DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

ANIMAL BLOOD BANKS

The California Department of Food and Agriculture (Department) proposes to amend the California Code of Regulations (CCR) Title 3, Division 2, Chapter 8 heading, and adopt new Articles 1 - 4 (commencing with section 1303) to implement, interpret, and make specific the laws related to animal blood banks.

PROBLEM STATEMENT

As a result of increased specialization in veterinary medicine, the demand for animal blood products has risen dramatically. A safe and adequate supply of animal 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.

Historically, California required commercial blood banks for animals to be closed colony establishments. In 2021, the legislature passed Assembly Bill 1282 (Chapter 752, Statutes of 2021), otherwise known as the California Pet Blood Bank Modernization Act (Act), to amend Section 4826 of, to amend, renumber, and add Section 4836.5 of, and to add Article 7 (commencing with Section 4920) to Chapter 11 of Division 2 of, the Business and Professions Code (BPC), and to amend Sections 9201, 9210, 9212, 9221, 9231, 9241, 9244, 9269, and 9272 of, to add Sections 9212.5, 9222, 9252, 9253, 9254, and 9255 to, and to repeal Sections 9202, 9203, 9204, 9205, and 9206 of, the Food and Agricultural Code (FAC). The goal of the Act is 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.

BPC Section 4920.6, FAC Section 9252, and FAC Section 9253 require commercial blood banks for animals selling or producing products in California to submit quarterly reports to the Department. These sections, however, do not define the dates of each quarterly period or specify when quarterly reports must be submitted to the Department. Similarly, FAC section 9253(b) requires that closed-colony blood banks licensed with the Department submit quarterly reports. This section, however, does not address the requirements of facilities under contract with closed colony blood banks. For instance, a closed-colony kennel that supplies dogs to the blood bank is not required to report the number of animals kept, housed, or maintained at their facility.

FAC section 9212.5 requires the Department to 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 making a finding 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. Calculation of canine blood totals are based on whole blood, packed red blood cells, and fresh-frozen plasma. However, this section does not specify if the discontinuation of the closed-colony blood bank licensing program should be based on total canine blood sold or if each category should be considered separately. Additionally, as only three blood and blood component products are included in the calculations,

this has created a disincentive for currently licensed closed colony blood banks to produce other blood component products.

FAC section 9221 requires that closed-colony blood banks register with the Department. BCP section 4920.4 states that community blood banks must register with the California Veterinary Medical Board. It is unclear who should license or register a commercial blood bank that is obtaining blood from community sourced animals but is not a veterinary premises, such as establishments that obtain blood or blood component products from a community blood bank for additional processing, distribution, or resale.

FAC section 9242 requires the Department to register blood and blood component products from community blood banks operating pursuant to Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code. Registration requirements are stated in FAC section 9244(a), but this section does not specify how the Department will ensure compliance with these product registration requirements.

FAC sections 9224(b) and 9231 require the Department set fees to cover the program's regulatory oversight and inspection costs. Current fees, which include a $1000 establishment license fee for closed-colony blood banks and a $500 registration application and renewal fee for each registered blood or blood component product, do not cover the Departments costs incurred to administer and enforce product safety standards.

The Act altered the animal blood bank market in California with the goal of transitioning from closed colony blood banks to community blood banks. The revision of statute requires the Department to take regulatory actions to carry out its core mission: of providing inspectional oversight – to protect product safety and animal welfare while increasing the supply of animal blood and blood component products available for transfusion.

PURPOSE

This proposed regulatory action is intended to interpret and make specific the requirements for operating a commercial blood bank in California. It aims to guarantee veterinarians will have access to high quality, lifesaving blood and blood component products for their patients throughout the transition from closed-colony blood banks for animals to community blood banks for animals. A robust regulatory structure is necessary to create 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 facilitate a smooth transition from closed-colony blood banks to community-based blood banks.

BENEFITS OF THIS REGULATORY PROPOSAL

This rulemaking proposal will make certain veterinarians, commercial blood banks for animals, and the public clearly understand when the Department will discontinue its licensing program for closed-colony blood banks, allowing all stakeholders to plan accordingly. In allowing additional animal blood products to be included in the estimated amount of canine blood sold in the California, it is anticipated that this will result in additional life-saving products being offered for

sale to California veterinarians and ultimately improve the quality of veterinary transfusion medicine in the State.

Additionally, the regulation ensures that commercial blood banks for animals and facilities that they contract with are routinely inspected. It specifies that all facilities must submit quarterly reports to the Department in a timely manner. Facility inspections and submission of comprehensive quarterly reports will allow the Department to monitor animal blood bank business practices more accurately, including animal health and welfare. It is anticipated that veterinary hospitals and the public will benefit from knowing animal blood and blood component products are produced in a safe and humane manner. By setting clear requirements and fee structures for those want to sell animal blood and blood component products, the Department anticipates more community blood banks will begin entering the market.

SPECIFIC PURPOSE AND RATIONALE FOR EACH SECTION, PER GOVERNMENT CODE 11346.2(b)(1):

Chapter 8 heading is proposed to read “Animal Blood Banks” to clarify that this chapter contains regulations related to animal blood banking and the former Animal Biologics program has been repealed.

Add proposed new Article 1. Definitions to specify the contents of the article.

Section 1303 is proposed to establish definitions of terms used in this Chapter. Although the Act includes the meaning of some terms, it is necessary to additionally include a list of terms as defined in these proposed regulations.

Section 1303(a) is proposed to add the term “adverse event” and establish that it has the same meaning as defined in FAC section 9201(a).

Section 1303(b) is proposed to add the term “animal” and establish that it has the same meaning as defined in FAC section 9201(b).

Section 1303(c) is proposed to add the term “biologics” and establish that it has the same meaning as defined in FAC section 9201(c).

Section 1303(d) is proposed to add the term “blood and blood component products” and specify that this definition includes lyophilized plasma and albumin, in addition to the products defined in FAC 9201(d). Lyophilized plasma and albumin are animal blood component products frequently requested by California veterinarians. The proposed definition specifies that antibody products, such as hyperimmune serums, are excluded from this definition of blood and blood component products.

Section 1303(e) is proposed to add the term “captive closed colony” and establish that it has the same meaning as defined in FAC section 9201(e).

Section 1303(f) is proposed to add the term “closed-colony blood bank” and establish that it has the same meaning as defined in FAC section 9201(f).

Section 1303(g) is proposed to add the term “commercial blood bank for animals” and specify that it includes facilities that obtain blood or blood component products for additional processing, distribution, and resale; in addition to those defined in FAC section 9201(g).

Section 1303(h) is proposed to add the term “community blood bank” and establish that it has the same meaning as defined in FAC section 9201(h).

Section 1303(i) is proposed to add the term “community sourced animal” and establish that it has the same meaning as defined in FAC section 9201(i).

Section 1303(i)(1) – (3) are proposed to specify the criteria required to be considered a Community Sourced Animal. Subsections (1) and (3) are the same as defined in FAC 9201(i)(1) and (3). Subsection (i)(2) specifies that caregivers, in addition to owners, may bring a Community Sourced Animal to a Community Blood Bank to have its blood collected. It is common in the pet industry for someone other than the owner to bring an animal to a veterinary premises.

Section 1303(j) is proposed to add the term “department” and establish that it means the California Department of Food and Agriculture, which is necessary to explain the meaning of the term as used throughout the Chapter.

Section 1303(k) is proposed to add the term “production” and establish that it has the same meaning as defined in FAC section 9201(j).

Section 1303(l) is proposed to add the term “quarterly reporting period” and establish that it means a calendar year quarter. It specifies dates for each quarter for the purposes of general usage and understanding by the regulated industry and public.

Add proposed new Article 2. Facility Licensing and Product Registration to specify the contents of the article.

Section 1304.1 is proposed to specify what must be included on an application for a license for an establishment that produces, or proposes to produce, blood and blood component products from a closed-colony blood bank.

Subsections 1304.1(a), (b), and (d) are the same as those listed in FAC subsections 9221(a), (b), (c), respectively.

Subsections 1304.1(b), (c), (e), (f), and (g) are proposed to clarify that the application must include information about facilities that keep, house, or maintain animal blood donors used by closed colony blood banks. This includes providing all the information required by FAC subsections 9221(a) – (e) for each of these types of facilities. This will help the Department ensure all closed-colony blood donors are being adequately cared for and treated humanely.

Section 1304.1(h) is proposed to specify the acceptable period for reporting changes to the Department. This is necessary to ensure that the Department has the most up-to-date and accurate information for licensed blood banks. Thirty days is adequate time for licensees to report changes in their operations.

Section 1304.2 is proposed to specify when the Department will discontinue its licensing program for commercial blood banks for animals that produce canine blood from captive closed-colony dogs.

Subsections 1304.2(a) and (b) are consistent with those listed in FAC subsections 9212.5 (a)(1)(A) and (B).

Section 1304.2(c) is proposed to clarify that all three product types referenced in FAC section 9212.5, which include whole blood, packed red blood cells, and fresh frozen plasma, must meet the criteria in subsections (a) and (b) for the captive closed-colony licensing program to be discontinued. This will ensure an adequate supply of all blood and blood component products throughout the transition from closed-colony blood banks to community blood banks. See the discussion of alternatives below.

Section 1304.2(d) is proposed to establish that blood component products other than whole blood, packed red blood cells, and fresh-frozen plasma to be included in the calculations required by this section. California veterinarians would like to be able to purchase blood and blood component products such as platelet concentrate, cryoprecipitate, cryosupernatant, and albumin. Currently, these products are only made by captive closed-colony blood banks. In limiting calculations to whole blood, packed red blood cells, and fresh-frozen plasma, there is a disincentive for closed-colony blood banks to offer additional blood component products for sale, as these other products often require using whole blood, fresh-frozen plasma, and/or packed red blood cells. Allowing additional products to count in calculated totals will guarantee a wide variety of animal blood component products for transfusion are available to California veterinarians during the transition from closed-colony blood banks to community blood banks.

Section 1304.2(d)(1) is proposed to establish that the blood component product must be registered with the Department to meet the standards for blood or blood component product registration set forth in FAC section 9242 and be in compliance with FAC section 9241(b).

Section 1304.2(d)(2) is proposed to establish that the amount of the product sold must be reported on quarterly reports submitted to the Department in a section separate from other totals. This ensures accurate record keeping and allows the Department to efficiently calculate blood and blood component totals.

Section 1304.2(d)(3) is proposed to allow the Department to determine what equivalents of whole blood, packed red blood cells, or fresh-frozen plasma will be used for each product in the calculations required by this section.

Section 1304.2(d)(4) is proposed to make certain that only blood and blood component products that will be useful to California veterinarians are included in the calculations required by this section.

Section 1304.3 is proposed to clarify that all commercial blood banks for animals that are not licensed by the California Veterinary Medical Board will be licensed by the Department.

Subsections 1304.3(a)(1) - (4) are consistent with the requirements for closed-colony blood banks for animals as listed in FAC subsections 9221 (a) - (d). These are necessary to ensure the Department has information vital to the oversight of facilities that produce blood and blood component products.

Subsections 1304.3(a)(5) and (a)(6) are proposed to establish that the licensee will only be permitted to obtain and process blood and blood component products from establishments that meet the requirements of FAC section 9210.

Section 1304.3(a)(7) is proposed to establish that thirty (30) calendar days is the acceptable period for reporting changes in the information contained in a license application or license renewal application to the Department. This is necessary to ensure that the Department has the most up-to-date and accurate information for licensed blood banks. Thirty days is adequate time for licensees to report changes in their operations and for the Department to adequately record the changes.

Section 1304.3(b) is proposed to establish the license application and license renewal fee.

Section 1304.3(b)(1) is proposed to establish that the license application and license renewal fee shall be $500. This is the same fee charged by the California Veterinary Medical Board for a veterinary premises application. This fee is less than the $1000 application fee for a closed-colony blood bank licensed by the Department because the facilities licensed by this subsection will not require oversight of animal husbandry and housing. Section 1304.3(b)(1) is also proposed to establish that the fee is for the fiscal year, or portion thereof, ending June 30 of each year. Section 1304.3(b)(1) is also proposed to establish that when an applicant is a city, county, state, or district, or an official thereof, no fee shall be required under this section.

Section 1304.3(b)(2) is proposed to establish that licenses must be renewed annually and that the fee must be paid before the start of the Department's fiscal year. These requirements are the same as the requirements for closed-colony blood banks as outlined in FAC section 9231(b).

Section 1304.3(b)(3) is proposed to establish that the license application fee and licensee renewal fee shall be adjusted annually for inflation. The California Consumer Price Index was selected as the measure for inflation because it represents the most appropriate measure for determining the change in the cost of operating within California and reflects the annual change in costs incurred by the Department. Section 1304.3(b)(3) is also proposed to specify that adjustments shall be rounded off to the nearest whole dollar.

Section 1304.3(c) is proposed to establish that facilities operating under this section must register their products to comply with Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code.

Section 1304.4 is proposed to establish the acceptable period for reporting changes in the information contained in a product registration application or product registration renewal application to the Department. This is necessary to ensure that the Department has the most up-to-date and accurate information for registered blood and blood component products. Thirty days is adequate time for commercial blood banks for animals to report changes in their operations and for the Department to adequately record the changes.

Add proposed new Article 3. Quarterly Reporting to specify the contents of the article.

Section 1305.1 is proposed to clarify quarterly reporting requirements for closed-colony blood banks.

Subsections 1305.1(a)(1), (a)(5), and (b) are the same as those listed in FAC subsections 9253(b)(1), 9253(b)(4), and 9253(c) respectively.

Section 1305.1(a)(2) is proposed to establish that additional products may be included in quarterly reports if they the meet criteria specified in CCR section 1304.2(d)(1) – (4).

Section 1305.1(a)(3) is proposed to clarify that the number of animals at each facility that houses animals that serve as blood donors must be included in quarterly reports.

Section 1305.1(a)(4) is proposed to clarify that disposition records and adoption records must include information from each facility that houses animals that serve as blood donors.

Section 1305.1(a)(6) is proposed to establish that the name of pathogens detected by infectious disease screening must be reported to the Department. This definition clarifies that the name of the pathogens detected must be submitted in quarterly reports to the Department. Knowing which disease agents are present in donor animals is important in monitoring animal health and ensuring product safety standards.

Section 1305.1(c) is proposed to clarify that disposition includes natural death and removal from the donor pool for any reason, in addition to the criteria listed in FAC section 9253(d). The remainder of this section is the same as listed in FAC section 9253(d).

Section 1305.2 is proposed to establish that quarterly reports must be submitted to the Department within 45 days of the end of the quarter. This is necessary to ensure that the Department has up-to-date and accurate information from commercial blood banks for animals. Currently, licensed blood banks have informed the Department that this is adequate time to calculate totals and submit the information.

Add proposed new Article 4. Inspections and Fees to specify the contents of the article.

Section 1306.1 is proposed to establish that once per year the Department, or humane officers under contract with the Department, will inspect commercial blood banks that have products registered with the Department. This is necessary to confirm commercial blood banks are following approved protocols and that products are safe and efficacious for use in veterinary transfusion medicine.

Section 1306.2 is proposed to clarify that facilities that keep, house, or maintain blood donor animals used by closed-colony blood banks will be inspected by the Department once per year. This is necessary to ensure animals are being treated humanely and facilities are following approved protocols.

Section 1306.3 is proposed to establish a fee of $0.05 per milliliter(mL) of blood and blood component products sold in California, as reported on quarterly reports. Requiring that the fee be paid at the time of submission of quarterly reports will ensure accurate record keeping and timely submission of fees. This fee is necessary to cover the Departments costs incurred to administer and enforce product safety standards. In fiscal year 2024/25, oversight of animal blood banks is anticipated to cost the Department $308,205.28. Facility licensing fees and product registration

fees are anticipated to provide $14,500 in funding. Based on quarterly reports submitted to the Department in 2022, the proposed per mL fee would generate an additional $99,802 per year. Once community blood banks begin operations and register products, additional funding will be generated. As the fee is based on the milliliters of blood sold in California, program funding will be directly tied to anticipated workload and required staffing. Additionally, a per milliliter fee does not increase startup costs for new commercial blood banks and will not inhibit new blood banks from entering the marketplace. See below for discussion of alternatives.

Section 1306.4 is proposed to establish that the annual inflation adjustment will be based on the California Consumer Price Index.

Section 1306.4(a) is proposed to specify the inflation adjusted license application fee for closed-colony blood banks. This inflation adjustment is required by FAC section 9231(c). The following formula was used in this calculation:

California (All Urban Consumers) February 2022 Index Value: 311.048
California (All Urban Consumers) February 2023 Index Value: 327.819
327.818 / 311.048 = 1.054
1.054 * $1000 = $1054

Section 1306.4(b) is proposed to specify the inflation adjusted animal blood and blood component product application and annual renewal fee. This inflation adjustment is required by FAC section 9244(b)(3). The following formula was used in this calculation:

California (All Urban Consumers) February 2022 Index Value: 311.048
California (All Urban Consumers) February 2023 Index Value: 327.819
327.818 / 311.048 = 1.054
1.054 * $500 = $527

Section 1306.5 Is proposed to establish that the Department may, at its discretion, perform additional inspections of commercial blood banks for animals to investigate complaints of noncompliance. This is necessary to verify that commercial blood banks for animals are compliant with rules and regulations and to ensure only compliant products are available for California veterinarians to purchase and use for transfusion.

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENT

The following supportive factual data was used in the formulation of this proposal:

1. Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine.

2. California Consumer Price Index 2022/2023.

3. Animal Blood Bank Program Expenditure/Revenue Report.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

As required by FAC section 9253(b)(5), this regulation requires animal blood banks to test animal blood donors for bloodborne pathogens. These tests require technical equipment, but the proposed regulations do not prescribe the type of equipment that licensees are required to use to test for bloodborne pathogens. Blood tests may be performed at the animal blood bank or at a commercial animal diagnostic laboratory. This regulation does not mandate the use of any other specific technologies or equipment.

ECONOMIC IMPACT ASSESSMENT

California Government Code Section 11346.3(b) requires state agencies to assess the potential economic impact on California businesses and individuals when proposing, proposing to adopt, or amend any administrative regulation. The Department has initially determined that the proposed regulatory action will not have any significant economic impact. The Department has made the following determinations:

a) It is unlikely that this proposal will result in the creation or elimination of jobs within the State of California. There is no indication that this regulation will result in currently licensed commercial blood banks hiring more workers or letting any go. By clarifying the requirements to offer blood and blood component products, it is likely the proposal will create an unknown number of jobs in new, community blood banks.

b) The proposal may result in the creation of new businesses or the elimination of existing businesses within the State of California. The Act requires that the Department discontinue its licensing program for closed-colony blood banks once a specified threshold is reached. This proposal clarifies when this will happen. If currently licensed closed-colony blood banks elect to not transition to community-based models, as permitted by FAC section 9212.5(c), this will result in the elimination of these businesses. As the Act also permits the formation of new community blood banks and this proposal clarifies the requirements of these potential businesses, it is reasonable to believe the proposal will result in the creation of an unknown number of new blood banks.

c) The proposal may result in the expansion of businesses currently doing business within the State of California. Based on California Veterinary Medical Board veterinary premises applications, over thirty veterinary hospitals in California currently perform blood banking activities. Currently, these hospitals are only producing enough blood and blood component products for their own operations. By clarifying requirements to sell animal blood and blood component products commercially, the proposal may result in these veterinary businesses expanding their operations and offering blood and blood component products for sale.

d) The proposal does not have an impact on the health and welfare of California residents, worker safety, or the state’s environment.

Business Impact

The Department has made an initial determination that the proposed regulatory action will have no significant, statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

Persons/Businesses affected by this proposal:

Closed-colony blood banks for animals – In California, there are currently two closed-colony blood banks exclusively dedicated to selling blood and blood component products for animals. According to quarterly reports submitted to the Department, these blood banks collectively sell approximately 1,900,000 mL of blood in the state annually. Consequently, this proposal would lead to an estimated increase of approximately $95,000 per year in fees for these businesses. It is expected that this additional cost would be transferred to emergency veterinary hospitals, manifesting as higher prices for blood and blood component products sold to them.

This proposal also clarifies when the Department will discontinue its licensing program for closed-colony blood banks, as required by FAC 9212.5. Current closed-colony blood banks will no longer be permitted to conduct business when this happens. These businesses will either cease operations or transition to community-sourced models and continue to operate in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code. By clarifying the criteria for discontinuing the closed-colony licensing program, these businesses will be able to plan for this transition. If the current closed-colony blood banks elect to discontinue operations, the Department anticipates experienced blood bank workers will be able to find employment in new, community blood banks for animals.

Emergency veterinary hospitals – The vast majority of animal blood and blood component products produced by commercial blood banks for animals are sold to emergency veterinary hospitals, as these products play a crucial role in treating critically ill or injured animals. Publicly available information from one of the licensed blood banks (source: https://www.abrint.net/products/canine-blood-blood-components/) indicates that blood products are priced between $71 and $595. Based on the volume of blood products available for sale, the Department predicts that each blood and blood component product would incur an additional cost of $3.00 to $25.00 for emergency veterinary hospitals. It is expected that this increase in the cost of blood and blood component products will be passed on to the owners of pets undergoing blood transfusions.

Owners of pets undergoing blood transfusions – The cost of an emergency veterinary visit can vary significantly due to several factors. Hospitalization and treatment expenses typically span from $800 to over $5,000, as stated in an article by the Sacramento Bee (source: https://www.sacbee.com/health-wellness/article274311875.html). The Department expects a slight rise in the cost of procedures involving blood transfusions, but it will not be substantial enough to deter pet owners from opting for such treatments. This regulation is not anticipated to decrease the number of pet owners seeking life-saving blood transfusions for their animals.

Economic Impact Assessment Conclusion

Based on the reasons stated in the economic impact assessment/analysis, the Department has initially determined that these regulations will not have a significant adverse economic impact on persons that are compliant with Food and Agricultural Code and Title 3 of the California Code of Regulations.

Alternatives Determination

Discontinuation of Closed-Colony Licensing Program Alternative 1: The calculation of canine blood pursuant to section 1304.2 shall be done with whole blood, packed red blood cells, and fresh frozen plasma being measured as separate amounts in estimated milliliters based on weight in grams. Actively licensed closed-colony blood banks may continue to operate until each of these separate amounts meet the provisions in 1304.2(b). (Selected/preferred alternative.)

Analysis: This option would allow closed-colony blood banks to continue until community blood banks are producing more of each product type. This option ensures an adequate supply of canine blood in California throughout the transition from closed-colony blood banks to community blood banks.

Discontinuation of Closed-Colony Licensing Program Alternative 2: The calculation of canine blood pursuant to this Section 1304.2 shall be done based on the sum of whole blood, packed red blood cells, and fresh frozen. Actively licensed closed-colony blood banks may continue to operate until each of the sum of these products meet the provisions in 1304.2(b).

Analysis: This alternative would end the closed-colony licensing program more quickly. As it is based on the total of three products, it may result in an inadequate supply of certain blood and blood component products available to California veterinarians.

Fee Alternative 1: There shall be a fee of $0.05 per milliliters (mL) blood and blood component products sold in this State, as reported on quarterly reports required under Section 4920.6 of the Business and Professions Code, 9252(c) of Food and Agricultural Code, and Section 9253(b) of Food and Agricultural Code. These fees shall be paid at the time of submission of quarterly reports. (Selected/preferred alternative).

Analysis: This approach satisfies the requirement for the Department's blood banks program to be supported by user fees. This fee structure is less burdensome than the fees that Fee Alternative 2 would establish. The per milliliter fee proposed by this option keeps initial fees low, making it easier for new small businesses to enter the animal blood and blood component marketplace. Establishing a per mL fee for animal blood and blood component products sold in California is a fair and equitable way to cover the Department's costs incurred to administer and enforce product safety standards.

Fee Alternative 2: Increase annual product registration fees from $500 per product to $5,000 per product.

Analysis: This alternative would rely on product registration fees to satisfy the requirement for the Department's blood banks program to be entirely supported by user fees. In fiscal year 2022-23

the Department registered 15 blood and blood component products. For the Department's blood banks program to be entirely supported by user fees, an additional 63 products would need to be registered. This option would require a larger upfront expense for existing blood banks and create a barrier to entry for new businesses to enter the animal blood and blood component marketplace, making it unlikely new blood and blood component products would be registered. This may also lead to a decrease in the variety of blood component products offered for sale in California, decreasing the quality of veterinary transfusion medicine in the state.

DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS

This proposal does not duplicate or conflict with federal regulations.