FDA slaps U.S. Red Cross with $16 million in fines over blood safety violations

Mass Device

The Food & Drug Administration fined the American Red Cross $16 million for failing to meet federal rules about the collection and manufacture of blood products.

The federal watchdog agency said it found no evidence of danger ton patients or of any compromise to the blood supply, despite the violations.

"Multiple layers of safeguards are in place to protect and enhance the safety of blood products. However, these types of violations decrease the assurance that blood products manufactured by American Red Cross will continue to be safe and have the potential to compromise the safety of the blood supply," according to a press release [1].

The $16.2 million in fines stem from two separate violations. The FDA levied $9.8 million in penalties for "mismanagement of certain blood products" — namely red cells, plasma and platelets — and $6.4 million for violations of good manufacturing practice. In October 2009, the agency told the charity that FDA inspections in 2008 and 2009 turned up "violations that included failure to identify problems that occur during manufacturing and failure to adequately investigate identified problems."

The fines were assessed under an amended 2003 consent decree outlining the charity's obligation to ensure the safety of the U.S. blood supply. The agency sent 12 similar letters to the Red Cross, imposing more than $21 million in fines under the terms of the consent decree.

SOURCE [2]

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