,

UNITED STATES DISTRICT COURT

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 ORDER GRANTING PLAINTIFF'S REQUEST FOR ORDER TO SHOW CAUSE WHY RESPONDENTS SHOULD NOT BE HELD IN CIVIL CONTEMPT (Doc. 50)

This matter involves a previously issued preliminary injunction order against Defendants for having violated certain provisions of the Federal Food, Drug, and Cosmetic Act. On March 27, 2023, the Government requested that the Court issue an order to show cause why Defendants and Aaron McAfee should not be held in civil contempt for violating the Court's preliminary injunction order. (Doc. 50.) For the reasons set forth below, the Government's request is **GRANTED**.

I. BACKGROUND

Organic Pastures Dairy Company, LLC, now doing business as Raw Farm, LLC, operates a farm and business in Fresno, California, producing unpasteurized dairy products. (Doc. 58 at 6-7.) Mark McAfee founded the business in 1998 and developed farming and processing practices to produce "raw" milk and cheese. (*Id.*) In 2008, the Government initiated both criminal

proceedings and a civil action against Organic Pastures and Mark McAfee for selling and distributing in interstate commerce raw milk products for human consumption under a "pet food" label, which was alleged to be in violation of the Federal Food, Drug, and Cosmetic Act. (Doc. 48 at 1.) Defendants entered into prosecution agreements with the government and admitted fault in the criminal action. (*Id.*) The Court then granted the Government's request for a permanent injunction against Defendants. (*Id.* at 23-29.) The order largely prohibited Defendants from engaging in future interstate sales of raw milk or raw milk products. (*Id.*) Pertinent terms of the injunction include:

> **Paragraph 2(B)**
>
> Defendants and their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them must not introduce or deliver for introduction into interstate commerce any "unapproved new drugs" within the meaning of 21 U.S.C. § 321(p).
>
> **Paragraph 2(D)**
>
> Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from directly and indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce any raw milk and raw milk products as defined at 21 C.F.R. § 1240.3(I) and (j), including any products that contain raw milk and/or raw colostrum, in any form (e.g., frozen, partially-frozen, liquid, dry, powdered) for any intended use (e.g., human consumption, pet food, and any other use) regardless of how labeled, described, represented or designated, unless specifically authorized in writing by the FDA in advance of any such introduction or delivery for introduction into interstate commerce. If the FDCA is amended or modified to allow the interstate sale of raw milk or raw milk products, advanced FDA approval is not necessary and this order is amended accordingly without the necessity for further Court action.
>
> **Paragraph 2(F)**
>
> Upon entry of this Order, Defendants shall add the following statement to the individual retail invoices and packaging slips for each of Defendants' raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum): "Organic Pastures will no longer offer for introduction, introduce, or cause to be introduced into interstate commerce, or deliver or cause to be delivered for introduction into interstate commerce, any unpasteurized raw milk or raw milk products." Upon entry of this Order, Defendants shall also post this written statement on all websites that Defendants own or control and on all websites on which Defendants make available for purchase (either via a hyperlink or reference to another website) its raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum), including but not limited to www.organicpastures.com. This statement shall be continuously displayed on each

> websites' home page and on each page from which Defendants' products can be ordered through their website(s), by mail, or by telephone. Upon entry of this Order, Defendants shall also remove from their corporate vehicle or other locations it is displayed, any reference to raw milk as a cure for asthma or any statement/slogan promoting raw milk's health benefits.
>
> **Paragraph 2(G)**
>
> Upon entry of this Order, Defendants shall provide notice to its commercial buyers, defined as those persons or entities purchasing in excess of 2% of Defendants' gross sales from raw milk/raw milk products (combined on a yearly basis), or for wholesale and/or retail redistribution, that its raw milk and raw milk products are not to be sold or distributed outside the state of California. Such notice can be accomplished by adding such a statement to the commercial retail invoices and packaging slips, obtaining a signed written statement from the person or entity, or sending a notarized letter to the appropriate mailing address (person's place of business or entity's headquarters). Defendants shall maintain copies of the selected method of notification and shall make them immediately available to FDA upon request. If the FDCA is amended or modified to allow the interstate sale of raw milk or raw milk products, this provision shall no longer have effect.

(Doc. 48 at 23-27.)

On March 27, 2023, the Government filed a motion to reopen the case and a request for an order to show cause why Defendants and Aaron McAfee[1] ("Respondents") should not be held in civil contempt for violating the Court's permanent injunction order. (Doc. 50.) The Government contends that Respondents are violating the Court's preliminary injunction order by distributing an unapproved new drug in interstate commerce, namely their new raw cheddar cheese product. (*Id.* at 9.) It further alleges that this violation is a "continuation of Defendants' decades-long attempts to unlawfully distribute their unpasteurized" products on a national level and "touting the products' purported wonders to prevent or treat disease." (*Id.*) Respondents' alleged history of noncompliance with the order includes: interstate distribution of its kefir meal-topper for dogs and cats without prior approval, in violation of paragraph 2(D); failing to consistently maintain the disclosure required by paragraph 2(F)[2] on its websites, invoices, and shipping packaging slips; promoting its products as having health benefits, in violation of 2(F); and failing to notify its

[1] Aaron McAfee, who was not named as a Defendant in the original lawsuit, currently serves as the current president of Raw Farm, LLC. (Doc. 50-2 at 9.)

[2] The 2(F) disclosure refers to the following statement: "Organic Pastures will no longer offer for introduction, introduce, or cause to be introduced into interstate commerce, or deliver or cause to be delivered for introduction into interstate commerce, any unpasteurized raw milk or raw milk products." (Doc. 48 at 25-26.)

commercial buyers that its raw milk/raw milk products are not to be sold or distributed outside of California as required by 2(G). (*Id.* at 13-15.) The Government alleges Respondents are currently violating 2(B) through the distribution of the raw cheddar cheese as an unapproved new drug and promoting it as having health benefits and violating 2(F) for the failure to affix the required disclosure on its websites and/or social media accounts. (*Id.* at 15-16.)

In April 2019, the FDA notified Respondents of their violations with the preliminary injunction order. (Doc. 50-2 at 14.) According to the Government, Respondents' response to the FDA's warning and their subsequent communications regarding the alleged noncompliance were uncooperative and did not sufficiently take responsibility for their failure to abide by the order. (*Id.*) The Government maintains that Respondents have continued to make numerous attempts to distribute its raw milk on the national market, and the FDA has consistently reminded them that such distribution is prohibited. (*Id.* at 15.)

According to Respondents, they have made many efforts to comply with FDA's requests and consistently communicated with the FDA to obtain guidance on how to bring their business practices into compliance with the order. (Doc. 58 at 7-17.) They contend that in April 2019, the FDA conducted an inspection of their facilities and explained they needed approval for their raw cheese and kefir product. (*Id.* at 8.) In 2017, Respondents requested preapproval for their kefir product, but the FDA informed them that it does not process pre-market approvals for pet food. (*Id.*) Throughout April to October of 2019, Mark and Aaron McAfee exchanged several communications with the FDA explaining their efforts to comply with the preliminary injunction order. (*Id.* at 8-12.) For example, they explained their sales software did not have the capability of printing the full 2(F) disclosure but that they purchased new software that would permit them to place a stamp on their invoices and packaging slips. (*Id.* at 9-10.) Additionally, on May 24, 2019, they requested approval to transport their raw milk interstate for testing, but the FDA did not reply until September 6, 2019. (*Id.* at 10.) Respondents sent multiple subsequent communications to the FDA inquiring about the approvals for its cheese and kefir products. (*Id.* at 10-11.) On September 6, 2019, the FDA presented Respondents with an inspection report, which warned them of their noncompliance, denied approval of the kefir dog food for their failure to obtain

preapproval in accordance with the order's requirement under 2(D), but granted approval of their raw cheddar cheese as a food product. (*Id.*) Respondents replied by explaining their many efforts to comply with the Court's order and renewed their request for approval of the kefir dog food. (*Id.*) On December 17, 2019, the FDA granted approval for the kefir dog food for distribution interstate. (*Id.* at 13.)

Approximately one year prior to filing the request for an order to show cause, an attorney for the DOJ contacted to Respondents' counsel regarding their violations of the preliminary injunction order. (Doc. 58 at 16.) They discussed potential ways to modify the order. (*Id.*) Respondents' counsel stressed the need to update the order's restrictions to reflect current FDA regulations. (*Id.*) The DOJ did not accept the suggested revisions and made a counterproposal that included a sunset clause for the order and eliminated some of the order's financial burdens. (*Id.*) Respondents' counsel rejected the counterproposal. (*Id.* at 17.) The DOJ confirmed receipt of the communication and indicated they would respond the following week. (*Id.*) Respondents' counsel contends they received no further communication from the DOJ until the Government filed the instant order seeking to hold them in civil contempt. (*Id.*)

II. DISCUSSION

A. Legal Standards Civil Contempt

A party that prevailed in securing a court order may seek to hold the opposing party in civil contempt for the party's failure to comply with that order. *Reno Air Racing Ass'n., Inc. v. McCord*, 452 F.3d 1126, 1130 (9th Cir. 2006) (citing *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir. 1993)). "Civil contempt sanctions . . . are employed for two purposes: to coerce the defendant into compliance with the court's order, and to compensate the complainant for losses sustained." *Whittaker Corp. v. Execuair Corp.*, 953 F.2d 510, 517 (9th Cir. 1992) (citing *United States v. United Mine Workers of Am.*, 330 U.S. 258, 303-04, (1947)). "Generally, the minimum sanction necessary to obtain compliance is to be imposed." *Id.* (internal citations omitted).

To establish a civil contempt claim, the petitioner must show "(1) that [the opposing party] violated the court order, (2) beyond substantial compliance, (3) not based on a good faith

and reasonable interpretation of the order, (4) by clear and convincing evidence." *United States v. Bright*, 596 F.3d 683, 694 (9th Cir. 2010) (internal quotations omitted); *see also Knupfer v. Lindblade (In re Dyer)*, 322 F.3d 1178, 1190-91 (9th Cir. 2003) (quoting *Renwick v. Bennett (In re Bennett)*, 298 F.3d 1059, 1069 (9th Cir. 2002)) ("The standard for finding a party in civil contempt is well settled: The moving party has the burden of showing by clear and convincing evidence that the contemnors violated a specific and definite order of the court."). If the petitioner satisfies that burden, the respondent "bears the burden of demonstrating that they were unable to comply" and to articulate reasons why compliance was not possible. *See Donovan v. Mazzola*, 716 F.2d 1226, 1240 (9th Cir. 1983). The respondent must have performed "'all reasonable steps within [its] power to insure compliance' with the court's order." *Stone v. City and Cnty. of San Francisco*, 968 F.2d 850, 856 (9th Cir. 1992) (quoting *Sekaquaptewa v. MacDonald*, 544 F.2d 396, 404 (9th Cir. 1976)). The Court may consider the respondent's history of noncompliance when evaluating the proffered reasons why compliance was not possible. *Id.* at 857.

A petitioner for civil contempt must typically initiate a civil contempt claim by requesting an order to show cause. *See K.M. v. Tehachapi Unified Sch. Dist.*, No. 117CV01431-LJO-JLT, 2020 WL 6145113, at *10 (E.D. Cal. Oct. 20, 2020), report and recommendation adopted, No. 117CV01431-NONE-JLT, 2021 WL 1291958 (E.D. Cal. Apr. 7, 2021). If the Court, "is satisfied that the application presents sufficient grounds for contempt, it will issue the order to show cause and set a time and date for the hearing." Judge Karen L. Stevenson & James E. Fitzgerald, Rutter Practice Guide—Federal Civil Procedure Before Trial § 13:245 (Calif. and 9th Cir. Ed. 2023). In assessing whether sufficient grounds for contempt exist, courts evaluate the request to show cause based on the underlying standards applicable to the merits of a civil contempt claim. *See Eaconomy, LLC v. Auvoria Prime, LLC*, 482 F. Supp. 3d 1030, 1037 (E.D. Cal. 2020) (denying request for order to show cause because the petitioner "failed to justify civil contempt by clear and convincing evidence"); *HSBC Bank USA v. Dara Petroleum, Inc.*, No. 2:09-CV-2356-WBS-EFB, 2016 WL 2853584, at *2 (E.D. Cal. May 16, 2016). After an order to show cause issues, the opposing party has opportunity to file a responsive pleading. *Id.* The Court must hold a hearing on the merits of the civil contempt claim unless uncontroverted affidavits support finding the

respondent in contempt. *Peterson v. Highland Music, Inc.*, 140 F.3d 1313, 1324 (9th Cir. 1998).

B. Respondents' Alleged Noncompliance

In support of its request for an order to show cause, the Government detailed Respondents' several historical violations, as previously explained; however, it focuses its arguments regarding Respondents' noncompliance on two current violations of the preliminary injunction order: (1) distributing an unapproved new drug, i.e., the cheddar cheese, in interstate commerce under paragraph 2(B); and (2) failing to include the 2(F) disclosure statement on all its invoices, packaging slips, and websites. (Doc. 50-2 at 18-24; Doc. 60 at 2.)

First, regarding the alleged 2(B) violation, the Government argues that the raw cheddar cheese product qualifies as an unapproved drug because Respondents intended the product's use for diagnosis, cure, mitigation, treatment, or prevention of disease. (Doc. 50-2 at 18-24.) The statements on Respondents' websites and social media allegedly demonstrate this intended use because they claim that their products "help prevent heart disease and osteoporosis" and "contain lactoferrin, which is a special protein that protects against viral infections." (*Id.* at 20); *see also* 21 C.F.R. § 201.128 ("The words *intended uses* or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of an article. . . The objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.") (emphasis in original)). New drugs require the FDA to approve a "new drug application" or an "abbreviated new drug application." (Doc. 50-2 at 23); 21 U.S.C. § 355(a). The Government represents that Respondents do not have these necessary drug approvals for their products. (Doc. 50-2 at 23.)

Respondents deny that their raw cheddar cheese constitutes a "drug." (Doc. 58 at 22-25.) They maintain that it is a food product as defined by the FDA, i.e., an "article[] used for food or drink for man or other animals." (Doc. 58 at 22 (quoting FDCA ¶ 201(f)).) More particularly, the FDA defines cheddar cheese to include unpasteurized cheese if "the cheese is cured at a temperature of not less than 35°F for at least 60 days." 21 C.F.R. § 133.113(a)(1). Respondents contend that their raw cheddar cheese meets the FDA standards and that the FDA granted them approval to distribute their cheddar cheese interstate on September 6, 2019. (Doc. 58 at 23-25.)

Respondents maintain that they never intended to market the raw cheddar cheese product as a drug, and therefore, never sought approval of it as a drug under the FDA. (*Id.*)

Second, regarding the alleged noncompliance with the 2(F) disclosure requirement, the Government argues Respondents have historically and currently violate this provision. (Doc. 50-2 at 15-16.) According to the Government, Organic Pastures only maintained the required disclosure on its website for a year following the Court's order in 2010 but then stopped doing so. (Doc. 50-2 at 13-14.) During the inspection in April 2019, the FDA discovered Organic Pastures' invoices and packaging slips did not contain the disclosure statement. (*Id.*) Respondents maintain that their sales software did not permit printing the full statement, and once the FDA notified them of the violation, they invested in new software that allowed full compliance. (Doc. 58 at 9-10.) Respondents assert that the 2(F) statement appears on "its website and all its social media platforms." (Doc. 58 at 20-21.) However, Aaron McAfee's declaration, on which they rely for this assertion, states only that their "website homepage" displays the required disclosure but not whether the statement currently appears on all Organic Pastures/Raw Farm's internet sites. (*See* Doc. 58-1 at 4-5, ¶ 13.) The Government asserts that the required disclosure did not appear on Organic Pastures/Raw Farm's Facebook home page, Facebook shopping page, or Instagram profile as recently as March 2023. (Doc. 60 at 4.)

Undisputedly, Respondents have violated at least some terms of the Court's preliminary injunction order. Even if the raw cheddar cheese qualifies as a food product, not an unapproved drug, under the FDA, Respondents' public statements that the cheddar cheese "protects against illness," "protects against virus infection," and "help[s] prevent heart disease[] and osteoporosis" violate 2(F)'s provision that required Organic Pastures to remove all statements promoting their raw milk products as having health benefits. (Doc. 50 at 15-16.) Moreover, the FDA's investigations revealed that Respondents, at least historically, failed to affix the 2(F) disclosure statement on their invoices, websites, and packaging slips, and did not display the disclosure on certain sites as of March 2023 when the Government initiated these proceedings. (Doc. 50-2 at 13-14.) Although it remains unclear whether the 2(F) disclosure currently appears on all necessary sites, the totality of the evidence provides sufficient grounds to demonstrate that

Respondents violated the preliminary injunction order.

C. Proffered Reasons for Substantial Compliance or Compliance Not Possible

Even if Respondents violated the order, they contend their noncompliance was justified because they took reasonable steps to substantially comply, and full compliance was not possible. (Doc. 58 at 21-22.) For example, Respondents allege that they believed they were compliant with the preliminary injunction order until notified by the FDA in April 2019. (Doc. 58 at 9.) They contend they had been "open and transparent with the FDA at every inspection and, at every inspection, the FDA had approved and affirmed [Organic Pastures'] sale of legally produced raw cheddar cheese products." (*Id.*) With regard to their raw kefir pet food, Respondents maintain they sought FDA approval in September 2017, but the FDA informed them that pre-market authorization was not available for pet food. (*Id.* at 22.) They allegedly ceased distribution of the kefir product on June 5, 2019, after the FDA notified them of their violation of the Court's order, until they received FDA approval on September 6, 2019. (Doc. 58-1 at 26.) Conversely, the Government alleges Respondents did not submit a request for authorization of the kefir product before April 24, 2019. (Doc. 50-3 at 76-77.) According to the Respondents, they maintained constant and prompt communication with the FDA since its notification of noncompliance in April 2019 and attempted to resolve any issues the FDA raised. (Doc. 58 at 21-22.)

On the other hand, the Government alleges the FDA made multiple attempts over the course of three years to obtain voluntary compliance before initiating proceedings for civil contempt through the instant motion. (Doc. 60 at 8.) The FDA sent at least eight letters/reports reminding Respondents of their obligations under the Court's order. (*Id.* at 3.) Despite these attempts, the Government asserts that Respondents continued to violate the order. (Doc. 50 at 15-16.) The Government offered to resolve the matter before litigation by proposing the parties jointly petition the Court to amend the original preliminary injunction order. (Doc. 60 at 8.) Respondents allegedly struck every substantive provision proposed by the Government. (*Id.*) The Government contends that it offered reasonable concessions to the original order, including adding a sunset clause to the obligations. (*Id.*) Respondents flatly rejected the counterproposal. (*Id.*) According to Respondents, after they rejected the counterproposal, the Government

indicated they would follow up but provided no communication before filing the instant motion. (Doc. 58 at 16-17.) The Government alleges that negotiations broke down after Respondents refused to comply with the obligations under original preliminary injunction order unless the amended order contained a two-year or less sunset clause. (Doc. 60 at 2.) The Government argues that Respondents' repeated violations, their misrepresentations to the FDA about their compliance, and their refusal to adhere to the FDA's instructions warrant finding Respondents in civil contempt. (Doc. 50-2 at 25.)

The Court finds the Government has presented sufficient grounds to issue an order to show cause why Respondents[3] should not be held in civil contempt for their violations of the preliminary injunction order. The parties' conflicting versions of events create material disputes of fact regarding Respondents' ongoing violations and their efforts to comply with the original order. Although the Court has not delineated each dispute of fact the parties' raise in their briefs, sufficient disputes exist to necessitate further factual development at a hearing regarding the dispositive issues underlying the Government's civil contempt claim.

III. ORDER

For the reasons stated above, the Court **ORDERS**:

1. The Government's request for an order to show cause why Respondents should not be held in civil contempt is **GRANTED** (Doc. 50).
2. Respondents **SHALL** show cause in writing, within **twenty-one days** of this order, why they should not be held in civil contempt. Alternatively, Respondents may rest upon their previously filed brief (Doc. 58) as their substantive response. Should Respondents file an additional brief, the Government may file a reply within **ten days** of their response. The Court would also entertain any reasonable stipulation to permit a different briefing pattern and schedule.
3. An evidentiary hearing in this matter is set for **July 5, 2023 at 8:30 a.m.** at the

[3] The Court acknowledges that Respondents contend that holding Aaron McAfee in civil contempt of the preliminary injunction order would violate his due process rights because he was not a party to the original action. (Doc. 58 at 18-19.) Because this argument relates to the ultimate finding of civil contempt and not to whether an order to show cause may issue, the Court need not address the matter at this time.

Robert E. Coyle United States Courthouse, 2500 Tulare Street, Fresno, California, Courtroom 4.

4. **Fourteen days in advance** of the hearing date, the parties are directed to submit witness lists, indicating the anticipated length of testimony of each witness and providing a brief proffer of their anticipated testimony.

5. The parties are **strongly encouraged** to file a joint request seeking a settlement conference with the assigned magistrate judge. If they do so, the Court will delay the briefing schedule and evidentiary hearing until after the settlement efforts are exhausted.

IT IS SO ORDERED.

Dated: **May 19, 2023**

Jennifer L. Thurston
UNITED STATES DISTRICT JUDGE