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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ORGANIC PASTURES DAIRY COMPANY, LLC, a corporation, and MARK McAFEE, an individual, Defendants.	CASE NO. 1:08-CV-01786-JLT-SAB **STIPULATION AND [~~PROPOSED~~] ORDER TO ENTER CONSENT DECREE AND VACATE HEARING; EXHIBIT A**

STIPULATION

Pursuant to Local Rule 143(a)(1), it is hereby stipulated by and between Plaintiff United States of America ("Plaintiff") and Defendants RAW FARM, LLC f/k/a Organic Pastures Dairy

Company, LLC and Mark McAfee, and Non-Party Aaron McAfee (collectively, "Respondents") as follows:

1. On March 27, 2023, Plaintiff filed its Motion To Reopen Case (the "Motion") And Petition For An Order To Show Cause Why RAW FARM, LLC f/k/a Organic Pastures Dairy Company, LLC; Mark McAfee; And Aaron McAfee Should Not Be Held In Civil Contempt (the "Petition").

2. On May 19, 2023, the Court granted Plaintiff's Petition, and set an evidentiary hearing regarding whether Respondents should be held in civil contempt for July 5, 2023, which was later continued to August 9, 2023, at the Parties' request.

3. In advance of the above-referenced hearing, counsel for Plaintiff and Respondents pursued negotiations to resolve this matter.

4. Plaintiff and Respondents now jointly agree and hereby stipulate to entry of the Consent Decree, attached as Exhibit A, as a final settlement of the dispute raised in the Petition, pursuant to Court approval.

5. In light of the settlement, Plaintiff and Respondents respectfully request that the Court sign and enter the attached Consent Decree and vacate the August 9, 2023, hearing date and any associated deadlines.

Date: July 26, 2023 U.S. DEPARTMENT OF JUSTICE

By: /s/Roger J. Gural
Roger J. Gural, Esq.
Attorney for Plaintiff
United States of America

Date: July 26, 2023 STRUCTURE LAW GROUP, LLP

By: /s/ Mark Figueiredo
Attorneys for Defendants Raw Farm, LLC fka Organic Pastures Dairy Company, LLC; Mark McAfee; and Non-Party Aaron McAfee

~~[PROPOSED]~~ ORDER

The Stipulation (Doc. 66) is approved.

The Consent Decree (attached hereto as Exhibit A) is entered as a final resolution of the dispute raised in Plaintiff's Petition For An Order To Show Cause Why RAW FARM, LLC f/k/a Organic Pastures Dairy Company, LLC; Mark McAfee; And Aaron McAfee, Dkt. No. 50-1.

The hearing set for August 9, 2023, and any related deadlines, are hereby **VACATED**.

IT IS SO ORDERED.

Dated: **July 26, 2023**

UNITED STATES DISTRICT JUDGE

Exhibit A

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA Plaintiff, vs. ORGANIC PASTURES DAIRY COMPANY, LLC, a corporation, and MARK McAFEE, an individual, Defendants.	Case No.: 1:08-CV-01786 **CONSENT DECREE**

WHEREAS Plaintiff the United States of America ("Plaintiff") filed its Petition for an Order to Show Cause Why RAW FARM, LLC f/k/a Organic Pastures Dairy Company, LLC, Mark McAfee, and Aaron McAfee [("Respondents")] Should Not Be Held in Civil Contempt, Dkt. No. 50-1;

WHEREAS this Court held that Respondents violated this Court's Order of Permanent Injunction dated April 20, 2010, Dkt. No. 48 (the "April 2010 Order"), and issued an Order Granting Plaintiff's Request for Order to Show Cause Why Respondents Should Not Be Held in Civil Contempt, Dkt. No. 62;

WHEREAS RAW FARM, LLC f/k/a Organic Pastures Dairy Company, LLC (together, "Organic Pastures") and Mark McAfee (collectively, "Defendants") have appeared and consented to entry of this Decree without contest and before any testimony has been taken; and

WHEREAS the United States of America has consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter as well as over Defendants.

2. The April 2010 Order remains in full force and effect with respect to Defendants and their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them (collectively, "Associated Persons").

3. Defendants and their Associated Persons shall comply with all of the provisions of this Decree.

4. Within fifteen (15) business days after entry of this Decree, Defendants shall retain, at their expense, an independent person or persons (the "Labeling Expert"), who is without personal or financial ties (other than the retention agreement) to any of them and/or their families, and who by reason of background, training, education, or experience, is qualified to inspect 7221 South Jameson Avenue, Fresno, California 93706; 128 North 9th Street, Fowler, California 93625; or any other location(s) under the control or direction of Defendants (the "Facilities") and to review the representations that Defendants make for each of their products on product labels; labeling; promotional material; websites or social media pages owned by, created by, controlled by, or related to Defendants including, but not limited to, rawfarmusa.com, the Instagram account named raw_farm_usa, the Instagram account named markmcafee_, the Facebook account named RAW FARM, and any website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants. Defendants shall notify the FDA in writing of the identity of the Labeling Expert within ten (10) business days of retaining such Labeling Expert.

5. Within thirty (30) business days after retaining the Labeling Expert, Defendants shall ensure that the Labeling Expert submits a written report certifying to FDA that:

A. he or she has inspected the Facilities;

B. he or she has identified all of Defendants' products and reviewed their representations for each product on their product labels; labeling; promotional material; websites or social media pages owned by, created by, controlled by, or related to Defendants (including but not limited to those listed in Paragraph 4);

C. Defendants are not making any representations on product labels; labeling; promotional material; websites or social media pages owned by, created by, controlled by, or related to Defendants (including but not limited to those listed in Paragraph 4) that cause any of their products to be drugs within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(g); and

D. based upon the Labeling Expert's inspection and review, Defendants are operating in conformity with this Decree, the April 2010 Order, and the FDCA, the Public Health Service Act ("PHSA"), and their implementing regulations. The Labeling Expert's written certification shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed.

6. After complying with the requirements of Paragraph 5, Defendants shall retain an independent person or persons who shall meet the criteria for, and may be the same person as, the Labeling Expert described in Paragraph 4 to conduct audit inspections of the Facilities every six (6) months, beginning no more than six (6) months after the Labeling Expert's submission of the report to FDA pursuant to Paragraph 5 (the "Auditor").

A. At the conclusion of each Audit Inspection, Defendants shall ensure that the Auditor prepares a detailed written audit report (the "Audit Report") analyzing whether they are in compliance with this Decree, the April 2010 Order, and the FDCA, the PHSA, and their implementing regulations, and identifying any deviations from such requirements (the "Audit Report Observations") and recommended corrective actions, and shall provide a list of all materials reviewed, including all websites and social media, as well as copies of all such materials;

B. Defendants shall ensure that each Audit Report contains a written certification stating (1) that the Auditor has personally reviewed all of Defendants' product labels; labeling; promotional material; websites and social media pages owned, created by, controlled by, or related to Defendants (including but not limited to those listed in Paragraph 4); and (2) whether the products are in compliance with the requirements of this Decree, the April 2010 Order, and the FDCA, the PHSA, and their implementing regulations;

C. Defendants shall further ensure that, as part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

D. Defendants shall ensure that the Audit Reports are delivered contemporaneously to Defendants and FDA no later than ten (10) business days after the date the

Audit Inspection is completed. Defendants shall maintain the Audit Reports in separate files at the Facilities and shall promptly make the Audit Reports available to FDA upon request;

E. If an Audit Report contains any Audit Report Observations indicating that Defendants' products are not in compliance with this Decree, the April 2010 Order, or the FDCA, the PHSA, or its implementing regulations, Defendants shall immediately correct such deviations; and

F. If, after any two (2) year period of continuous compliance, as reflected in the four periodic Audit Reports corresponding to those two years, the Auditor certifies in writing to FDA that Defendants have maintained compliance with this Decree, the April 2010 Order, and the FDCA, the PHSA, and their implementing regulations, and, if applicable, have adequately implemented corrective actions recommended by the Auditor, and FDA notifies Defendants in writing that it agrees with the Auditor's certification, the Auditor need not perform additional audits.

7. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, websites, or social media pages owned or controlled by Defendants (including but not limited to those listed in Paragraph 4), an Audit report, or any other information, that Defendants have failed to comply with any provision of this Decree or the April 2010 Order, or have violated the FDCA, the PHSA, or their implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the April 2010 Order, or the FDCA, the PHSA, or their implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order them to take appropriate corrective actions, including, but not limited to, ordering them to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all food or drugs.

B. Recall, at the expense of Defendants any unapproved new drug or any other FDA-regulated product otherwise in violation of this Decree, April 2010 Order, or the FDCA, the PHSA, or their implementing regulations;

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

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

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the April 2010 Order, or the FDCA, the PHSA, or their implementing regulations.

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.

8. Upon receipt of any order issued by FDA pursuant to Paragraph 7 of this Decree, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 7 shall continue until Defendants receive written notification from FDA that they appear to be in compliance with this Decree, the April 2010 Order, and the FDCA, the PHSA, and their implementing regulations, and that Defendants may resume operations.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the April 2010 Order, and the FDCA, the PHSA, and their implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to buildings (including but not limited to 7221 South Jameson Avenue, Fresno, California 93706 and 128 North 9th Street, Fowler, California 93625), equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other promotional material therein; take photographs and make video recordings; take samples of in-process materials or unfinished and finished products, containers, packaging material, labeling, and other promotional material; and examine and copy all records relating to the receiving, manufacturing, preparing, packing, labeling, holding, or distributing of any and all drugs and food and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate and apart from, and in addition to, the authority to make inspections under the FDCA, 21 U.S.C. § 374.

10. All notifications, correspondence, and communications to FDA required by the terms of this Decree and the April 2010 Order shall be prominently marked "Injunction Correspondence" and reference this civil action by case name and civil action number, and shall be sent to: Director, Compliance Branch, Office of Human and Animal Food Operations, West Division 5, Office of Regulatory Affairs, Food and Drug Administration, 1201 Harbor Bay Parkway, Alameda, California 94502, along with an electronic copy to ORAHAFWEST5FirmResponses@fda.hhs.gov. This provision supersedes Paragraph 2(K) of the April 2010 Order.

11. All deadlines in this Decree may be modified by mutual consent of the parties in writing, without leave of Court.

12. Should Defendants fail to comply with any provision of this Decree, the April 2010 Order, or the FDCA, the PHSA, or their implementing regulations, then Organic Pastures shall pay to the United States of America One Hundred Dollars ($100.00) and Mark McAfee shall pay to the United States of America One Hundred Dollars ($100.00), for a total of Two Hundred Dollars ($200.00) per day for each day such violation continues. Within twenty (20) business days of receiving an electronic invoice for payment, which shall be sent by FDA to aaron.m@rawfarmusa.com and lizbeth.v@rawfarmusa.com, Defendants shall make payment in full 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.

13. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this 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.

14. No sooner than sixty (60) months after issuance of this Decree, Defendants may make a written request to FDA for leave to ask this Court for relief from this Decree. Such written request shall be made pursuant to Paragraph 10 of this Decree. FDA shall respond in writing to such written request as soon as reasonably practicable. If, upon consideration of the written request, in FDA's

judgment, Defendants have maintained a state of continuous compliance with this Decree, the April 2010 Order, the FDCA, the PHSA, and their implementing regulations for at least sixty (60) months, FDA will advise Defendants that they may request the Court to grant such relief and that the United States will not oppose that request.

15. This Court retains jurisdiction over this action and Defendants for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

DONE AND ORDERED in chambers in Fresno, California, this

26th day of July, 2023.

Jennifer L. Thurston

HONORABLE JENNIFER L. THURSTON
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

Mark L. McAfee

MARK MCAFEE
Individually and on behalf of
RAW FARM, LLC f/k/a Organic Pastures Dairy Co., LLC

MARK FIGUEIREDO

FOR PLAINTIFF

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