



A Joint Statement to the Food and Drug Administration's Blood Product Advisory Committee

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Cold Stored Platelets for Transfusion

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AABB, America's Blood Centers and the American Red Cross appreciate the opportunity to present this statement in support of FDA's stated interest in engaging stakeholders to explore the scientific considerations for cold stored platelets intended for transfusion, and the clinical indications for use. We appreciate FDA's recent approval of the alternative procedure submitted by the Armed Services Blood Program which permits the storage of this innovative product "at 1-6 C for up to 14 days without agitation" for use in treating "actively bleeding patients" without the need to perform bacterial risk control strategies.

We believe cold stored platelets may have an important role in the treatment of actively bleeding patients in civilian populations. The availability of cold stored platelets could significantly improve patient care by expanding transfusion options for actively bleeding patients and positively impacting the availability of this challenging product through the extended expiration date of "up to 14 days," while decreasing patient risk for bacterial contamination through cold storage.

As FDA engages stakeholders, blood collectors also have many questions that must be answered. We are interested in the collection and product management requirements that would support the logistics for the collection of these products, including storage and transport temperatures, as well as timelines necessary to manufacture and label these cold stored products. We are interested in the data that will be presented today for collection devices, product types, including the potential use of pathogen reduction technology.

We are pleased that FDA is pursuing new information and look forward to hearing the evidence and the Blood Product Advisory Committee's recommendations that will ultimately inform FDA's decisions on the safety and efficacy of this innovative product in civilian clinical settings. Thank you for the opportunity to offer these comments on behalf of our members.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.