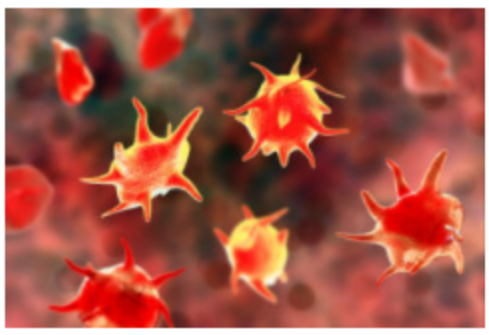
FDA Update about Bacterial Contamination of Platelets

December 8, 2021



The United Stated Food and Drug Administration (FDA) issued guidance to reduce the risk of septic transfusion reactions associated with platelets. One of the approved mitigation strategies is pathogen reduction. The FDA issued a new bulletin that there have been three reported cases of septic transfusion reactions in the United States since 2019 from bacterial contamination of platelets. Two of three of these cases were fatal. All three were contaminated with either *Acinetobacter* spp, *Staphylococcus saprophyticus*, *Leclercia adecaboxylata*, or combinations of these species despite these units being pathogen reduced. Since 2018, seven cases of platelet septic transfusion reactions have been reported. Based on genetic testing by the U.S. Centers for Disease Control and Prevention (CDC) all of these cases may have a common, unidentified source. The U.S. CDC and FDA will continue to monitor the situation and ask blood establishments and transfusion services to be alert and report any additional cases of potential septic transfusion reactions.

Reference:

U.S. Food & Drug, Safety and Availability (Biologics) Bulletin. Important information for blood establishments and transfusion services regarding bacterial contamination of platelets for transfusion.

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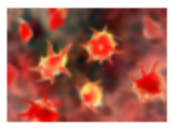

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