

**USAMMDA INFORMATION PAPER****PRODUCT:** HEMOGLOBIN BASED OXYGEN CARRIER (HBOC)

**DESCRIPTION:** This product is a solution of hemoglobin polymer derived from either human or animal blood. Hemoglobin is the oxygen-carrying component of red blood cells. Manufacturers have designed HBOC to be used in the event of a massive hemorrhage resulting in the rapid loss of blood when whole blood is not available for transfusion. This product is more advantageous than whole blood since it is stable for longer periods of time and at higher temperatures (up to a year at room temperature depending on the manufacturer) and up to two years at 4°C as compared to whole blood, which can be stored refrigerated for a maximum of 42 days. This product is also universally compatible and does not require blood typing prior to use.

**PROGRAM RELEVANCE to the ARMY:** This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities." In any conflict or civilian disaster, it is an unfortunate fact that there will be casualties with severe bleeding. This product is intended to save soldiers' lives in those situations. The medic will use this product far forward to replace lost blood and allow the casualty to be evacuated to available medical assets further back, again reducing the logistical burden far forward. This product supports Future Operational Capability MD97-003 (Patient Treatment and Area Support), MD97-005 (Far-Forward Surgical Support), MD97-008 (Combat Health Logistics System [CHLS] and Blood Management).

**ISSUES/ ACTIONS:**

- Support for troops deployed in the war against terrorism and Operation Enduring Freedom (OEF)/ Operation Iraqi Freedom (OIF) increased the urgency in making this product available. There are at least three manufacturers of this product. None of these products are Food and Drug Administration (FDA) approved. Each manufacturer has a product in a different level of development for different indications. At least one manufacturer has a product in a pivotal Phase 3 trial for licensure.
- Previous experience with products of this type and the toxicities associated with them will have to be addressed in order to continue development of this product. While none of these products under evaluation exhibit any toxicity, this is one area that the FDA will be very interested in and will monitor closely.
- It is necessary for this product to be officially designated as a Contingency Protocol for Force Health Protection in order for this product to have the Human Subject Research Review Board designated the Investigational Review Board of record.
- There is no draft Capabilities Development Document (CDD). The Research Area Directorate has a Mission Needs Statement (MNS). Since this is not an Army-developed item, the need for a Joint Operational Requirements Document (JORD) is not required.
- There is no out-year monetary support of this product. Present funding comes from a year-to-year Congressional set-aside. Until funding is programmed for this product in the POM, Army/Department of Defense (DoD) program initiation will not occur.
- Presently, the commercial market is developing this product without Army or DoD sponsorship or funding. It is not a DoD-developmental item.

**BPL #:** 437**DA PROJECT/TASK:** Combat Casualty Care  
PE/PROJ 643807.836BC**MAMP RANK:** NA**ARMY ORD:****CARDS#****SCHEDULE:**

Decision Review 4QFY04

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