically above the powder bottle.
12. Open the clamp; the WFI flows automatically into the powder bottle.
13. Start with gently swirling the powder bottle during the WFI transfer.
14. When the transfer is completed, remove the spike from the powder bottle and discard the transfer set and the empty WFI bag. Continue with gently swirling the powder bottle until the powder is fully dissolved.
15. Do not shake the bottle to avoid foam formation.

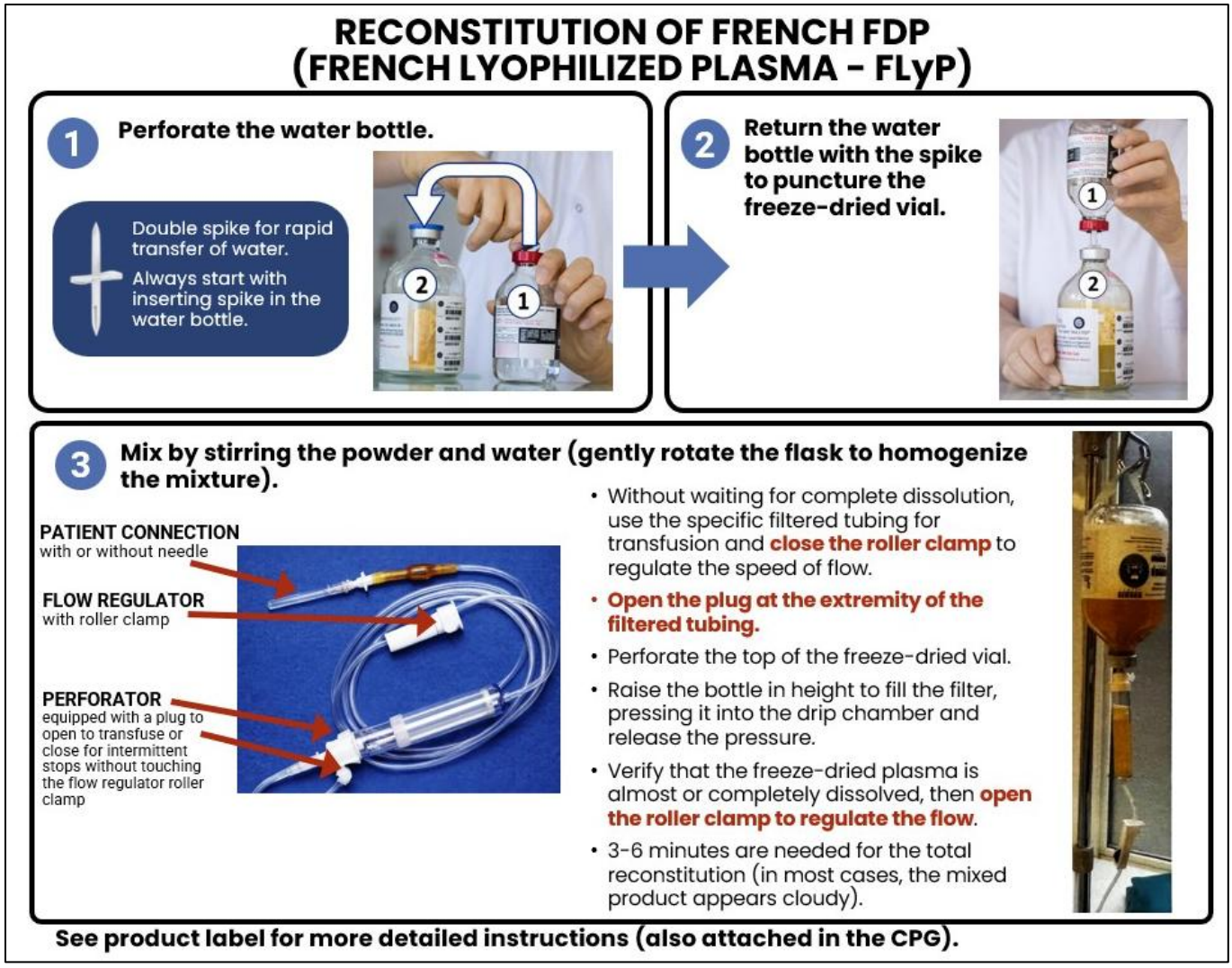
16. The reconstituted solution should be clear or slightly opalescent.

Health care professionals or other authorized providers need to familiarize themselves with the fact sheet for providers (Appendix C) and with the following steps for product administration:

1. Always use aseptic technique when connecting the transfusion set with the vented spike adaptor and the vial.
2. Remove the blister from the transfusion set and the blister from the vented spike adaptor.
3. Remove the protective cap from the spike of the transfusion set. Slide the vented spike adaptor onto the spike of the transfusion set. Then remove the protective cap from the spike of the adaptor.
4. Connect the transfusion set with the adaptor to the powder bottle (octaplasLG Powder) by perforating the rubber stopper centrally with the spike of the adaptor.
5. Ensure the spike is fully inserted into the vial so that liquid can flow through the tubing.
6. Gently squeeze the drip chamber of the transfusion set to fill it partially with liquid.
7. Transfuse the product according to your established clinical protocols. Patients' vital signs should be closely monitored throughout the infusion as conditions permit.
8. Repeat administration as medically necessary.

FRENCH FDP (FRENCH LYOPHILIZED PLASMA – FLYP) PRODUCT ADMINISTRATION

The EUA for French FDP (French Lyophilized Plasma - FLYP) allows use 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."



Health care professionals or other authorized providers need to familiarize themselves with the fact sheet for providers (Appendix G) and with the following steps for product administration:

1. Bring the two flasks (powder and solvent) to room temperature (+20°C to +25°C) (68°F- 77°F) if necessary.
2. Remove the protective capsules from the two flasks.
3. Disinfect the surface of each lid.
4. Pierce the lid of the flask containing the water first with one of the bevels of the transfer set. Be sure that you spike the water first. If you accidentally spike the powder first, you will lose the vacuum and then be unable to transfer the water to the bottle of powder using the transfer set.
5. Use the other bevel to pierce the lid of the flask containing the powder.
6. Pour the entire contents of the water flask into the flask containing the powder via the transfer set.
7. Gently agitate the flask making horizontal rotations without generating a foam (do not shake) to homogenize the mixture.
8. Wait 3 to 5 minutes for the product to dissolve entirely before injecting.
9. Before infusion, check that the glass flask is intact. Do not use the contents of a damaged flask under any circumstances.
10. Obtain a set of pre-infusion vital signs if tactical conditions permit.
11. Prior to infusion, you must open the vent on the sterile tubing set. Using the intravenous infusion set provided, immediately administer the entire preparation intravenously.
12. Obtain a set of post-infusion vital signs if tactical conditions permit.
13. Closely monitor the patient for signs of an adverse reaction (e.g., fever, rash, hives, difficulty breathing, flank pain, darkening urine) and for adequacy of resuscitation (return of radial pulse or improvement in systolic blood pressure to approximately 90 mm Hg, improvement in mental status, improved hemorrhage control).

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All trauma patients who receive Dried Plasma transfusion(s) as part of a resuscitation strategy, whether in lieu of or in conjunction with whole blood and/or balanced component blood products.

INTENT (EXPECTED OUTCOMES)

1. Dried plasma will NOT be transfused when whole blood or balanced component therapies are readily available.
2. Indication for transfusion of dried plasma will be clearly documented.
3. The Dried Plasma Case Report Form will be completely filled out for each patient receiving dried plasma.
4. Reconstitution of dried plasma products will be done only with sterile water, as reconstitution effects using products other than sterile water have not been tested.
5. Pre- and post-transfusion vital signs will be clearly documented for each transfusion of dried plasma.
6. All instances of adverse reaction will be documented on the Severe Adverse Event Form.

PERFORMANCE / ADHERENCE METRICS

1. Instances of dried plasma transfusion in which the Dried Plasma Case Report Form was entirely completed and submitted.
2. Dried plasma transfusion in accordance with specified indications and clear documentation of indication.
3. Dried plasma product reconstituted with sterile water.
4. Documentation of pre- and post-transfusion vital signs.
5. Severe Adverse Event form was completed to document any adverse reaction or event.

DATA SOURCE

- Blood transfusion databases: Theater Medical Data Store (TMDS) or Theater Blood Mobile
- DoD Trauma Registry
- Patient Record
- EUA forms

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed. The system review and data analysis will be performed by the Joint Trauma System (JTS) Chief and the JTS PI team.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance, and PI monitoring at the local level with this CPG.

DOTMLPF-p and Documentation Requirements for the Use of Dried Plasma in the Deployed Trauma System and Contingency Operations	
Doctrine	Joint Publication 4-02, Joint Health Services; TM 8-227-12, Joint Blood Program Handbook; TM 8-227-11, Operational Procedures for the Armed Services Blood Program; Service specific policies and warfighting publications.
Organization	Prehospital, enroute and forward surgical teams from each Service must be organized to support the delivery of dried plasma at each Role of Care. Teams must be organized and equipped to deliver dried plasma as part of planned hemostatic resuscitation strategy. ASBP should serve as enterprise lead for dried plasma accountability and reporting.
Training	Applicable Service units must have the appropriate training to deliver dried plasma, document the care, and monitor clinical effectiveness as required under the EUAs.
Materiel	Dried plasma products are currently available for fielding. Expect this to expand to include additional commercial product availability. Service specific medical units must be aware of the different types of dried plasma being delivered to the Joint Force.
Leadership & Education	Military Medical Services, ASBP, and JTS leadership must ensure that units are prepared, trained and understand the indications for the use of all dried plasma products. Dried plasma should be prioritized for prehospital providers and forward deployed medical units. Leaders must emphasize that dried plasma is not a substitute for whole blood resuscitation.
Personnel	Ensure deploying providers complete dried plasma reconstitution and administration training prior to deployment.
Facilities	Units which store dried plasma will need to maintain accountability of the number of units and report their status to the regional Joint Blood Program Officer and Trauma Medical Director. Storage temperatures and expiration dates of the dried plasma must be maintained within acceptable limits.
Policy	Policies as necessary to support production and utilization of dried plasma.
Documentation Requirements	1)Pretransfusion vitals; 2) Mechanism of Injury; 3) Time of transfusion of each blood product transfused; 4) Type of dried plasma transfusion; 5) post transfusion vital signs

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APPENDIX A: OCTAPLASLG POWDER CASE REPORT FORM

EUA FDP LOA 08-AUG-2024
(Octapharma; OctaplasLG Powder; ABO Compatibility)

Case Report Form
v.1.0 (01-APR-2026) FINAL

Participant ID: 000 - 000 (Site # - Patient #) Reset

A. Participant's Information

a1. Recipient Informed Date	or ☐ Not Reported
a2. Birth Date	or Age: yrs
a3. Sex (at birth) *(Check (✓) only one)*	☐ Male ☐ Female ☐ Not Reported
a4. Race/Ethnicity *(Check (✓) all that apply)*	☐ American Indian or Alaska Native, *specify national origin:* ☐ Asian, *specify national origin:* ☐ Black or African American, *specify national origin:* ☐ Hispanic or Latino, *specify national origin:* ☐ Middle Eastern or North African, *specify national origin:* ☐ Native Hawaiian or Pacific Islander, *specify national origin:* ☐ White, *specify national origin:* ☐ Unknown

B. Disposition

b1. EUA Treatment Participation Completion Status

1. Completion Status: ☐ *Completed* ☐ *Incomplete*
2. If Incomplete, Reason Code:
3. Final Participation Date: dd-mmm-yyyy
4. Any reportable AEs or product treatment errors? ☐ Yes, specify # of: (AEs) (product errors) ☐ No

b2. Survival Status

Before Transfer of care	*After Transfer of care*
☐ S: Survived	☐ S: Survived
☐ D: Deceased	☐ D: Deceased
☐ U: Unknown	☐ U: Unknown

C. OctaplasLG Powder Administration Log

	c1. Product Administration Date and Time ***Start***		***End***		c2. Dose *(mL)*	c3. Product Identifiers (IDs) *Unique ID, Lot #*	c4. Treatment Indication *(Check (✓) one or specify other indication)*
1.	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
2. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
3. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
4. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
5. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
6. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
7. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
8. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or
9. ☐ NA	dd-mmm-yyyy	hh:mm	dd-mmm-yyyy	hh:mm		UID: Lot #:	☐ Coagulopathy ☐ Hemorrhage or

Provider's Statement: *I attest that I have reviewed the entered data on this Case Report Form booklet and their associated supportive documents and materials for the treatment under the subject EUA, and they deem complete and accurate to the best of my knowledge.*

Provider's Signature — Signed Date (dd-mmm-yyyy)

Transcribed Date & By: SDV Date & By: DE Date & By: QC Date & By:

EUA FDP LOA 08-AUG-2024

(Octapharma; OctaplasLG Powder; ABO Compatibility)

Abbreviated Case Report Form Completion Instructions

Version Date: 01-APR-2026

A. Participant's Information

1. *Recipient Informed Date:
   - 1.1. Enter the date in dd-mmm-yyyy (e.g., 02-FEB-2025) of when the participant was provided with the Fact Sheet or information about the product and consenting the participation under this EUA OR
   - 1.2. Not Reported: Select "Not Reported" option if the information is unavailable/not reported.
2. *Birth Date:
   - 2.1. Enter the date in dd-mmm-yyyy (e.g., 02-FEB-1993) of when the participant was born OR
   - 2.2. Age: If birth date is unknown, then specify the participant's age rounded to the nearest tenths in years at the time of the first treatment under this EUA.
3. *Sex (at birth):
   - 3.1. Select either "*Male*" or "*Female*" checkbox OR "*Not Reported*" if the information is unavailable/not reported.
4. *Race and/or Ethnicity:
   - 4.1. Select *all* checkboxes that apply identified by the participant.

Race/Ethnicity	Definition	National Origin Examples
American Indian or Alaska Native	Individuals with origins in any of the original peoples of North, Central, and South America	Aztec, Navajo Nation, Nome Eskimo Community
Asian	Individuals with origins in any of the original peoples of Central or East Asia, Southeast Asia, or South Asia	Chinese, Vietnamese, Asian Indian, Pakistani
Black or African American	Individuals with origins in any of the Black racial groups of Africa	African American, Nigerian, Jamaican, Kenyan
Hispanic or Latino	individuals of Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, and other Central or South American or Spanish culture or origin	Mexican, Puerto Rican, Cuban, Salvadoran
Middle Eastern or North African	Individuals with origins in any of the original peoples of the Middle East or North Africa	Lebanese, Iraqi, Saudi Arabian, Egyptian
Native Hawaiian or Pacific Islander	Individuals with origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands	Native Hawaiian, Marshallese, Palauan, Tahitian
White	Individuals with origins in any of the original peoples of Europe	English, Italian, German, French, Irish, Swedish
Unknown	Race/ethnicity is unknown.	N/A

   - 4.2. *National Origin: Specify the known national origin(s) corresponding to the selected Race/Ethnicity, please see the table under 4.1 above for examples. If national origin is unknown, then write "unknown".

B. Disposition

1. *EUA Treatment Participation Completion Status:
   - 1.1. *Completion Status: Select only one item from the list, where:
     - "*Completed*" indicates the participant received the EUA treatment product as intended.
     - "*Incomplete*" indicates the participant did not receive the EUA treatment product as intended.
   - 1.2. If Incomplete, Reason Code: Select only *one* code from the list to indicate the *primary incomplete reason* for not receiving the EUA treatment product as intended.

Code	Description	Code	Description	Code	Description
01	Adverse event	06	Lack of efficacy	11	Approved drug available for indication
02	Death	07	Logistical problem	12	Failure to meet continuation criteria
03	Pregnancy	08	Technical problems	13	Potential risk of drug-condition interaction(s)
04	Recovery	09	Physician decision	14	No longer clinically benefiting
05	Lost to follow-up	10	Withdrawal by participant	99	Other, specify below

   - 1.3. Other, specify below: Enter the other primary reason in the provided space if "*99: Other, specify below*" is selected.
   - 1.4. *Final Participation Date: Enter the date in dd-mmm-yyyy (e.g., 02-FEB-1993) of when the participant ended the EUA treatment participation.
   - 1.5. *Any reportable AEs or product treatment errors?: Select "Yes" or "No" whether there were any suspected adverse reactions, including serious and unexpected adverse reactions, and any medication errors associated with the use of the authorized octaplasLG Powder.
   - 1.6. Yes, specify # of: If "Yes" is selected, then specify the total number of reportable of the following:
     - AEs: Adverse events (including suspected, serious, and unexpected adverse reactions)
     - Product errors: Medication errors associated with the use of the authorized octaplasLG Powder
2. *Survival Status:
   - 2.1. *Before Transfer of Care: Select the corresponding checkbox to indicate whether the participant survived ("*S: Survived*") or deceased ("*D: Deceased*"") after receiving the EUA treatment product and *prior to* transfer of care. If unknown, then select "*U: Unknown*" checkbox.
   - 2.2. *After Transfer of Care: Select the corresponding checkbox to indicate whether the participant survived ("*S: Survived*") or deceased ("*D: Deceased*"") after receiving the EUA treatment product and *after* transfer of care. If unknown, then select "*U: Unknown*" checkbox.

C. OctaplasLG Powder Administration Log

1. *Product Administration Date and Time: Enter a product treatment transfusion event into an individual line separately.
   - 1.1. *Start: Of each line in the first 2 boxes, enter the start of the transfusion as follows:
     - Date: Infusion start date in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - Time: Infusion start time in HH:MM 24 hour clock format (e.g., 13:00, 23:59)
   - 1.2. *End: Of each line in the last 2 boxes, enter the end of the transfusion as follows:
     - Date: Infusion end date in in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - Time: Infusion end time in HH:MM 24 hour clock format (e.g., 13:00, 23:59)
2. *Dose:
   - 2.1. Enter the actual dose in mL for the corresponding transfusion event.
3. *Product Identifiers:
   - 3.1. *Unique ID (UID): Enter the product unique identifier in the provided space next to the UID prompt.
   - 3.2. *Lot #: Enter the product Lot # in the provided space next to the Lot # prompt.
4. *Treatment Indication:
   - 4.1. Select the corresponding checkbox to indicate whether the EUA product was given to the participant to treat either "*Coagulopathy*" or "*Hemorrhage*" OR if for other indication(s), then specify in the provided space next to the "*or*" prompt.
5. NA checkbox: For lines 2 to 9, select the NA checkbox for the corresponding line to indicate the corresponding line is blank intentionally.

General Instructions

1. *Form Header:
   - 1.1. *Participant ID: This ID is comprised of the following:
     - Site #: 3 digit site number, pre-assigned and pre-filled by ORA Data Management
     - Patient #: 3 digit number starting with 001, assigned and managed by the provider of his/her location
2. *Form Footer:
   - 2.1. *Transcribed Date & By: Enter the date of when and by whom the CRF was transcribed by:
     - Date: Date of the transcription completion in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - By: 2 letter initials from the first and last name of the transcriber.
3. *Provider's Statement: The person responsible for reviewing the accuracy of the transcribed data prior to the submission to ORA Data Management team is to review and sign off the transcription completion:
   - *Provider's Signature: Sign to signify the approval of the content on the transcribed CRF.
   - *Signed Date: Enter the signed date in dd-mmm-yyyy (e.g., 02-FEB-2025).
4. Submission of CRF Transcription Completion:
   - 4.1. The CRF transcription is to be completed *within 14 days* after the participant has received the EUA octaplasLG transfusion.
   - 4.2. The signed transcribed CRF is to be submitted via DOD SAFE (Secure Access File Exchange) to ORA Group Mailbox (DHA Ft Detrick MRDC Mailbox ORA-CDSA): dha.detrick.mrdc.mbx.ora-cdsa@health.mil

Note: * indicates entry for the corresponding field is required.

APPENDIX B: OCTAPLASLG POWDER FDA AUTHORIZATION LETTER FOR EMERGENCY USE AUTHORIZATION

FDA U.S. FOOD & DRUG ADMINISTRATION

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.

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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.

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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.

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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

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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.

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- 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.

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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.

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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.

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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

APPENDIX C: OCTAPLASLG POWDER PROVIDER FACT SHEET

Fact Sheet for Health Care Professionals or Other Authorized Providers

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Octapharma's octaplasLG Powder (blood group types A and AB) by U.S. military forces for the emergent treatment of hemorrhage or coagulopathy involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available or when the use of plasma is not practical. This EUA also permits the treatment of other individuals, such as troops, civilians, contractors, and allied military personnel operating with Department of Defense.

What is octaplasLG Powder and why is it needed?

octaplasLG Powder is an unapproved lyophilized form of Octapharma's FDA-approved pooled plasma Octaplas. Octaplas is a solvent/detergent (S/D) treated, pooled human plasma that has been on the global market since 1992 (12.8 million bags sold) with an established safety profile based on substantial post-marketing data. Agents of military combat have the potential to cause imminently life-threatening hemorrhage or coagulopathy in U.S. military personnel. octaplasLG Powder is for use under emergency conditions when plasma is not available or when the use of plasma is not practical. Importantly, octaplasLG Powder does not require refrigeration and is supplied in a form compatible with the logistical constraints of a military operational environment. Given the urgent need for a therapeutic to treat life-threatening hemorrhage and/or coagulopathy under austere combat conditions for U.S. military personnel, the Secretary of Health and Human Services (HHS) has declared that circumstances exist to justify the 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. Therefore, FDA has issued this EUA to allow access to and use of octaplasLG Powder, an unapproved product. This EUA Fact Sheet provides information about the significant known and potential risks and benefits of the emergency use of octaplasLG Powder.

Controlled clinical studies of octaplasLG Powder have not been performed. Information on safety and effectiveness of octaplasLG Powder is derived from information on safety and effectiveness of Octaplas, and laboratory studies suggesting similar composition and quality of octaplasLG powder (when reconstituted) to Octaplas.

Product Use and Inventory Management

It is expected that U.S. military medical personnel or other Authorized Providers trained in the use of octaplasLG Powder will administer routine standard of care for hemorrhage. This may include, but is not limited to, the following: tourniquets, compression dressings, hemostatic agents, and dressings. If in the opinion of the treating provider, the patient is experiencing life-threatening hemorrhage or coagulopathy, the use of octaplasLG Powder would be appropriate. It is the recipient's choice whether or not to receive octaplasLG Powder. However, it is possible that octaplasLG Powder may be administered in a life-threatening situation where the recipient is not able to make a decision or provide consent.

DoD will distribute the octaplasLG Powder to medical units as needed. The medical units will be responsible for the storage, documentation, and accountability of product usage and will return and warehouse all unused product for final disposition.

The octaplasLG Powder products authorized under FDA EUA are limited to only blood groups A and AB. In the emergency treatment of hemorrhage or coagulopathy, group A and group AB octaplasLG Powder may be used prior to determining the recipient's blood group. Patients should be observed for at least 20 minutes after the administration.

Data Collection

Data collected under this EUA will be used to evaluate the appropriate and safe use of octaplasLG Powder under combat conditions. Record, to the extent practicable given the emergency circumstances, the following whenever octaplasLG Powder is transfused to patients:

- Suspected adverse reactions
- Medication errors associated with the use of the authorized octaplasLG Powder

For the purposes of this EUA, a suspected adverse reaction means any untoward medical occurrence associated with transfusion of octaplasLG Powder for which the healthcare provider believes there is evidence to support that transfusion of octaplasLG Powder caused the untoward medical occurrence. If a suspected adverse reaction is determined to be serious and unexpected, or results in death, report the suspected adverse reaction as soon as reasonably possible according to a process defined by the Department of Defense.

For the purposes of this EUA, serious and unexpected means a reaction that results in death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly or birth defect, and which is not described under 'Risks and Adverse Events' below.

Adverse events may also be submitted directly to FDA using MedWatch FDA Form 3500 available at http://www.fda.gov/medwatch.

Product Description, Storage Conditions and Product Expiration

octaplasLG Powder is an unapproved lyophilized plasma product created from an FDA-approved pooled 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. Octaplas is created from pooled plasma (comprising 370-1,520 individual donations) of single ABO blood groups which undergoes solvent/detergent treatment and nanofiltration. The Octaplas product is then dried using a freeze-drying process to create the octaplasLG Powder. The authorized octaplasLG Powder is of blood groups A and AB. Titers of blood group antibodies were tested in 113 Octaplas batches with blood group A. Mean anti-B antibody titers in blood group A plasma were relatively low, in a range of 4-128. Since the manufacturing processes of Octaplas and octaplasLG Powder are identical, except for the freezing vs. freeze-drying process, similar antibody levels are expected for both products.

- The shelf-life of octaplasLG Powder is 2 years.
- Store between 2°C to 25°C. Stable for 24 months. Do not freeze. Protect from light.
- Reconstituted octaplasLG Powder is stable for 8 hours at standard room temperature (25°C).

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octaplasLG Powder 2/7

- The reconstituted solution should be used immediately if possible and must not be frozen or stored in a refrigerator.
- Significant excursions from the labelled storage conditions should be documented if conditions permit.

Each pack of octaplasLG Powder is packaged as follows:

- 9 - 14 g human plasma protein in a bottle (type I glass), with a stopper (bromobutyl rubber), and a flip-off cap
- 190 ml solvent (water for injections) in a bag
- 1 transfer set
- 2 alcohol swabs
- Transfusion set with filter
- Vented spike adaptor

Global coagulation parameters and specific coagulation factors and inhibitors in octaplasLG Powder compared to Octaplas Pooled Plasma

Parameter	octaplasLG Powder Mean ± standard deviation (n = 3)	Octaplas Mean (min-max) (n = 12)
Activated partial thromboplastin time [sec]	29 ± 2	28 (27-31)
Prothrombin time [sec]	11 ± 0	11.8 (11.2-12.6)
Fibrinogen [mg/ml]	3.1 ± 0.2	3.0 (2.7-3.2)
Coagulation factor II [IU/ml]	0.90 ± 0.00	1.1 (1.0-1.1)
Coagulation factor V [IU/ml]	0.90 ± 0.00	0.9 (0.9-1.0)
Coagulation factor VII [IU/ml]	1.13 ± 0.06	1.1 (1.0-1.2)
Coagulation factor VIII [IU/ml]	0.93 ± 0.12	1.1 (0.8-1.3)
Coagulation factor IX [IU/ml]	1.40 ± 0.10	1.2 (1.0-1.3)
Coagulation factor X [IU/ml]	1.03 ± 0.06	1.1 (1.0-1.1)
Coagulation factor XI [IU/ml]	0.80 ± 0.00	0.9 (0.9-1.0)
Coagulation factor XII [IU/ml]	1.00 ± 0.04	1.2 (1.0-1.4)
Coagulation factor XIII [IU/ml]	0.90 ± 0.02	0.9 (0.9-1.0)
Antithrombin [IU/ml]	1.06 ± 0.05	1.0 (0.9-1.0)
Heparin cofactor II [IU/ml]	1.18 ± 0.06	1.23 ± 0.06
Protein C [IU/ml]	1.03 ± 0.06	1.0 (1.0-1.0)
Protein S [IU/ml]	0.67 ± 0.06	0.7 (0.6-0.8)
Von Willebrand factor ristocetin cofactor activity [IU/ml]	0.95 ± 0.10	0.87 ± 0.08
ADAMTS13# activity [IU/ml]	0.92 ± 0.03	1.0 (0.8-1.2)
Plasminogen [IU/ml]	0.86 ± 0.03	0.9 (0.8-0.9)
Plasmin inhibitor## [IU/ml]	0.47 ± 0.06	0.4 (0.4-0.5)

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[#]A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13. Also known as von Willebrand factor-cleaving protease (VWFCP).

[##]Also known as α_2-antiplasmin.

Instructions for Use and Administration

The included transfusion set with a 170-200 µm filter together with the vented spike adaptor should be used for the administration of octaplasLG Powder via intravenous infusion to remove residual particulate matter.

Before reconstitution, both the unopened powder (octaplasLG Powder) and the sterile water for injection (WFI) should be warmed up to room temperature.

The product generally reconstitutes within approximately 15 minutes at room temperature. If the powder is not dissolved within 30 minutes, the product should be discarded.

One vial of octaplasLG Powder contains 9 – 14 g of A or AB blood group specific human plasma proteins. After reconstitution with 190 ml of solvent, the final solution of 200-210 ml contains 45 – 70 mg/ml of A or AB blood group specific human plasma proteins.

The dosage depends on the clinical situation and underlying disorder, but 12-15 ml octaplasLG Powder /kg body weight is a generally accepted starting dose. This should increase the patient's plasma coagulation factor levels by approximately 25%.
Because the protein levels are similar to Octaplas (see table above) octaplasLG Powder can be used the same way as Octaplas.

Reconstitution

1. Reconstitution of octaplasLG Powder should be done at room temperature. Remove the flip-off cap from the powder bottle (octaplasLG Powder) to expose the central portion of the rubber stopper. Disinfect the rubber stopper with an alcohol swab and allow the rubber stopper to dry.
2. Remove the blister from the transfer set and close the clamp on the transfer line.
3. Remove the outer packaging of the WFI bag. Remove the blue protective cap from the bag outlet. Do not touch the rubber stopper of the outlet to maintain sterility.
4. Connect the transfer set to the powder bottle (octaplasLG Powder) by perforating the rubber stopper centrally with the spike. Open the vent next to the spike.
5. Connect the transfer set to the WFI bag by pushing the needle through the blue outlet.
6. Make sure that the transfer set is well connected, hold/hang the WFI bag vertically above the powder bottle and open the clamp. The WFI flows automatically into the powder bottle (octaplasLG Powder). Gently swirl the powder bottle during the WFI transfer.
7. When the transfer is completed remove the spike from the powder bottle and discard the transfer set and the empty WFI bag.
8. Continue to gently swirl the powder bottle until the powder is fully dissolved. Do not shake the bottle to avoid foam formation. In general, the powder should be

EUA Fact Sheet for Health Care Professionals or Other Authorized Providers
octaplasLG Powder 4/7

dissolved completely within approximately 15 minutes. The reconstituted solution should be clear or slightly opalescent.

9. Examine the glass bottle prior to infusion to ensure the bottle is intact. Do not use a broken bottle under any circumstances.

Product Administration

1. Always use aseptic technique when connecting the transfusion set with the vented spike adaptor and the vial.
2. Remove the blister from the transfusion set and the blister from the vented spike adaptor.
3. Remove the protective cap from the spike of the transfusion set. Slide the vented spike adaptor on the spike of the transfusion set. Then remove the protective cap from the spike of the adaptor.
4. Connect the transfusion set with the adaptor to the powder bottle (octaplasLG Powder) by perforating the rubber stopper centrally with the spike of the adaptor.
5. Ensure the spike is fully inserted into the vial so that liquid can flow through the tubing.
6. Gently squeeze the drip chamber of the transfusion set to fill it partially with liquid.
7. Transfuse the product according to your established clinical protocols. Patients' vital signs should be closely monitored throughout the infusion as conditions permit.
8. Repeat administration as medically necessary.

Use in Specific Populations

Pediatric Use:

Octaplas was evaluated in 91 pediatric patients (age range 0-20 years) in two post-marketing requirement studies. Patients were dosed based on body weight and doses were adjusted as needed. There were no hyperfibrinolytic or treatment-related thromboembolic events reported by investigators.

Pregnancy:

Animal reproduction studies have not been conducted with Octaplas. It is not known whether Octaplas can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Octaplas should be given to a pregnant woman only if clearly needed.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Geriatric Use:

Clinical studies of Octaplas did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects. Other reported

clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Risks and Adverse Events

- Transfusion reactions (e.g., severe hypotension, anaphylactic shock) can occur with administration of any blood derived product. Closely monitor patient status during infusion for signs of a reaction. If a reaction occurs, stop the infusion immediately and treat the symptoms as appropriate.
- High infusion rates can induce hypervolemia with subsequent pulmonary edema or heart failure.
- Excessive bleeding due to hyperfibrinolysis can occur due to low levels of alpha 2-antiplasmin.
- Thrombosis can occur due to low levels of Protein S.
- octaplasLG Powder is made from human blood and may carry the risk of transmitting infectious agents, e.g., viruses and theoretically, the variant Creutzfeldt-Jakob disease and Creutzfeldt-Jakob disease agent.
- Hemolytic reactions due to ABO incompatibility
- Citrate toxicity can cause a decreased ionized calcium caused by the presence in the circulation of large quantities of citrate anticoagulant. Citrate toxicity can occur when the infusion rate and volume exceed one milliliter of octaplasLG Powder per kg per minute. The octaplasLG Powder infusion rate should not exceed 0.020-0.025 mmol citrate per kilogram per minute (i.e., less than one milliliter octaplasLG Powder per kg per minute). Symptoms attributable to citrate toxicity (hypocalcemia) include fatigue, paresthesia and muscle spasms, especially in patients with liver function disorders. Calcium may be administered to treat citrate toxicity.
- Transfusion-related acute lung injury has been reported spontaneously in patients receiving octaplasLG and other blood products.

Contraindications

- IgA deficiency
- Severe deficiency of Protein S
- History of hypersensitivity to fresh frozen plasma (FFP) or to plasma-derived products including any plasma protein
- History of hypersensitivity reaction to Octaplas/octaplasLG Powder

Risk Benefit Statement

Data obtained from clinical trials demonstrate that Octaplas is non-inferior to fresh frozen plasma (FFP) in the treatment of hemorrhage and coagulopathy. octaplasLG Powder is a lyophilized form of Octaplas that has been shown to have a similar biochemical profile to Octaplas. It is expected octaplasLG Powder will maintain a similar safety profile as Octaplas. In contrast to Octaplas and plasma components, the lower logistical requirements of octaplasLG Powder allow it to be delivered to patients in environments where plasma is not available or when the use of plasma is not practical. Therefore, in these cases of life-threatening hemorrhage and/or coagulopathy FDA has concluded that that the known and

EUA Fact Sheet for Health Care Professionals or Other Authorized Providers
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potential benefits of octaplasLG Powder, when used in accordance with the scope of authorization, outweigh the known and potential risks.

Alternative treatment options

Plasma transfusions are primarily used for the emergent treatment of hemorrhage or coagulopathy. Plasma products available for transfusion include the plasma components described in the AABB Circular of Information or Octaplas solvent-detergent treated plasma. Other replacement strategies can also be considered depending on the underlying condition; these include whole blood, packed red blood cells, platelets, prothrombin complex concentrate, fibrinogen concentrate and human albumin. octaplasLG Powder is for use when other plasma products are not available, or their use is not practical.

Contact information for reporting adverse events and additional information about the product

To report SUSPECTED ADVERSE REACTIONS, contact Octapharma USA Inc. at phone # 866-766-4860 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

APPENDIX D: OCTAPLASLG POWDER RECIPIENT FACT SHEET

Fact sheet for Recipients

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of octaplasLG Powder (blood group types A and AB) by U.S. military forces for the emergency treatment of hemorrhage or coagulopathy involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available or when the use of plasma is not practical. This EUA also permits the treatment of other individuals, such as troops, civilians, contractors, and allied military personnel operating with Department of Defense.

What is octaplasLG Powder and why might I need it?

octaplasLG Powder is an unapproved dried form of Octapharma's FDA-approved pooled plasma product, Octaplas. Octaplas is made entirely from plasma obtained from U.S. licensed blood establishments. All plasma donations are tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. The plasma also undergoes solvent/detergent treatment manufacturing process to inactivate infectious agents further increasing its safety. This product is then dried using a freeze-drying process to create the octaplasLG Powder.

octaplasLG Powder does not require refrigeration making it compatible with use under battlefield conditions where plasma is not available or when it is not practical. You may receive octaplasLG Powder from trained U.S. military medical personnel if an injury results in life-threatening bleeding (hemorrhage) or problems with blood clotting (coagulopathy) and if plasma is not available or the use of plasma is not practical.

In the emergency treatment of hemorrhage or coagulopathy, octaplasLG Powder may be used prior to determining your blood group. The octaplasLG Powder products authorized under FDA EUA are limited to only products of blood groups A and AB, which can be transfused to recipients of any blood group when their blood group cannot be determined in an emergency. Plasma of blood group AB and A with low titers of anti-B may reduce the risk of hemolytic transfusion reactions when your blood group cannot be determined in an emergency.

The dosage depends on the clinical situation and underlying disorder and is typically administered one unit at a time (approximately 200ml). Patients should be observed for at least 20 minutes after the administration.

Controlled clinical studies of octaplasLG Powder have not been performed. Information on safety and effectiveness of octaplasLG Powder is derived from information on safety and effectiveness of Octaplas, and laboratory studies suggesting similar composition and quality of octaplasLG powder (when reconstituted) to Octaplas.

Who can receive octaplasLG Powder?

Members of the U.S. armed forces, and other individuals such as allied military personnel operating with the Department of Defense may receive octaplasLG Powder if they experience hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available or when the use of plasma is not practical. octaplasLG Powder may replace lost blood volume and may help prevent or treat life threatening bleeding. Given the operational environment,

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octaplasLG Powder may be the only treatment available for hemorrhage or coagulopathy in an emergency situation.

What are the risks of octaplasLG Powder?

octaplasLG Powder may be contraindicated if you had previous reactions to any plasma or plasma derived product, or Octaplas. It may also be contraindicated if you have low levels of protein S or specific antibodies against a protein called immunoglobulin A (IgA).

Since octaplasLG Powder is created from the FDA-approved plasma product Octaplas, octaplasLG Powder likely will have a similar safety profile. As with any plasma product, octaplasLG Powder may carry a risk of transmitting infectious agents that cause hepatitis and other diseases e.g HIV. This risk is very low since plasma used to manufacture octaplasLG Powder is screened for these agents and undergoes further steps to inactivate infectious agents.

Other risks include receiving too much octaplasLG Powder which may lead to heart failure and pulmonary edema (fluid accumulation in the lungs which makes it difficult to breathe), low calcium levels which can cause muscle cramps and numbness around your mouth; allergic reactions, lung injury (like transfusion-related acute lung injury), blood clots and red blood cell destruction (hemolysis). Your medical provider is trained to respond to all these potential complications.

octaplasLG Powder is not FDA-approved and there may be other risks that are unknown.

Can I refuse treatment with octaplasLG Powder?

It is your choice whether or not to receive octaplasLG Powder. However, it is possible that octaplasLG Powder may be given to you in a life-threatening situation where you are not able to make a decision or provide consent. If you choose not to be treated with octaplasLG Powder, the chance of dying from severe or life-threatening bleeding may increase. Even with octaplasLG Powder treatment, there is still a risk of death depending on the nature or your injuries.

Alternative treatment options

Plasma transfusions are primarily used for the emergency treatment of hemorrhage or coagulopathy. There are different plasma products available for transfusion such as Fresh Frozen Plasma, Liquid Plasma, or Octaplas. Your health care provider may consider other treatment strategies depending on the underlying condition; these include whole blood, packed red blood cells, platelets, prothrombin complex concentrate, fibrinogen concentrate, and human albumin. octaplasLG Powder is for use when other plasma products are not available, or their use is not practical.

Questions for Your Healthcare Provider

If you obtain this fact sheet and have a chance to speak with a provider using octaplasLG Powder before an injury has occurred, you may want to ask the following:

- Are there other treatment options besides octaplasLG Powder?
- What are the potential side effects?
- What if I refuse treatment in an emergency where plasma is not available?

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- How is octaplasLG Powder given?

Is octaplasLG Powder FDA approved?

octaplasLG Powder is not an FDA approved product.

For More Information and to Report Adverse Reactions Regarding This Product

Tell your U.S. military medical health care provider if you experience side effects that bother you or that do not go away.

You may also report adverse reactions to Octapharma USA Inc. at phone # 866-766-4860 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

APPENDIX E: FRENCH FDP (FRENCH LYOPHILIZED PLASMA – FLYP) CASE REPORT FORM

U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulated Activities (ORA)
Data Management Branch

Mock Electronic Case Report Form (eCRF) Book

CRF Version: 1.1 (August 30, 2018)

FINAL

Sponsor: The Surgeon General, Department of the Army (TSG-DA)

Project #: S-18-03; EUA FDP

Project Title: "EUA: *Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma (FDP)"*

EUA Product: Pathogen Reduced Leukocyte-Depleted Freeze Dried Plasma (Centre de Transfusion Sanguine des Armées)

EUA Authorization Letter Version: July 9, 2018

Prepared By: Brianna Johnson, USAMMDA Data Manager

Document Control No.: FORM.5.7.11 Version No.: 01
Effective Date: 25 January 2016

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma**
	Mock Electronic Case Report Form (eCRF) Book **Version 1.1 (August 30, 2018)**

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System Registration	
1. System Subject Registration	X
System Enrollment	
1. System Subject Enrollment	X
EUA Participation	
1. Subject Management	X
2. Start of Participation	X
3. Treatment Administration	X
4. End of Participation	X

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma**
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Domain: System Registration – ZS (System Requirement)		
Visit:	SYSTEM REGISTRATION	
Page:	SYSTEM SUBJECT REGISTRATION	
Section:	SUBJECT INITIALS	
Line #	**Question**	**Response**
1.	Recipient Initials (derived)	- - - Defaulted with dashes, no actual values collected.

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Domain: System Enrollment – ZE (System Requirement)		
Visit:	SYSTEM ENROLLMENT	
Page:	SYSTEM SUBJECT ENROLLMENT	
Section:	SUBJECT NUMBER ASSIGNMENT	
Line #	**Question**	**Response**
1.	Recipient ID Code (3 digits)	___ ___ ___ # # # *Manual entry by Site where:* • *### represents a sequential 3 digit number based on the order of enrollment into the project at Site level, starting with 001.*
2.	Recipient Number	SITEID -___ ___ ___ # # # • *Derived from the values of Site ID + Recipient ID Code (3 digits) to promote value uniqueness across study.* • *Site ID examples are USASOC, MARSOC, AFSOC, NSW*

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma** **Mock Electronic Case Report Form (eCRF) Book** **Version 1.1 (August 30, 2018)**

Domain: Subject Management – ZM		
Visit:	EUA PARTICIPATION	
Page:	SUBJECT MANAGEMENT	
Section:	SUBJECT NUMBER UPDATE	
Line #	**Question**	**Response**
1.	Recipient Number	SITEID -___ ___ ___ # # # *Derived from SYSTEM SUBJECT ENROLLMENT page with edit mode*
2.	Recipient Deletion Flag (Equivalent to "DELETION"; to be excluded from Data Entry, SDV, Query, and Analysis, "D" suffix added to Recipient Number)	[ ] DELETION
3.	Recipient Deletion Reason	_____

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma**
	Mock Electronic Case Report Form (eCRF) Book **Version 1.1 (August 30, 2018)**

Domain: Start of Participation – DS/DM (Project Defined)		
Visit:	EUA PARTICIPATION	
Page:	START OF PARTICIPATION	
Section:	ENROLLMENT	
Line #	**Question**	**Response**
1.	How did the recipient receive the information about the product under the EUA?	Check All That Apply: [ ] FM: Fact Sheet for U.S. Military [ ] FR: Fact Sheet for Recipients [ ] IC: IND Informed Consent [ ] U: Unknown [ ] O: Other, specify
2.	Other Information for Recipient	_____
3.	Recipient Informed Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___/___ ___ ___/___ ___ ___ ___ D D M O N Y Y Y Y
Section:	DEMOGRAPHY INFORMATION	
Line #	**Question**	**Response**
4.	Date of Birth (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___/___ ___ ___/___ ___ ___ ___ D D M O N Y Y Y Y
5.	Sex	Dropdown: [ ] F: Female [ ] M: Male
6.	Ethnicity	Dropdown: [ ] HL: Hispanic or Latino [ ] NHL: Not Hispanic or Latino [ ] UNK: Unknown
7.	Race	Dropdown: [ ] 1: White [ ] 2: Black or African American [ ] 3: American Indian or Alaska Native [ ] 4: Asian [ ] 5: Native Hawaiian or Other Pacific Islander [ ] 96: Unknown [ ] 99: Other or Multiple
8.	Other or Multiple Races *(If "Other or Multiple" is selected, specify other/multiple race)*	_____

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma**
	Mock Electronic Case Report Form (eCRF) Book **Version 1.1 (August 30, 2018)**

Domain: Exposure – EX (Interventions)		
Visit:	EUA PARTICIPATION	
Page:	TREATMENT ADMINISTRATION	[ADD ENTRY
Section:	ADMINISTRATION COMPLETION	
Line #	**Question**	**Response**
1.	Dose Entry Number	#
2.	Dose Administered?	Dropdown: [ ] Y: Yes [ ] N: No
3.	Product Name	Dropdown: [ ] FF: French FDP from France Collection [ ] FS: French FDP from US Collection [ ] CA: USP-Grade Calcium Solution
4.	Treatment Indication	Dropdown: [ ] C: Coagulopathy [ ] H: Hemorrhage [ ] O: Other Specify
5.	Specify Other Treatment Indication	_____
6.	Administration Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___ / ___ ___ ___ / ___ ___ ___ ___ D D M O N Y Y Y Y
7.	Administration Time (24 hr Clock)	Dropdown: ___ ___ : ___ ___ H H M M
8.	Actual Dose	_____
9.	Dose Unit	mL *Defaulted to "mL" for FF and FS but editable.
10.	Lot Number	_____
11.	Trace Number	_____

	Project #: S-18-03; EUA FDP **EUA: Freeze Dried Plasma**
	Mock Electronic Case Report Form (eCRF) Book **Version 1.1 (August 30, 2018)**

Domain: Disposition – DS (Events)		
Visit:	EUA PARTICIPATION	
Page:	DISPOSITION: END OF PARTICIPATION	
Section:	FINAL PARTICIPATION STATUS	
Line #	**Question**	**Response**
1.	Recipient Final Participation Status (30 days following treatment)	Dropdown: [ ] 101: Completed [ ] 301: Withdrawal by subject [ ] 302: Physician decision, specify detail [ ] 303: Lost to follow-up [ ] 304: Adverse event, specify AE Line No and/or detail [ ] 305: Protocol deviation, specify detail [ ] 308: Site terminated by sponsor [ ] 309: Study terminated by sponsor [ ] 318: Death [ ] 999: Other, specify detail
2.	Specify Status Detail	_____
3.	Recipient Final Participation Date (DD/MON/YYYY)	Dropdown(Calendar Pick): ___ ___/___ ___ ___/___ ___ ___ ___ D D M O N Y Y Y Y
Section:	TREATMENT OUTCOME	
Line #	**Question**	**Response**
4.	Recipient Survival Status (Until transfer of care)	Dropdown: [ ] S: Survived [ ] D: Deceased [ ] U: Unknown
5.	Recipient Survival Status (30 days following treatment)	Dropdown: [ ] S: Survived [ ] D: Deceased [ ] U: Unknown
6.	Study Completion Status	xxx *Derived based on Subject Status to meet system's requirements*
7.	Drop-out Reason	xxx *Derived based on Subject Status to meet system's requirements*

APPENDIX F: FRENCH FDP (FRENCH LYOPHILIZED PLASMA – FLYP) FDA AUTHORIZATION LETTER FOR EMERGENCY USE AUTHORIZATION

July 9, 2018

Robert E. Miller, Ph.D.
Senior Regulatory Affairs Advisor
Office of Regulated Activities
Department of the Army
Headquarters, U.S. Army Medical Research and Materiel Command
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Dear Dr. Miller:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (CTSA) (for purposes of this EUA, "French FDP")[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).[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

[1] On the date of issuance of this EUA, the authorized French FDP product under this EUA refers specifically to French FDP product that is manufactured using French-derived, pathogen-reduced, Leukocyte-Depleted fresh frozen plasma (FFP). As discussed in Section II of this letter, at this time the authorized French FDP product under this EUA does not include French FDP that is manufactured using Department of Defense (DoD)-derived plasma or other U.S.-derived plasma.

[2] For purposes of this EUA, to meet DoD military needs "U.S. military forces" may include U.S. troops and military members of an allied force or other personnel operating with DoD. Also, for purposes of this EUA, it is anticipated that U.S. military medical personnel trained in the use of French FDP will administer the authorized French FDP 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 French FDP during an emergency as set forth in this authorization.

[3] At the time of issuance of this EUA, French FDP was approved in at least one country (i.e., France) but not approved in the U.S. This EUA, including its Conditions of Authorization in Section IV, applies only to French FDP product that is manufactured and distributed by Centre de Transfusion Sanguine des Armées (CTSA) and its authorized agent(s) specifically for DoD procurement and further DoD distribution, stockpiling, and use during an emergency as set forth in this authorization.

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with an imminently life-threatening and specific risk to those forces."[4,5,6] 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 FDP 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 21 U.S.C. § 360bbb-3(a).[7]

DoD requested this EUA so that French FDP, which is not FDA-approved, may be 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 during an event or post-event for the treatment of hemorrhage or coagulopathy caused by exposure to such agents 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 use of this unapproved 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 French FDP 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 French FDP (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

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[4] 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.

[5] As amended by H.R. 4374 (Pub. L. No. 115-92, December 12, 2017), 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.

[6] 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.

[7] 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.

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.

This EUA applies in all circumstances when DoD reasonably believes that there is a need to store, distribute, and/or administer the authorized French FDP in an emergency because of U.S. military forces' known, suspected, or likely imminent exposure to 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.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of French FDP 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 meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

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

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that French FDP, 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 French FDP for this use outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of French FDP 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.[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 to the use of the authorized French FDP 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

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

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use of plasma is not practical. The emergency use of the authorized French FDP product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The Authorized French FDP:

I am authorizing the use of French FDP. French FDP is a biologic 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.[9] DoD may request the authorization of additional sources of plasma (e.g., DoD-derived or other U.S.-derived) for French FDP, which may be authorized by FDA in consultation with, and with concurrence of, the Office of Blood Research and Review (OBRR)/Center for Biologics Evaluation and Research (CBER), the Counterterrorism Office (CT)/Office of the Center Director (OD)/CBER, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).[10]

The current formulation of the authorized French FDP is a lyophilized, Leukocyte-Depleted, pathogen-reduced (Intercept-treated), pooled apheresis fresh frozen plasma (FFP) product collected from volunteer donors. The authorized French FDP is a packaged unit, which includes a bottle of freeze dried plasma, 200 mL of water for injection, a transfer set, and an intravenous infusion set specially designed for administration by U.S. military medical personnel. When reconstituted, the volume of the authorized French FDP is equivalent to 210 mL of human plasma. One or more units are infused under the direct care of U.S. military medical personnel; repeat administration may be necessary until evacuation to definitive care is possible. French FDP does not require refrigeration and is supplied in a form compatible with the logistical constraints of a military operational environment.

The authorized French FDP, and any sources of plasma for the manufacture of French FDP that are authorized at a later time under this EUA, are authorized to be distributed by DoD for pre-event storage and further redistribution, if appropriate, and for post-event storage, distribution, and administration, when packaged in the authorized packaging and with the authorized labeling (e.g., carton and container labels, fact sheets, and technical notice and summary of product characteristics).

The authorized French FDP is authorized to be administered without a prescription and by U.S. military medical personnel under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

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[9] DoD treatment and management of hemorrhage or coagulopathy subsequently may include other supportive measures and treatments, including evacuation to definitive care.

[10] On the date of issuance of this EUA, French FDP using DoD-derived or other U.S.-derived plasma was not authorized for use under this EUA. However, DoD may request authorization under this EUA of French FDP using DoD-derived or other U.S.-derived plasma at a later time. If FDA authorizes use of DoD-derived or other U.S.-derived plasma based on a review of the scientific data, communication about such authorization will be posted on FDA's EUA website at the time of amendment of this EUA (e.g., through a memorandum and updated EUA Fact Sheets). https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

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The authorized French FDP is authorized to be accompanied by the authorized labeling in consultation with FDA and DoD. The authorized French FDP is also authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to U.S. military medical personnel and U.S. military forces ("recipients") to facilitate understanding of 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, the risks and benefits of French FDP, and proper administration:

- Fact Sheet for U.S. Military Medical Personnel
- Fact Sheet for Recipients

Other Fact Sheets developed by DoD in consultation with, and with concurrence of, OBRR/CBER, CT/OD/CBER, and OCET/OCS/OC may be authorized to accompany the above described French FDP and to be made available to U.S. military medical personnel and U.S. military forces, as appropriate.

As described in Section IV below, DoD is also authorized to make available additional information relating to the emergency use of the authorized French FDP that is reasonably consistent with, and does not exceed, the terms of this letter of authorization.

Authorized French FDP is authorized to have its manufacturer labeled expiry dating extended by OBRR/CBER, CT/OD/CBER, and OCET/OCS/OC based on scientific data supporting such an extension.

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 French FDP 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 French FDP 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 French FDP, 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

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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 French FDP 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 French FDP 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.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

This letter authorizes use of French FDP previously manufactured by CTSA under U.S. Government contract as of the date of this letter, as well as authorized French FDP that may be manufactured by CTSA under U.S. Government contract after such date.

The authorized French FDP should be held in accordance with the manufacturer's labeled and appropriate product storage conditions for the product (i.e., when possible, at temperatures between 2°C (36°F) and 8°C (46°F), with excursions permitted to 25°C (77°F), protected from light). However, to ensure the delivery and availability of the authorized French FDP 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 when there is a decision on the part of DoD to distribute and administer the product under the terms of this EUA, the authorized French FDP may require transportation and/or temporary storage for rapid administration without the capacity to maintain labeled storage conditions in the midst of the response. Significant excursions from the labeled storage conditions should be documented to the extent practicable given the circumstances of an emergency.

IV. Conditions of Authorization

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

DoD

A. DoD will distribute the authorized French FDP 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.

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B. Through a process of inventory control, DoD will maintain records regarding distribution under its direction of the authorized French FDP (i.e., lot numbers, quantity, receiving site, receipt date).

C. DoD will ensure that the terms of this EUA are made available to applicable DoD components through applicable DoD communication channels and procedures.[11] 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).

D. DoD will inform applicable DoD components that the authorized French FDP may be used only 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.

E. DoD will be responsible for authorizing components acting as part of a DoD response to administer the authorized French FDP in accordance with the terms of this EUA, including instructing such components about the terms of this EUA with regard to pre-event storage and distribution and post-event storage, distribution, and administration, and for instructing them about the means through which they are to obtain and use the authorized French FDP.

F. DoD will train applicable DoD components and/or personnel on the use of the authorized French FDP in accordance with this EUA and any applicable DoD procedures or protocols.

G. DoD will make available to applicable DoD components through applicable DoD communication channels and procedures the authorized Fact Sheet for U.S. Military Medical Personnel, the authorized Fact Sheet for Recipients, and any other Fact Sheets that FDA may authorize, as well as any authorized amendments thereto.[12] U.S. military forces administering the authorized French FDP will ensure that the authorized Fact Sheet for Recipients has been made available to U.S. military forces that receive French FDP 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.[13]

H. DoD may request changes to the authorized Fact Sheet for U.S. Military Medical

[11] For example, through pre-deployment training, hard copy, web posting, etc.
[12] For example, through pre-deployment training, hard copy, web posting, etc.
[13] FDA recognizes that the complex environment in which French FDP may be used may prevent dissemination of Fact Sheets at the time of use of the French FDP. 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.

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Personnel and the authorized Fact Sheet for Recipients and may request the development of additional Fact Sheets. Such requests will be made by DoD in consultation with, and require concurrence of, OBRR/CBER, CT/OD/CBER, and OCET/OCS/OC.

I. DoD is authorized to issue additional recommendations and instructions related to the emergency use of the authorized French FDP as described in this letter of authorization, to the extent that additional recommendations and instructions are necessary to meet military needs 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 they are reasonably consistent with the authorized emergency use of the product.

J. DoD may request changes to the authorized labeling (e.g., carton and container labels, label on each packaged unit, technical notice and summary of product characteristics) and authorized packaging for the authorized French FDP, or to the manufacturing, labeling, and packaging processes of CTSA or its authorized agent(s) for the authorized product. Such requests will be made by DoD in consultation with, and require concurrence of, OBRR/CBER, OD/CT/CBER, and OCET/OCS/OC.

K. DoD may request the authorization of additional sources of plasma (e.g., DoD-derived or other U.S.-derived) of the authorized French FDP under this EUA. Such requests will be made by DoD in consultation with, and require concurrence of, OBRR/CBER, OD/CT/CBER, and OCET/OCS/OC.

L. DoD will inform applicable DoD components about the need to have a process in place for performing adverse event monitoring and compliance activities designed to ensure that adverse events and all medication errors associated with the use of the authorized French FDP are reported to FDA, to the extent practicable given emergency circumstances, as follows: complete the MedWatch FDA Form 3500 online at www.fda.gov/medwatch, by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088. Submitted reports should state that French FDP was used under an EUA. DoD will conduct any follow-up requested by FDA regarding adverse events, to the extent feasible given the emergency circumstances.

M. DoD will ensure that the authorized French FDP is distributed for use under its direction within the expiry dating on the manufacturer's labeling. If FDA authorizes any expiry dating extensions of the authorized French FDP under this EUA, DoD will inform applicable DoD components holding and/or receiving the authorized French FDP of such extensions and any conditions related to such extensions under this EUA. DoD will maintain adequate records regarding the expiry dates by which authorized French FDP may be used.

N. DoD will inform CTSA about this EUA and its Conditions of Authorization, including the Conditions Related to Descriptive Printed Material outlined below.

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O. DoD will ensure that any records associated with the use of this product under this EUA are maintained, to the extent feasible given the emergency circumstances, until notified by FDA. Such records will be made available to FDA for inspection upon request.

P. DoD will facilitate FDA inspections of the French FDP manufacturing facility in the future at a mutually agreeable date.

Q. DoD will post on its website the following statement: "For information about the FDA-authorized emergency use of the Freeze Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (French FDP), please see: https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm."

R. DoD will promptly notify FDA of any suspected or confirmed quality, manufacturing, distribution, and/or other issues with the authorized French FDP of which it becomes aware.

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

Conditions Related to Descriptive Printed Material

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

U. All descriptive printed matter relating to the use of the authorized French FDP shall clearly and conspicuously state that:

- This product has not been FDA approved or cleared;
- 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 FDP 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.

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No descriptive printed matter relating to the use of the authorized French FDP 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.

The emergency use of the authorized French FDP as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of FDP 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,

--/S/--

Rachel E. Sherman, M.D., M.P.H.
Principal Deputy Commissioner of Food and Drugs

APPENDIX G: FRENCH FDP (FRENCH LYOPHILIZED PLASMA – FLYP) PROVIDER FACT SHEET

Fact Sheet for Health Care Professionals or Authorized Providers

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Centre de Transfusion Sanguine des Armées Leukocyte-Depleted Freeze Dried Plasma (French FDP) 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. The EUA also permits use of French FDP if needed to treat other individuals, such as allied military personnel operating with Department of Defense.

What is French FDP and why is it needed at this time?

French FDP is a lyophilized, leukocyte-depleted, pooled apheresis Fresh Frozen Plasma product collected from volunteer donors and manufactured by the Centre de Transfusion Sanguine des Armées. French FDP may be manufactured from either pooled French-sourced, pathogen-reduced (INTERCEPT™ -treated) apheresis plasma or pooled United States-sourced, FDA-licensed apheresis plasma. U.S.-sourced plasma has been subjected to standard donor screening and tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. The source of plasma will be identified in the labeling of the final product. Following reconstitution with water for injection, French FDP can be administered intravenously. The Department of Defense (DoD) determined that agents of military combat (e.g., firearms, projectiles, and explosive devices) may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces, in this case, hemorrhage or coagulopathy. French FDP is anticipated to be used for U.S. military forces for the treatment of individuals with 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. French FDP does not require refrigeration and is supplied in a form compatible with the logistical constraints of a military operational environment.

Based on this determination, the U.S. Department of Health and Human Services (HHS) has declared that circumstances exist to justify the emergency use of French FDP 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. The EUA will terminate when the HHS Secretary's declaration terminates unless FDA revokes it sooner. French FDP is not an FDA-licensed product. Therefore, FDA has issued this EUA to allow access to and use of French FDP. This EUA Fact Sheet provides information about the significant known and potential risks and benefits of the emergency use of French FDP.

Operational Setting and Management of Product

The product and standard Tactical Combat Casualty Care will be administered by U.S. military medical personnel specifically trained on use of French FDP. All hemorrhage will be controlled when possible and as early as tactically feasible in accordance with Tactical

Combat Casualty Care guidelines and U.S. Military Forces standard operating procedures with adjunct measures, to include approved tourniquets, compression, and hemostatic dressings, before treatment with French FDP. Pre- and post-product administration vital signs (heart rate [HR], blood pressure [BP], respiratory rate [RR], and temperature [T]) will be obtained if tactical circumstances permit, or at the first safe opportunity.

If a patient is determined to be in a life-threatening situation requiring intervention and the likelihood of death is high, use of this product would be justified. When practicable, in view of the circumstances of the imminently life-threatening combat casualties and the patient's capacity to make a knowledgeable decision, the patient will be given an option to accept or refuse administration of French FDP. When it is not practicable to do so because of the circumstances, the health care provider will act in the best interest of the patient.

Prior to deployment, an allotment of French FDP units, based on projected mission need, will be issued to each participating military medical unit, which will be responsible for product storage, accountability, and use documentation. Upon return, the military health care provider will return unused French FDP to the Logistic Warehouse for final disposition. Logs of product distribution, turn-in, and use will be maintained in the EUA file, which will be sent to the sponsor's representative at the U.S. Army Medical Research and Development Command annually and at the termination of the EUA. All French FDP units lost during contingency operations will be reported in accordance with standard procedures for sensitive/controlled items.

Data Collection

This EUA requires minimal data collection. The data collected under this EUA is intended to support the safety of the use of French FDP in combat settings. The following data will be collected by the health care provider who administers the product and subsequent health care providers to the extent feasible given the emergency circumstances:

- Patient survival until transfer of care
- Patient survival at Day 30 following treatment with French FDP
- Adverse events related to French FDP administration until transfer of care

Storage Conditions and Expiry Dating

French FDP can be stored for 2 years from the date of manufacture at temperatures between +2°C (36°F) and +25°C (77°F). When possible, the product should be stored at 2°C (36°F) to 8°C (46°F). During an emergency, the French FDP may require transportation or temporary storage for rapid administration without the capacity to maintain labeled storage conditions during the response. Significant excursions from the labeled storage conditions should be documented to the extent practicable given the circumstances of an emergency.

Product Description

The current formulations of the authorized French FDP are:

- A lyophilized, Leukocyte-Depleted, pathogen-reduced (Intercept-treated), pooled apheresis FFP product collected from French volunteer donors

  OR

- A lyophilized, Leukocyte Depleted, pooled apheresis FFP product collected from U.S. volunteer donors.

French FDP is a packaged unit that includes:

- One (1) bottle of freeze dried plasma,
- One (1) bottle containing 200 mL or 250 mL water for injection; CAUTION: The plasma bottle must be reconstituted with the volume of water indicated on the plasma bottle label
- One (1) transfer set
- One (1) transfuseur pour sang et derives (transfuser for blood and derivatives); the transfuser is a sterile tubing set that contains: a toggle, an in-line 200 µ filter, a vent, and a needle for product administration

Instructions for Product Reconstitution

It is recommended to have all the French FDP used to treat an individual patient come from the same batch to limit the number of donors involved in the treatment of an individual patient. French FDP is supplied as a powder and is reconstituted with water for injection immediately before use to form an injectable preparation. Reconstitution should be completed at room temperature in less than 5 minutes, and the solution in most cases is a cloudy liquid. Sometimes the solution will have visible particles. These do not constitute signs of degradation. When reconstituted, the volume of French FDP is equivalent to about 210 - 270 mL of human plasma.

French FDP is reconstituted in the following manner:

- Bring the 2 flasks (powder and solvent) to room temperature (+20°C to +25°C) (68°F- 77°F) if necessary.
- Remove the protective capsules from the 2 flasks.
- Disinfect the surface of each lid.
- Pierce the lid of the flask containing the water first with one of the bevels of the transfer set. **Be sure that you spike the water first. If you accidentally spike the powder first, you will lose the vacuum and then be unable to transfer the water to the bottle of powder using the transfer set.**

- Use the other bevel to pierce the lid of the flask containing the powder.
- Pour the entire contents of the water flask into the flask containing the powder via the transfer set.
- Gently agitate the flask making horizontal rotations without generating a foam (do not shake) to homogenize the mixture.
- Wait 3 to 5 minutes for the product to dissolve entirely before injecting.

Instructions for Product Administration:

- Before infusion, check that the glass flask is intact. Do not use the contents of a damaged flask under any circumstances.
- Obtain a set of pre-infusion vital signs if tactical conditions permit.
- Prior to infusion, you must open the vent on the sterile tubing set. Using the intravenous infusion set provided, immediately administer the entire preparation intravenously.
- Obtain a set of post-infusion vital signs if tactical conditions permit.
- Closely monitor the patient for signs of an adverse reaction (e.g., fever, rash, hives, difficulty breathing, flank pain, darkening urine) and for adequacy of resuscitation (return of radial pulse or improvement in systolic blood pressure to approximately 90 mm Hg, improvement in mental status, improved hemorrhage control).

Repeated administration may be necessary until evacuation to a higher capability of care where more sophisticated treatment can be rendered. Following administration of French FDP, patients should be monitored as closely as circumstances permit. Ideally, vital signs will be checked and recorded 15 minutes after the first infusion, and this will be repeated in 15 minutes, then every 30 minutes (twice), and then hourly or until transfer of care occurs. Patients need to be observed for signs and symptoms of reaction to blood products including chills, back or chest pain, hives, rash, fever, shortness of breath, and/or wheezing.

Risks and Adverse Events and Emergency Measures

As with transfusion of standard blood plasma, the use of French FDP carries infectious risks. French FDP may contain viruses and other infectious agents that cause hepatitis and other diseases (e.g., HIV and variant Creutzfeldt-Jakob disease (vCJD), a transmissible spongiform encephalitis). However, the risk of infection is very low.

Other potential risks of French FDP transfusion include: over-transfusion, which is unlikely to occur since French FDP will be given only to treat hemorrhage or coagulopathy; system dysfunction; severe hypocalcemia; acute shortness of breath after transfusion (due to transfusion-associated circulatory overload or transfusion-related acute lung injury); hemolytic transfusion reactions; and non-hemolytic febrile transfusion reactions due to the presence of inflammatory mediators in French FDP. There also is the possibility of risks that are unknown or that cannot be foreseen based on current data. Anyone receiving this product may not be able to donate blood or blood products, such as plasma, in the future.

In the case of an adverse reaction to French FDP, the infusion should be stopped immediately, venous access should be maintained, and treatment appropriate for the severity of the symptoms should be initiated. A US Pharmacopeial (USP)-grade calcium solution (approved for parenteral administration) should be administered after 4 units of French FDP have been infused to avoid hypocalcemia secondary to citrate administration and if signs and symptoms of hypocalcemia develop. Signs and symptoms of hypocalcemia include seizures and other neuropsychiatric symptoms, increased neuromuscular irritability, cardiovascular symptoms, and autonomic symptoms.

Risk and Benefit Statement

The known and potential benefits of French FDP, when used to treat 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, outweigh the known and potential risks. Treatment of hemorrhage or coagulopathy should be instituted immediately. In instances when plasma is not available and treatment with French FDP is needed, the potential risk of developing serious treatment-related adverse events must be weighed against the risk of death due to hemorrhage or coagulopathy. The expected benefit of treatment with French FDP is to increase human survival by mitigating the consequences 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.

Contraindications

Hypersensitivity to the active substance or one of the excipients. History of hypersensitivity to FFP or to plasma-derived products.

Adverse Event Reporting and Additional Product Information

Report adverse events to your service component coordinator and the U.S. Army Medical Research and Development Command. Reports should state that French FDP was used under an EUA.

For additional information about French FDP and this EUA, contact the U.S. Army Medical Research and Development Command:

US Army Medical Research and Development Command
ATTN: FCMR-ORA
1430 Veterans Drive
Fort Detrick, MD 21702-5009 Fax: 301-619-0197
Telephone: 301-619-0317
Email: usarmy.detrick.medcom-usamrdc.mbx.sae-reporting@health.mil

To the extent feasible given emergency circumstances, U.S. military personnel receiving French FDP under this EUA should receive the authorized *Fact Sheet for Recipients* about this product. However, given operational conditions under which French FDP may need to be administered under this EUA, in an emergency some patients may not be able to read a fact sheet due to life-threatening medical conditions or U.S. military medical personnel might not be able to provide the fact sheet. Therefore, the fact sheet information may also be provided to U.S. military forces prior to or during deployment (e.g., in training).

APPENDIX H: FRENCH FDP (FRENCH LYOPHILIZED PLASMA – FLYP) RECIPIENT FACT SHEET

Fact Sheet for Recipients

You have been given this Centre de Transfusion Sanguine des Armées Leukocyte-Depleted Freeze Dried Plasma (French FDP) fact sheet to review because you have, or at some point during your deployment you may experience, hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that could cause injury, harm, or death. French FDP may be 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, because it may increase your chance of survival.

What is French FDP?

French FDP is leukocyte-depleted, freeze-dried plasma manufactured by the Centre de Transfusion Sanguine des Armées in France. French FDP may be manufactured from either pooled French-sourced, pathogen-reduced (INTERCEPT™-treated) apheresis plasma or pooled United States-sourced, FDA-licensed apheresis plasma. U.S.-sourced plasma has been subjected to standard donor screening and tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. The source of plasma will be identified in the labeling of the final product. French FDP is for the treatment of severe or life-threatening blood loss (hemorrhage) or coagulopathy when plasma is not available for use or when the use of plasma is not practical. Coagulopathy is a condition that affects the way the blood clots. It is characterized by excessive bleeding following an injury or medical procedures. French FDP will only be used by trained U.S. military medical personnel in an emergency situation in settings where plasma is not available or when treatment with plasma is not practical.

Who can receive French FDP?

U.S. military forces and other individuals, such as allied military personnel, who experience 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 may receive French FDP from U.S. military medical personnel. French FDP may prevent serious blood clotting abnormalities from developing and may restore circulating blood volume, possibly saving your life. Because conventional plasma or other blood products might not be available due to operational considerations, French FDP might be the only available treatment for hemorrhage or coagulopathy in an emergency situation.

What are the risks or side effects of French FDP?

As with transfusion of standard blood plasma, the use of French FDP carries infectious risks. Since it is manufactured from plasma obtained from blood donors, French FDP may contain viruses and other infectious agents that cause hepatitis and other diseases (e.g., HIV and variant Creutzfeldt-Jakob disease (vCJD), a transmissible spongiform encephalitis sometimes referred to as "Mad Cow" disease, which causes severe brain degeneration). However, the risk of infection is very low.

Fact Sheet for Recipients

Other potential risks of French FDP transfusion include excessive volume replacement, which may lead to acute heart failure and pulmonary edema (lung congestion which makes it difficult to breathe); severe hypocalcemia (low calcium levels), which can cause muscle cramps and numbness around your mouth (however, the effects of hypocalcemia can be reversed with intravenous calcium solutions which may be carried along with French FDP); hemolytic transfusion reactions (breakdown of your red blood cells); acute shortness of breath after transfusion; and in rare cases, severe allergic reactions (anaphylaxis-like reactions) may be observed. These can be treated with medications, such as antihistamines and epinephrine, carried by medics.

There is also the possibility of risks that are unknown or that cannot be foreseen based on current information. In addition, you may not be able to donate blood or blood products, such as plasma, in the future.

What if I decide not to receive French FDP?

If you are conscious, you will be given the choice whether to receive French FDP. However, it is possible that French FDP may be given to you in a life-threatening situation when you are not able to make a decision or provide consent. During an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) where plasma is not available or practical, hemorrhage or coagulopathy are serious and potentially deadly conditions that can occur very fast; French FDP is a treatment for such conditions. If you decide not to be treated, the chance of dying from severe or life-threatening bleeding may be greater. There is still a chance of dying even with French FDP treatment.

If you are able to talk to the U.S. military medical health care provider administering the product, or if you receive this Fact Sheet in advance of an emergency (e.g., during training), you might want to ask the following questions:

- What will happen to me during treatment with this product?
- What alternative treatment options are available to me?
- What adverse reactions might I experience if I receive this product?

Is French FDP approved by the U.S. Food and Drug Administration (FDA)?

French FDP is not an FDA-licensed product. French FDP is approved by the French equivalent of the FDA, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) and has been used by French Military forces. French FDP has also been used by the U.S. military to treat severe hemorrhage of wounded Special Operations Forces (SOF) under an FDA Investigational New Drug Application (IND).

FDA has authorized the use of French FDP under an Emergency Use Authorization (EUA) because of the lack of available FDA-licensed FDP and because, while the standard of care for hemorrhage includes giving patients plasma and using standard bleeding control measures (e.g., tourniquets, direct pressure, bandages, and dressings), conventional plasma products may

Fact Sheet for Recipients

be unavailable or their use may not be practical in emergency situations. In addition, conventional plasma is typically kept frozen and then thawed immediately prior to use, thus making it impractical for battlefield use. The EUA also permits use of French FDP if needed to treat other individuals, such as allied military personnel.

An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The Secretary of the U.S. Department of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of FDP 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. FDA authorized the emergency use of French FDP for this purpose only for the duration of the threat of the emergency, unless the EUA is terminated or revoked by FDA sooner.

For More Information and to Report Adverse Reactions Regarding This Product

Tell your U.S. military medical health care provider if you experience side effects that bother you or that do not go away. If you have additional questions or concerns regarding this product and EUA, you can contact your U.S. military medical health care provider and/or:

U.S. Army Medical Research and Development Command
(USAMRDC)
1430 Veterans Drive
Fort Detrick, MD 21702-5009
Phone: 301-619-0317
Email: usarmy.detrick.medcom-usamrdc.mbx.regulatory-affairs@health.mil

APPENDIX I: FDA MED WATCH FORM 3500 (USED FOR BOTH OCTAPLASLG AND FRENCH FDP (FRENCH LYOPHILIZED PLASM A – FLYP)

Note: *FDA Med Watch Form 3500 is used for both octaplasLG and French FDP (French Lyophilized plasma -FLYP)*

Reset Form

FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH

FORM 3500

For use by Health Professionals for VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Form Approved: OMB No. 0910-0291
Expires: 09-30-2027
See PRA statement on page 8.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: *For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.*

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*

2. **Age**
☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s) **or Date of Birth** *(e.g., 01-Jan-1900)*

3. **Sex**
☐ Male ☐ Female

4. **Weight**
☐ lb ☐ kg

5. **Race and/or Ethnicity** *(Select all that apply)*
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Hispanic or Latino
☐ Middle Eastern or North African
☐ Native Hawaiian or Pacific Islander
☐ White

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Type of Report** *(Check all that apply)*
☐ Adverse Event
☐ Product Use/Medication Error
☐ Product Problem *(e.g., defects/malfunctions)*
☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death – Date of death *(e.g., 01-Jan-1900)*:
☐ Hospitalization (*Initial or prolonged*)
☐ Life-threatening
☐ Disability or Permanent Damage
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events

3. **Date of Event** *(e.g., 01-Jan-1900)*

4. **Date of this Report** *(e.g., 01-Jan-1900)*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

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5. **Describe Event, Problem or Product Use/Medication Error** Characters Remaining (max. 4,000):

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

* Please see instructions

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6. Relevant Test/Laboratory Data	Low Test Range	High Test Range	Date *(e.g., 01-Jan-1900)*

Additional comments Characters Remaining (max. 2,000):

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, pregnancy, tobacco product use, liver/kidney problems, etc.)* Characters Remaining (max. 2,000):

C. PRODUCT AVAILABILITY

1. **Product Available for Evaluation?** *(Do not send product to FDA)*
   - ☐ Yes
   - ☐ No
   - ☐ Returned to Manufacturer on *(e.g., 01-Jan-1900)* ☐

2. **Do you have a picture of the product? While not required, pictures of all sides of the product will help FDA review your report.** *(Check yes if you are including pictures.)*
   - ☐ Yes

D. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder** *(From product label).*

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name | Lot #

Place and Date of Purchase

Name

Address

City | State/Province/Region | ZIP/Postal Code

Country

Website (If purchased online) | Purchase Date

2. **Dose or Amount** | **Frequency** | **Route**

Unit | **Other Frequency** | **Other Route**

3. **Treatment/Therapy/Usage Dates** *(Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)*

Therapy/Usage started on *(e.g., 01-Jan-1900)*

Therapy/Usage stopped on *(e.g., 01-Jan-1900)*

Dose reduced on *(e.g., 01-Jan-1900)*

OR Duration | Unit

Is therapy/usage still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(Indication)*

5. **Product Type** *(Check all that apply)*

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-Counter (OTC)
- ☐ Compounded product *(By a Pharmacy or an Outsourcing Facility)*

Cosmetics *(Select One)*

- ☐ Cosmetics for professional use only
- ☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products *(Such as products containing CBD)*
- ☐ Other

6. **Expiration Date** *(e.g., 01-Jan-1900)*

7. **Event Abated after use Stopped or Dose Reduced?**

☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared after Reintroduction?**

☐ Yes ☐ No ☐ Doesn't apply

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SUSPECT PRODUCT #2

1. **Name, Strength, Manufacturer/Compounder** *(From product label).*

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name | Lot #

Place and Date of Purchase

Name

Address

City | State/Province/Region | ZIP/Postal Code

Country

Website (If purchased online) | Purchase Date

2. **Dose or Amount** | **Frequency** | **Route**

Unit | **Other Frequency** | **Other Route**

3. **Treatment/Therapy/Usage Dates** *(Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)*

Therapy/Usage started on *(e.g., 01-Jan-1900)*

Therapy/Usage stopped on *(e.g., 01-Jan-1900)*

Dose reduced on *(e.g., 01-Jan-1900)*

OR Duration / Unit

Is therapy/usage still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(Indication)*

5. **Product Type** *(Check all that apply)*

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-Counter (OTC)
- ☐ Compounded product *(By a Pharmacy or an Outsourcing Facility)*

Cosmetics *(Select One)*

- ☐ Cosmetics for professional use only
- ☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products *(Such as products containing CBD)*
- ☐ Other

6. **Expiration Date** *(e.g., 01-Jan-1900)*

7. **Event Abated after use Stopped or Dose Reduced?**

☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared after Reintroduction?**

☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Procode	2b. Common Device Name

3. Manufacurer Name, City and State

4. Model #	Lot #	Catalog #

Expiration Date *(e.g., 01-Jan-1900)*	Serial #

Unique Device Identifier *(UDI)* # Characters Remaining (max. 1,000):

5. Operator of device	6a. If Implanted, Give Date *(e.g., 01-Jan-1900)*	6b. If Explanted, Give Date *(e.g., 01-Jan-1900)*
☐ Health Professional ☐ Patient/Consumer ☐ Other		

7a. Is this a single-use device that was reprocessed and reused on a patient?	7b. If Yes to Item 7a, Enter Name, Address of Reprocessor	8. Was this device ever serviced by a third-party servicer?
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Product names and therapy dates *(Exclude treatment of event)*

	Product Name	Therapy Start Date *(e.g., 01-Jan-1900)*	Therapy End Date *(e.g., 01-Jan-1900)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

G. REPORTER *(See confidentiality section on next page)*

1. **Name and Address**

Last Name	First Name

Address

City	State/Province/Region	ZIP/Postal Code

Country

Phone #	Email

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer ☐ Packer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at:
https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Cannabinoid hemp products (such as products containing CBD)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Cosmetics (such as moisturizers, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)
- Just fill in the sections that apply to your report

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To report by mail: Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Av., Silver Sprint, MD 20993
- To fax report: 1-800-FDA (332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Where to submit adverse events related to the following products:

- If your report involves an animal drug, device, pet food and livestock feed problems, go to http://www.fda.gov/vetproductreporting
- If your report involves a health problem or a product problem with a tobacco product, including e-cigarettes (nicotine-coning vapes) or nicotine pouches, go to https://www.safetyreporting.hhs.gov or call 1-877-287-1373 to report.
- If your report involves a health problem or product problem with foods or special nutritional products such as infant formulas, dietary supplements, or medical foods, go to https://www.safetyreporting.hhs.gov or call 1-888-723-3366 to report.
- If your report involves an adverse event with a vaccine, go to https://www.vaers.hhs.gov to report or call 1-800-822-7967.

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Confidentiality:
The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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MedWatch Health Professionals Voluntary Reporting

APPENDIX J: MEDICAL MATERIEL CLASS VIII LIST

This itemized checklist supports implementation of the Use of Dried Plasma in the Deployed Trauma System and Contingency Operations CPG. These components represent the minimum materiel necessary to safely reconstitute, administer, and monitor dried plasma in accordance with the JTS CPG and the octaplasLG Powder EUA Fact Sheet.

DRIED PLASMA PRODUCT COMPONENTS REQUIRED CONSUMABLES

octaplasLG Powder vial (A or AB plasma)

- Sterile water for Injection bag (190 mL)
- Manufacturer-provided transfer set
- Manufacturer-provided vented spike adaptor
- Manufacturer-provided transfusion set with 170–200 µm filter

French FDP/FLYP Powder vial

- Sterile water for Injection (200mL or 250mL)
- Manufacturer-provided transfer set
- Manufacturer-provided tubing set (toggle, in-line 200 µm filter, a vent, and needle for product administration)

RECONSTITUTION SUPPLIES ASEPTIC PREPARATION

- Alcohol prep pads (minimum 2 per unit)
- Sterile gloves
- Clean field or sterile drape
- Waste disposal bag/container environmental requirements
- Timer/watch for reconstitution monitoring
- Product should dissolve within approximately 15 minutes
- Discard if not fully dissolved within 30 minutes

INTRAVENOUS ACCESS SUPPLIES PERIPHERAL IV ACCESS

- IV catheters 18 gauge, 16-gauge, 14-gauge
- IV extension tubing
- Saline flushes
- Transparent dressing
- IV securement tape alternative access
- Intraosseous (IO) device and needles when IV access cannot be obtained

ADMINISTRATION EQUIPMENT INFUSION COMPONENTS

- Vented transfusion set with 170–200 µm filter
- Vented spike adaptor
- IV pole or suspension device (optional)

PATIENT MONITORING EQUIPMENT PRE-INFUSION

- Blood pressure cuff
- Stethoscope
- Pulse oximeter
- Thermometer
- Cardiac monitor (if available)
- Vital signs documentation sheet pre and post-infusion

ADVERSE REACTION MANAGEMENT SUPPLIES.

The EUA specifically highlights risks of transfusion reactions, anaphylaxis, TRALI, hypervolemia, and citrate toxicity.

Emergency Medications:

- Epinephrine 1 mg/mL (1:1000)
- Diphenhydramine
- Methylprednisolone or Hydrocortisone
- Calcium gluconate or calcium chloride
- For citrate-induced hypocalcemia airway and oxygen support
- Oxygen source
  - Nasal cannula
  - Non-rebreather mask
  - Bag-valve-mask (BVM)
- Suction equipment

MATERIALS BLOOD PRODUCT DOCUMENTATION

- DD Form 1380 TCCC Card
- Blood product administration record
- Serious Adverse Event Form (if needed)
- Patient monitoring/vital signs worksheet product tracking
- FDA Med Watch Form 3500

RECOMMENDED MINIMUM

"One-Unit Dried Plasma Administration Kit" For an operational Role 1, prolonged casualty care, or far-forward team: The items that are unique and essential to octaplasLG powder administration are:

- octaplasLG powder vial
- Sterile water for injection (190 mL)
- Transfer set
- Vented spike adaptor
- Transfusion set with 170–200 µm filter
- Alcohol prep pads
- Large-bore IV/IO access
- Basic patient monitoring equipment
- Emergency medications for transfusion reactions

For additional information including National Stock Number (NSN), please contact dha.ncr.med-log.list.lpr-cps@health.mil
***DISCLAIMER:** This is not an exhaustive list. These are items identified to be important for the care of combat casualties.*

APPENDIX K: TELEMEDICINE / TELECONSULTATION

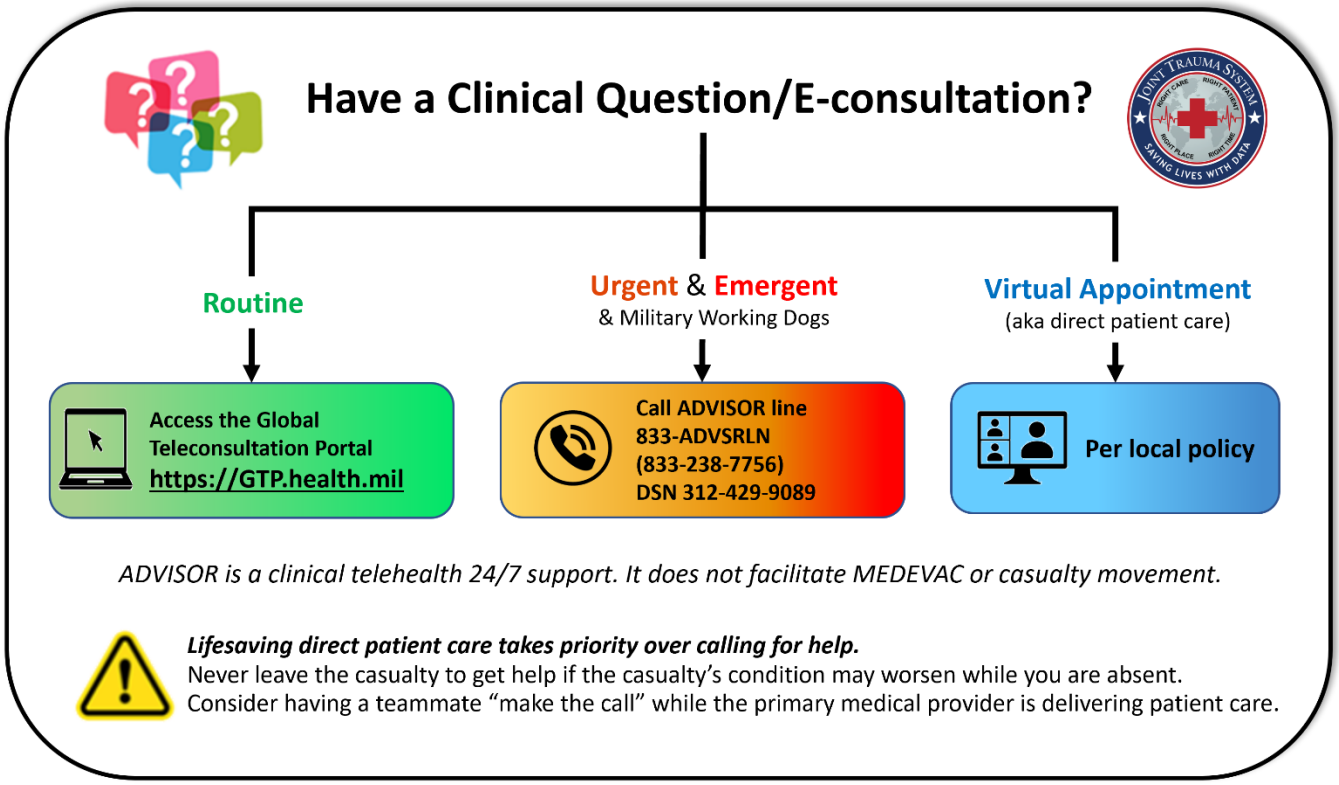

Illustration by Raymond Samonte
GTP: https://GTP.health.mil

Theater Patient Movement Requirements Center (TPMRC) to coordinate evacuation:

- *TPMRC-Americas (NORTHCOM & SOUTHCOM), 618-817-4200*
- *TPMRC- East (EUCOM, AFRICOM, CENTCOM), DSN 314-480-8040*
- *TPMRC- West (INDOPACOM), DSN 315-448-1062*

APPENDIX L: INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.