CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE
Karen Ross, Secretary

November 4, 2024

G. Allen Bridges, Ph.D.
Director, Global Nutritional Health Regulatory
Elanco Inc.
P.O. Box 708
2500 Innovation Way
Greenfield, IN 46140

Dear Dr. Bridges:

The California Department of Food and Agriculture (CDFA) Commercial Feed Regulatory Program and the Milk and Dairy Food Safety Branch (herein referred to collectively as CDFA), have received the information you provided regarding 3-nitrooxypropanol (3-NOP), marketed as Bovaer® 10. CDFA has regulatory oversight and authority over the safety of all milk and associated dairy products (Food and Agricultural Code (FAC), Division 15, Section 32501 et seq.), as well as commercial livestock feed, including feed additives and drugs, manufactured, distributed, or sold within or into the state of California (commencing with Division 7, Chapter 6, Commercial Feed, Section 14901 et seq.).

After conducting a review of the submitted information and materials, including copies of the two letters of enforcement discretion issued from the United States Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) and Center for Food Safety and Applied Nutrition (CFSAN) Milk and Milk Products Branch, CDFA has no current objection to the sale or use of Bovaer® 10 in California, provided it is used in accordance with its labeling and that CDFA and FDA continue to have no questions or public health concerns regarding its safety.

CDFA will rely upon FDA's use of enforcement discretion for the sale and use of Bovaer® 10. You may be responsible for other federal, state, or local requirements that are not addressed by this correspondence. Our intent to acknowledge the enforcement discretion letters that FDA has issued are based on our current understanding of the product from the information you provided. CDFA has the right to act under its authority, and it may reevaluate its position at any time if it becomes aware of information that raises a concern about the safety or effectiveness of Bovaer® 10 or under any other circumstances covered by its authority.

CDFA does not have a registration process for commercial feed and is considering this letter as confirmation that your company may market and sell Bovaer® 10 in California as subject to the provisions described in this letter.

CDFA will require the following of Elanco Inc.:

1. Notification of any changes to the status of the May 24, 2024, enforcement discretion letter issued by FDA, and/or FDA-CFSAN regarding use of Bovaer® 10 in the Grade “A” milk supply subject to the PMO.

2. Submission of any updates or changes to the label or safety and efficacy data.

3. Product is only sold and used in accordance with the attached label including feeding only to lactating dairy cattle at a rate of 27.2-36.3 mg 3-NOP per pound of dry matter intake in the total mixed ration, unless part of a research study where a Food Use Authorization from FDA has been obtained.

4. Manufacture, process, pack, and/or hold Bovaer® 10 and products containing Bovaer® 10 under conditions comparable to the standards of Title 21, Code of Federal Regulations, Part 507, “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.”

In addition, CDFA will require labeling of all commercial feeds containing Bovaer®10 to include all guarantees, limitations, warnings, and caution statements which appear on the Bovaer®10 label, attached. Labeling must also include adequate directions for use which are capable of being followed and likely to be followed in usual feeding practices including, at minimum, a statement of the concentration (mg/lb) of 3-NOP in the commercial feed and directions to further manufacture the feed to achieve a rate of 27.2-36.3 mg 3-NOP per pound of dry matter in the total mixed ration.

Similar to FDA, CDFA will not address methane reduction levels in this letter. CDFA will work with the California Air Resources Board (CARB) to develop greenhouse gas quantification and implementation verification methodologies for enteric products that allows California to track progress toward methane reduction goals set forth in California Senate Bill 1383 (Lara, Chapter 395, Statutes of 2016). If FDA changes the status of Bovaer® 10 to a Zootechnical Animal Food Substance or other product category under the pending federal legislation, then CDFA will reassess this product and advise of any changes to the status.

Sincerely,

Karen Ross

Karen Ross, Secretary
California Department of Food and Agriculture

Cc: Christine Birdsong, Undersecretary of Agriculture, CDFA
Virginia Jameson, Deputy Secretary, Climate and Working Lands, CDFA
Tawny Mata, Director, Office of Environmental Farming and Innovation, CDFA
Dr. Annette Jones, State Veterinarian and Director AHFSS Division, CDFA
Dr. Stephen Beam, Chief, Milk and Dairy Food Safety Branch, CDFA
Natalie Krout-Greenberg, Director, Inspection Services Division, CDFA
Jenna Leal, Chief, Feed, Fertilizer and Livestock Drugs Regulatory Services Branch, CDFA