Report to the Legislature CDFA Animal Blood Banks 2024



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BACKGROUND INFORMATION

As a result of increased specialization in veterinary medicine, the demand for animal blood products has risen dramatically. A safe and adequate supply of blood and blood component products for transfusion is vital to animal health. Commercial blood banks for animals produce and sell blood and blood component products, increasing the supply available for transfusions. The California Department of Food and Agriculture (CDFA) Animal Blood Banks program specifies current standards of care and practice for veterinary blood banks and works to ensure that animal blood and blood component products sold in California are efficacious and safe.

Historically, California required commercial blood banks for animals to be closed-colony establishments. On January 1, 2022, Assembly Bill 1282 (Bloom, Chapter 752, Statutes of 2021), the California Pet Blood Bank Modernization Act, went into effect. This law aims to address the shortage of animal blood available for veterinary transfusion medicine in California and transition the State from closed-colony blood banks to community blood banks.

Since January 1, 2022, importation and sale of canine blood and blood component products from out-of-state sources has only been permitted from community blood banks (Food and Agricultural Code (FAC) § 9252 (b)).

CDFA will discontinue its licensing program for commercial blood banks for animals that produce canine blood and blood component products sourced from captive closed-colony dogs within 18 months of determining that community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters. This will be announced on the CDFA website at: https://www.cdfa.ca.gov/AHFSS/CABB/ (FAC § 9212.5(a)).

OUTREACH

In 2023, CDFA collaborated with the California Veterinary Medical Association to host a series of continuing education webinars addressing the regulatory changes to animal blood banking in California. Additionally, CDFA joined forces with the University of California, Davis, to provide veterinarians and animal hospitals with technical information related to starting an animal blood bank. CDFA further reinforced its dedication to outreach efforts by having an active presence at the Pacific Veterinary Conference in Long Beach and establishing a dedicated support system to address inquiries from veterinarians interested in selling animal blood and blood component products for transfusion.

COMMUNITY BLOOD BANK PRODUCT REGISTRATION

In September 2023, the Animal Blood Banks program achieved a significant milestone by successfully registering the initial blood and blood component products from a community blood bank. In October, a second community blood bank completed the product registration process with CDFA. These registrations signify a pivotal step in the transition from closed-colony blood banks to community blood banks in California. For a comprehensive list of all registered blood and blood component products, please refer to: https://www.cdfa.ca.gov/ahfss/CABB/docs/ProductsRegisteredwithCDFA.pdf

ANIMAL BLOOD BANKING GUIDANCE DOCUMENT

In accordance with FAC § 9255, the CDFA Animal Blood Banks program developed and made available an Animal Blood Banking Guidance Resource in 2022. As the field of animal blood banking and transfusion medicine is rapidly evolving, the guidance document was updated several times in 2023. This resource is designed to provide veterinarians accurate, clear, and concise information regarding best management practices for operating blood banks for animals. This document is intended to establish standards of care and practice for veterinary blood banks to ensure that animal blood and blood component products will not only be efficacious, but also not be contaminated, dangerous, or harmful. The most up-to-date version of the guidance document is available at: https://

www.cdfa.ca.gov/AHFSS/cabb/docs/animal_blood_banking_guidance_resource.pdf

CANINE BLOOD COLLECTION INFORMATION

CDFA requires animal blood banks selling products in California to submit quarterly reports to CDFA (Business and Professions Code § 4920.6, FAC § 9252 (c), and FAC § 9253 (b)). These reports are used to calculate the total estimated amount of canine blood sold in California by community blood banks and, separately, the total estimated amount of canine blood that closed-colony blood banks sold in the state.

If CDFA finds that community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters, then the Animal Blood Banks program shall provide notice on the CDFA internet website that discontinues its licensing program for closed-colony blood banks for dogs within 18 months from the date of that notice (FAC § 9212.5).

2023 Canine Blood and Blood Component Quarterly Reports

January 1, 2023 - March 31, 2023

Blood Bank Type	Whole Blood (ml)	Red Blood Cells (ml)	Fresh-Frozen Plasma (ml)	Total (ml)
Closed-Colony Blood Banks	46,250	213,500	157,476	417,226
Community Blood Banks	0	0	0	0

The amount of blood sold by community blood banks did not exceed the amount sold by closed-colony blood banks this quarter.

April 1, 2023 – June 30, 2023

Blood Bank Type	Whole Blood (ml)	Red Blood Cells (ml)	Fresh-Frozen Plasma (ml)	Total (ml)
Closed-Colony Blood Banks	44,375	222,625	184,440	451,440
Community Blood Banks	0	0	0	0

The amount of blood sold by community blood banks did not exceed the amount sold by closed-colony blood banks this quarter.

July 1, 2023 – September 30, 2023

Blood Bank Type	Whole Blood (ml)	Red Blood Cells (ml)	Fresh-Frozen Plasma (ml)	Total (ml)
Closed-Colony Blood Banks	45,875	218,750	204,900	469,525
Community Blood Banks	0	0	0	0

The amount of blood sold by community blood banks did not exceed the amount sold by closed-colony blood banks this quarter.

October 1, 2023 - December 31, 2023

Blood Bank Type	Whole Blood (ml)	Red Blood Cells (ml)	Fresh-Frozen Plasma (ml)	Total (ml)
Closed-Colony Blood Banks	37,375	206,000	166,044	409,419
Community Blood Banks	300	500	480	1,280

The amount of blood sold by community blood banks did not exceed the amount sold by closed-colony blood banks this quarter.

Total for 2023: January 1, 2023 – December 31, 2023

Blood Bank Type	Whole Blood (ml)	Red Blood Cells (ml)	Fresh- Frozen Plasma (ml)	Total (ml)
Closed-Colony Blood Banks	173,875	860,875	712,860	1,747,610
Community Blood Banks	300	500	480	1,280

Based on these figures, the CDFA shall continue its licensing program for closed-colony blood banks in 2024. This information was published on the Animal Blood Banks program website.

INSPECTIONS

All commercial blood banks and associated facilities were inspected in 2023. No major deficiencies were identified.

2024 PLANS

In 2024, the CDFA Animal Blood Banks program is committed to the continued collection, reporting, and analysis of animal blood and blood component sales. Comprehensive inspections will be conducted for all blood banks with registered products. The program will continue outreach initiatives to inform veterinarians about the changes mandated by Assembly Bill 1282 (Bloom, Chapter 752, Statutes of 2021). Efforts will be directed toward the registration of additional products from community blood banks. Additionally, the program will promulgate regulations to clearly delineate the requirements for operating a commercial blood bank in California. A robust regulatory framework is essential to establish clear license, registration, reporting, and fee procedures to ensure that animal blood and blood component products are not only safe and efficacious, but also produced in a humane manner. This proposed regulatory action will help facilitate a smooth transition from closed-colony blood banks to community-based blood banks. In January 2024, the regulations were submitted to the Office of Administrative Law and a copy of the regulations were placed on the program website (https://www.cdfa.ca.gov/AHFSS/CABB/). The public comment period began February 2, 2024, and ends on March 18, 2024.