Title 3. Food and Agriculture Animal Blood Bank Program – Proposed Regulations Third 15-Day Notice of Modified Text

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (Department), Animal Blood Bank Program, is proposing to further modify the originally proposed text for the California Code of Regulations Title , Division 2, Chapter 8 heading, and new Articles 1 – 4 (commencing with section 1303) pertaining to Animal Blood Bank requirements as described in the California Regulatory Notice Register on February , 024, Register 2024, No. –Z, Notice File Number Z2024-0123-02. A copy of the third modified text is enclosed.

The portions of the originally proposed text, and the first, second, and third modified text are indicated as follows:

Text proposed to be adopted is displayed in <u>underline</u> type.

Text proposed to be deleted is displayed in <u>strikethrough</u> type.

Modified proposed text to be adopted is displayed in <u>double underline</u> type.

Modified proposed text to be deleted is displayed in <u>double strikethrough</u> type.

Second proposed modified text to be adopted is displayed in <u>bold underlined italics</u>.

Second proposed modified text to be deleted is displayed in <u>bold double underline</u> type.

Third proposed modified text to be deleted is displayed in <u>bold double underline</u> type.

Third proposed modified text to be deleted is displayed in <u>bold double strikethrough</u> type.

Summary of Changes to the Third Modified Text

Section 1303 (c) added definition for "best clinical practice" to provide clarity to the use of the term.

Section 1303 (d) through (m) re-lettered because of the addition of section 1303(c).

Section 1303(h) amended definition of "commercial blood banks for animals" to clarify what types of facilities are included in the definition.

Section 1303 (n) added definition for "standards of care" to provide clarity to the use of the term.

Section 1304.1 (e)(6) revised to specify the sections of the Code of Federal regulations that contain husbandry standards for dogs and cats.

Section 1305.1(c)(2), the word 'and' was deleted and added to the end of (c)(3) for grammar and clarity purposes.

Section 1305.2 revised to include the specific mailing address and e-mail address for submitting quarterly reports.

Article 4 amended title to clarify that this article only provides information on inspections.

Section 1306.1, struck "the product safety standards and" from the section for clarity. Compliance with protocols required by section 9244(a) of the Food and Agricultural Code will ensure product safety standards.

Section 1306.5 renumbered to section 1306.3 and amended to provide clarity on when the Department will investigate commercial blood banks.

Article 5 added and titled to specify the contents of the article.

Section 1306.3 moved to Article and renumbered to section 1307.1. Title and text amended to provide clarity on the type of fee being paid. Specified that the fee shall be adjusted annually for inflation.

Section 1306.4 moved to Article and renumbered to section 1307.2. Revised and added subsections to specify how annual inflation adjustments will be calculated.

Written Comments Regarding the Original Proposal

Any written comments received during the original -day public comment period which began on February , 2024 and ended on March 8, 024, with an extension to the public comment period ending on April , 2024 as published in the California Regulatory Notice Register 024, No. 12-Z, March 22, 2024 (Notice File Number Z2024–0311–01), remain in the rulemaking file.

Written comments regarding the first modified text, Addendum to the Initial Statement of Reasons, February 2024 California Consumer Price Index, Animal Blood Bank Program Expenses and Revenue 2024/25, and Economic and Fiscal Impact Statement (STD 399)

Any written comments received during the first -day notice of modified text and documents added to the rulemaking file, which began on June 6, 2024 and ended on June 20, 2024, remain in the rulemaking file.

Written Comments Regarding the Second Modified Text

Any written comments received during the second 15-day notice of modified text which began on July 1, 2024 and ended on July 15, 2024, remain in the rulemaking file.

Written Comments Regarding the Third Modified Text

The third 15-day notice of modified text begins on <u>December 0, 024</u> and ends <u>January 6, 025</u>. All written comments are to be restricted to the most recent modifications as shown in the attached third modified regulatory text. The Department is not required to respond to comments received in response to this notice on other aspects of the proposal. All written comments previously submitted regarding this proposal remain in the Department's rulemaking file. All written comments received by January 6, 025 which pertain to the indicated changes in the third modified text, will be reviewed and responded to by Departmental staff as part of the compilation of the rulemaking file.

Submit Written Comments to:

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The back-up person is:

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Website Access

Materials regarding this proposal can be found at the following Internet address:

https://www.cdfa.ca.gov/ahfss/regulations.html

Dated: 12-17-2024 Sean Brady

Digitally signed by Sean Brady Date: 2024.12.17 10:40:56 -08'00'

Dr. Sean Brady, Animal Blood Bank rogram