IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. RIZO LOPEZ FOODS, INC., a corporation, and EDWIN RIZO and TOMAS RIZO, individuals, Defendants.	Civil No. 2:24-cv-02624-DJC-JDP

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Rizo Lopez Foods, Inc., a corporation ("Rizo Foods"), and Edwin Rizo and Tomas Rizo, individuals (collectively "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 *et seq*.

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C.

§ 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing such articles of food, within the meaning of 21 U.S.C. § 321(f) that are held for sale after shipment of one or more of their ingredients in interstate commerce, to become adulterated under 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

5. For the purposes of this Decree, the following definitions shall apply:

A. "CGMP Rule" refers to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule set forth at 21 C.F.R. Part 117;

B. "Defendants' Facility" or "Facility" refers to Defendants' facility located at 201 South McClure Road, Modesto, California 95357, and/or any other locations(s) at or from which Defendants, now or in the future, directly or indirectly receive, prepare, process, pack, hold, and/or distribute articles of food;

C. "Pre-packaged food" refers to food that is in fully sealed packages that was manufactured by someone other than Defendants at a facility other than Defendants' Facility and for which the internal sealed package remains uncompromised, such that the food contained in the internal sealed package is not exposed to Defendants' Facility's environment; and

D. "February 2024 inspection" refers to the inspection conducted by FDA between January 24 and February 23, 2024 at Defendants' Facility.

6. Defendants represent to the Court that, at the time of entry of this Decree, they are not engaged in preparing, processing, or packing any articles of food at or from any location.

7. Defendants represent to the Court, at the time of entry of this Decree, that they are engaged in receiving, holding, and/or distributing pre-packaged food (as defined in paragraph 5(C) above) from Defendants' Facility. Nothing in paragraph 9 of this Decree shall preclude Defendants from receiving, holding, or distributing pre-packaged food that is in compliance with the Act and its implementing regulations.

8. With the exception of the limited activities noted in paragraph 7, if Defendants at any point after entry of this Decree intend to directly or indirectly resume receiving, preparing, processing, packing, holding, or distributing food at or from Defendants' Facility, they must first notify the United States Food and Drug Administration ("FDA") in writing at least forty-five (45) business days in advance of resuming operations and comply with paragraphs 9(A)-(I) of this Decree. This notice shall identify the type(s) of food Defendants intend to directly or indirectly receive, prepare, process, pack, hold, or distribute at or from the Facility. Defendants shall not resume operations until FDA has inspected Defendants' Facility and operations pursuant to paragraph 9(G) as FDA deems necessary to evaluate Defendants' compliance with the terms of this Decree, Defendants have paid the costs of such inspection(s) pursuant to paragraph 18, and Defendants have received written notice from FDA as required by paragraph 9(I), and then shall resume operations only to the extent authorized in FDA's written notice. In no circumstance shall FDA's silence be construed as a substitution for written notification. The preceding sentences of Paragraph 8 are not intended to apply to Defendant Edwin Rizo's or Defendant Tomas Rizo's employment activities at a facility that is receiving, preparing, processing, packing, holding, or distributing any type of food where neither Defendant Edwin Rizo

nor Defendant Tomas Rizo is an owner, director, officer, or manager. Defendant Edwin Rizo and/or Defendant Tomas Rizo shall notify FDA in writing within twenty (20) business days of being employed at any facility at or from which food is received, prepared, processed, packed, held, or distributed and such notification shall include: (i) the name(s) and address(es) of such employer(s) and facility(ies); and (ii) a detailed description of Defendant Edwin Rizo and/or Defendant Tomas Rizo's employment duties.

9. With the exception of the limited activities noted in paragraph 7, upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (collectively "Associated Persons"), who receive notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court from directly or indirectly receiving, preparing, processing, packing, holding, and/or distributing any article of food at or from Defendants' Facility unless and until:

A. Defendants retain, at their expense, an independent person or persons (the "Expert") having no personal or financial ties (other than retention agreement) to Defendants or their families, who, by reason of background, education, training, and/or experience, is qualified to: (1) develop and ensure the adequate implementation of a written Pathogen Control Program; (2) establish methods, facilities, and controls at Defendants' Facility to ensure that food is received, prepared, processed, packed, held, and/or distributed in compliance with the CGMP Rule; and (3) inspect the Facility and determine whether Defendants' methods, facilities, and controls are operated and administered in conformity with the Decree, the Act, and the CGMP Rule. Within

two (2) business days of retaining the Expert or entry of this Decree, whichever is later, Defendants shall notify FDA in writing of the identity and qualifications of the Expert;

B. Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to analyze environmental and food samples collected at Defendants' Facility for the presence of *Listeria monocytogenes* ("*L. mono*") in a manner that is acceptable to FDA. Within two (2) business days of retaining the Laboratory or entry of this Decree, whichever is later, Defendants shall provide FDA with a copy of the service contract, which shall contain provisions acceptable to FDA for conducting environmental and food analyses;

C. Defendants shall ensure the Expert, in consultation with the Laboratory and after reviewing all of FDA's inspectional observations documented on the Form FDA-483 issued at the conclusion of the February 2024 inspection, shall develop a written Pathogen Control Program to FDA's satisfaction. The Pathogen Control Program shall include, at a minimum:

(1) A written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, packing, holding, and/or distributing articles of food to minimize the risk of introducing *L. mono*, other pathogenic microorganisms, or filth into the food, and to ensure that food is not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' Facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food, and instituting standard sanitation operating procedures to ensure that the Facility and equipment therein are continuously maintained in a condition consistent with the CGMP Rule;

(2) Written procedures that identify the required preventive controls and manufacturing processes consistent with the CGMP Rule and are designed to ensure that Defendants' manufacturing processes, monitoring procedures, and corrective actions protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at Defendants' Facility;

(3) A written employee training program (in English and any other language necessary to convey the substance of the training to the employees) that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training. The employee training program shall include, at a minimum, basic training for all employees on the importance of controls for bacterial pathogens including, but not limited to, *L. mono* and their role in control strategies for bacterial pathogens, training for all employees who handle food or work in areas where finished product is exposed to the environment to ensure that they understand how to prevent cross-contamination of food, and training for all employees who conduct cleaning and sanitation tasks to ensure that they understand the sanitation procedures necessary to minimize the risk of bacterial pathogens including, but not limited to, *L. mono* in the Facility. Defendants' Expert shall ensure that each employee has completed the training program;

(4) A written program for environmental monitoring and testing of Defendants' Facility to ensure that organisms including, but not limited to, *Listeria* species (*L. spp*.) are systematically controlled and that the pathogen *L. mono* does not occur in finished food products. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the Facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared,

processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing the environmental samples for the presence of *L. mono* and/or other pathogenic organisms. Sampling shall be conducted according to a method that specifies, at a minimum, how, where, and when to sample; and the number and frequency of samples to be collected. The program shall also require that Defendants contract with a third-party laboratory to conduct Whole Genome Sequencing ("WGS") of any confirmed positive *L. mono* samples isolated from Defendants' Facility. Defendants shall ensure that the confirmed results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) business days after receipt by Defendants;

(5) A written plan for effective remedial action, including, but not limited to, intensified sanitation and intensified sampling measures that Defendants shall implement if *L. mono* or any other pathogenic organism is detected during the sampling and testing conducted pursuant to paragraph 9(C)(4). This plan shall include sampling the three (3) areas in closest proximity to the positive sample during production, conducting comprehensive investigations, and determining contamination-source (i.e., a root-cause analysis); and

(6) A sampling and testing plan appropriate for conducting finished product testing in accordance with paragraph 11(B) below;

D. FDA approves, in writing, the Pathogen Control Program developed by the Expert. FDA will review and provide this notification to Defendants as soon as reasonably practicable after receipt. Under no circumstances may FDA silence be construed as approval. In the event FDA does not approve the Pathogen Control Program, Defendants' Expert may revise and resubmit the plan to FDA for its review and written approval as outlined in this paragraph.

Defendants shall implement the Pathogen Control Program as soon as they receive FDA's written notification in accordance with paragraph 9(I);

E. Defendants complete the following requirements:

(1) Assign continuing responsibility for implementing and monitoring the FDA-approved Pathogen Control Program to a person or persons who, by reason of background, education, training, and/or experience, is qualified to maintain Defendants' Facility in a sanitary condition and implement any necessary remedial action(s), and Defendants provide such person with the authority and resources to achieve the necessary corrections;

(2) Make the FDA-approved Pathogen Control Program available and accessible (in English and any other language necessary to convey the substance of the document) to their officers, employees, and all other people who perform duties at Defendants' Facility;

(3) Successfully complete the FDA-approved employee training program;

(4) At their expense, clean and sanitize the Facility and equipment therein and make improvements to render the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and/or distributing articles of food in accordance with this Decree, the Act, and the CGMP Rule, and ensure that the Facility and equipment therein will be continuously maintained in a sanitary condition; and

(5) Report to FDA in writing the actions they have taken to bring their operations in compliance with this Decree, the Act, and the CGMP Rule, including but not limited to:

i. Documentation that Defendants have cleaned and sanitized the Facility and equipment therein and made improvements, rendering the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food;

ii. Documentation that Defendants have conducted environmental monitoring and testing, including the analytical data and results of the testing, to render the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food at or from the Facility; and

iii. Identification of specific measures that Defendants have taken to address the deficiencies observed by FDA during the February 2024 inspection;

F. Defendants shall ensure that the Expert conducts a comprehensive inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack, hold, and/or distribute articles of food to determine whether Defendants have effectively implemented all corrective actions and are in compliance with this Decree, the Act, and the CGMP Rule. This comprehensive inspection shall include environmental swabbing of Defendants' Facility for *Listeria* to ensure all harborage sites for *L. mono* have been eliminated. Defendants shall ensure that the Expert verifies, with supporting documentation, that:

(1) Defendants have corrected all violations observed by FDA during the February 2024 inspection; and

(2) Defendants' Facility and the methods and controls used to receive, prepare, process, pack, hold, and/or distribute articles of food are, in the Expert's opinion, in compliance with this Decree, the Act, and the CGMP Rule.

Defendants shall ensure that the Expert submits a written report ("Expert Report") of all findings, with supporting documentation, to Defendants and FDA concurrently, within ten (10) business days after completing the inspection or entry of this Decree, whichever is later;

G. As soon as reasonably practicable after receipt of the Expert Report and Pathogen Control Program, FDA without notice, and as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and the CGMP Rule, may inspect Defendants' Facility, including the building, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein. Defendants shall ensure that all relevant records are readily accessible at all times;

H. Defendants pay all costs of inspections, investigations, supervision, analyses, sampling, testing, and reviews for FDA's oversight with respect to paragraph 9 at the rates set forth in paragraph 18; and

I. Within forty-five (45) business days of the conclusion of FDA's inspection as described in paragraph 9(G) above, FDA will notify Defendants in writing as to whether Defendants appear to be in compliance with the requirements set forth in this paragraph of this Decree, the Act, and the CGMP Rule. If FDA elects not to conduct an inspection as described in paragraph 9(G) above, FDA will notify Defendants within forty-five (45) business days of receipt of the Expert Report and Pathogen Control Program as to whether Defendants appear to be in compliance with the requirements set forth in this paragraph of this Decree, the Act, and the CGMP Rule. If FDA determines that Defendants do not appear to be in compliance with the requirements set forth in this paragraph of this Decree, the Act, and the CGMP Rule, FDA will explain the basis for that determination in its written response. In no circumstance shall FDA's silence be construed as a substitution for written notification.

10. With the exception of the limited activities noted in paragraph 7, within twenty (20) business days after entry of this Decree, Defendants shall, under FDA's supervision and pursuant to a written destruction plan approved in writing by FDA prior to implementation, destroy all in-process and finished articles of food currently in their custody, control, or possession at their Facility as of the date of entry of this Decree. Defendants shall bear the costs of destruction and the costs of FDA's supervision incurred under this paragraph at the rates set forth in paragraph 18. Defendants shall not dispose of any article of food in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory in which the products are disposed. For purposes of this subparagraph, raw ingredients will not be deemed to be in-process if they have remained unopened in their original packaging and if Defendants establish to FDA's satisfaction that the raw ingredients have been received and held under sanitary conditions since receipt.

11. Upon resuming operations at the Facility after complying with paragraph 9 and receiving FDA's written notification pursuant to paragraph 9(I), Defendants shall, in consultation with the Laboratory and the Expert, meet the following requirements:

A. Defendants shall continuously implement the FDA-approved Pathogen Control Program developed pursuant to paragraph 9(C). In the event that Defendants, the Expert, or the Auditor described in paragraph 11(C) below determine that the FDA-approved Pathogen Control Program requires revision, Defendants shall submit proposed changes to FDA in writing at least twenty (20) business days prior to the planned implementation, and shall not implement their proposed changes unless and until FDA approves those changes in writing;

B. Defendants shall conduct finished product testing in accordance with the finished product sampling and testing plan in the FDA-approved Pathogen Control Program, in the following manner:

(1) Immediately upon resumption of operations after the completion of the requirements of paragraph 9, Defendants shall test for *L. mono* in a randomly collected representative sample from all lots of each food product for at least five (5) consecutive production days using a testing method acceptable to FDA;

(2) After the completion of testing under paragraph 11(B)(1), Defendants shall test a randomly collected representative sample from at least one lot of each food product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 11(B)(2), Defendants shall test a randomly collected representative sample from at least one lot of each food product per every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 11(B)(3), Defendants shall test a randomly collected representative sample from at least one lot of each food product per month thereafter.

Defendants shall ensure that the confirmed results of all testing conducted pursuant to paragraph 11(B) are forwarded to FDA within two (2) business days after receipt by Defendants. If any laboratory test completed pursuant to paragraphs 11(B)(1)-(4) shows the presence of *L. mono* and/or any other pathogen in any article of food, then Defendants shall immediately cease production of all articles of food and notify FDA that production has ceased. Defendants shall also contract with a third-party laboratory to conduct WGS of any positive *L. mono* isolated from articles of food or from environmental samples. Defendants shall, under FDA's supervision and pursuant to a written destruction plan approved in writing by FDA prior to implementation, destroy all articles of food, except pre-packaged food as defined in paragraph 5(C) of this Decree prepared, processed, packed, held, and/or distributed from the time the laboratory sample(s) tested positive

for *L. mono* and/or any other pathogen. Defendants may resume production only when they have determined and corrected the cause of the contamination, and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and the CGMP Rule. Defendants shall bear the costs of destruction and FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel and subsistence expenses incurred to ensure compliance with this paragraph at the rates set forth in paragraph 18. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew; and

C. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for, and may be the same person as, the Expert described in paragraph 9(A), to conduct audit inspections of the Facility and the methods, processes, and controls used to receive, prepare, process, pack, hold, and/or distribute articles of food, as follows:

(1) Within twenty (20) business days after Defendants resume their operations, Defendants shall ensure that the Auditor conducts a comprehensive audit inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack, hold, and/or distribute articles of food, to determine whether Defendants are operating in compliance with this Decree, the Act, and the CGMP Rule, and to identify any deviations from those requirements;

(2) Thereafter, Defendants shall ensure that the Auditor conducts one audit inspection every three (3) months for one year, and then one audit inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their food operations, Defendants shall ensure that the Auditor conducts audit inspections annually unless FDA informs Defendants in writing that more frequent audit inspections are required.

During each audit inspection, Defendants shall ensure that the Auditor verifies that Defendants' Facility and the methods and controls that Defendants use to receive, prepare, process, pack, hold, and distribute articles of food are in compliance with the requirements of this Decree, the Act, and the CGMP Rule, and shall certify compliance in the Audit Report. As a part of every Audit Report (except the first one), Defendants shall ensure that the Auditor assesses the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this Decree, the Act, or the CGMP Rule. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or the CGMP Rule, Defendants shall make all necessary corrections within ten (10) business days after receipt of the Audit Report, unless (a) FDA notifies Defendants in writing that a shorter time period is necessary, or (b) the correction requires FDA's written approval of a proposed change to the Pathogen Control Program outlined under paragraph 11(A). In the event the correction requires a change to the Pathogen Control Program, Defendants shall submit the proposed change(s) to FDA within ten (10) business days after receipt of the Audit Report, and shall not implement their proposed change(s) unless and until FDA approves the change in writing; and

(3) Defendants shall ensure that the Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven (7) business days after completing the audit inspection.

12. If, after notifying FDA of the name of the Laboratory retained to conduct sample analyses pursuant to paragraph 9(B), Defendants terminate or in any way alter their service contract with the Laboratory, Defendants shall notify FDA within five (5) business days after terminating or altering the service contract. If Defendants terminate their service contract,

Defendants shall retain within ten (10) business days of terminating of the previous service contract, at their expense, a different independent laboratory having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to analyze environmental and food samples collected at Defendants' Facility for the presence of *L. mono* in a manner that is acceptable to FDA. Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days after retaining the new laboratory.

13. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 9(I), Defendants and their Associated Persons are restrained and enjoined under the provisions of 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violating 21 U.S.C. § 331(k), by causing such articles of food within the meaning of 21 U.S.C. § 321(f) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated under 21 U.S.C. § 342(a)(4); and

C. Failing to implement and continuously maintain the requirements of this Decree.

14. Representatives of FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of Defendants' Facility and to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and the CGMP Rule. During the inspections of Defendants' Facility, FDA shall be permitted to have

immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall immediately provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing, holding, and distributing of Defendants' food. Defendants shall maintain copies of their Pathogen Control Program, along with copies of all records required by that plan and this Decree, at the Facility from which Defendants receive, prepare, process, pack, hold, and/or distribute articles of food in a location where the records are readily available for inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

16. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, lease, sale, or any other change in the structure or identity of Rizo Foods, or the assignment, lease, or sale of any business assets, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) business days before the assignment or change in business, and shall provide FDA with

an affidavit of compliance with this paragraph within ten (10) business days after providing a copy of this Decree to a prospective successor or assign.

17. Any food manufacturing equipment sold, leased, transferred, relocated, and/or moved in any fashion from Defendants' Facility to any location where food is received, prepared, processed, packed, held, or distributed may not be used to receive, prepare, process, pack, hold, and/or distribute food unless and until Defendants submit written documentation to FDA certifying that the equipment has been cleaned and sanitized in a manner acceptable to FDA.

18. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment to FDA within 30 calendar days after receiving an electronic invoice for payment, which shall be sent to Corporate@rizolopez.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: $116.47 per hour or fraction thereof per representative for inspection and investigative work; $139.61 per hour or fraction thereof per representative for analytical or review work; $0.67 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates for FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

Defendants shall notify FDA within fifteen (15) business days if the email address at which Defendants receive electronic invoices changes.

19. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report, or data submitted by Defendants, the Expert, Auditor, or any other information, that Defendants have failed to comply with any applicable provision of this Decree, have violated the Act or the CGMP Rule, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or the CGMP Rule, FDA, may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, labeling, packing, holding and/or distributing any articles of food at or from Defendants' Facility;

B. Recall, at Defendants' expense, all articles of food that have been distributed and/or are under the custody and/or control of Defendants' agents, distributors, customers, or consumers;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Submit samples of articles of food to a qualified laboratory for analysis;

F. Institute or reimplement any of the requirements set forth in this Decree;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and the CGMP Rule.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in this paragraph, at the rates specified in paragraph 18 of this Decree.

20. Upon receipt of any order issued by FDA pursuant to paragraph 19, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations as described in paragraph 19 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and the CGMP Rule and may resume operations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, the CGMP Rule, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

21. Within five (5) business days after entry of this Decree, Defendants shall prominently post a copy of this Decree (in English and any other language necessary to convey the substance of the Decree) in a conspicuous location in an employee common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten (10) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

22. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe

the terms and obligations of this Decree (in English and any other language necessary to convey the substance of the Decree). Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

23. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service, by delivery via electronic mail with acknowledgment of receipt, or certified mail (return receipt requested) to each and all of their Associated Persons. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts or analogous electronic mail documentation confirming receipt.

24. In the event that any Defendant becomes associated with any additional Associated Persons at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such Associated Persons. Within five (5) business days after each time that any of the Defendants becomes associated with any additional Associated Persons, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

25. If any Defendant fails to comply with the provisions of this Decree, the Act, or the CGMP Rule, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: four thousand dollars ($4,000) in liquidated damages for each day such violation continues; an additional sum of three thousand dollars ($3,000) in liquidated damages per day per violation of this Decree, the Act, or the CGMP Rule; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or the CGMP Rule. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or this Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on the conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

26. All deadlines in this Decree may be extended or shortened by mutual consent of FDA and Defendants in writing, without leave of Court.

27. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

28. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based

exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

29. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall: be prominently marked "Decree Correspondence"; reference this civil action by case name and civil action number; and be submitted electronically to the Division Director, at orahafwest5firmresponses@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of the Division Director, U.S. Food and Drug Administration, Office of Human and Animal Food Operations – West Division 5, 1201 Harbor Bay Parkway, Alameda, CA 94502, using certified mail (return receipt requested). FDA will notify Defendants if the email and/or physical mailing address at which FDA receives these communications changes.

30. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

31. No sooner than sixty (60) months after the entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its regulations for at least sixty (60) months, the United States will not oppose the petition, and Defendants may request the Court grant such relief.

32. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 7th day of October, 2024

THE HONORABLE DANIEL J. CALABRETTA
UNITED STATES DISTRICT JUDGE

We hereby consent to the foregoing Decree:

FOR DEFENDANTS:

_/s/ - Edwin Rizo_____ _____
EDWIN RIZO
on behalf of RIZO LOPEZ, INC.
as its owner

_/s/ - Edwin Rizo_____ _ _____
EDWIN RIZO
in his individual capacity

_/s/ - Tomas Rizo_____
TOMAS RIZO
in his individual capacity

___/s/ - Maile J. Gradison_____
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AMANDA N. LISKAMM
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_/s/ - David G. Crockett, Jr. _____
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