IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. TOBY CARL MCADAM and GRETA S. ARMSTRONG, Individuals, d/b/a RISINGSUN HEALTH, Defendants.	CV 10-128-BLG-SEH-CSO FINDINGS AND RECOMMENDATIONS OF UNITED STATES MAGISTRATE JUDGE

I. Introduction

This case was closed in 2010 after the parties stipulated to entry of a Consent Decree, which Judge Cebull signed on November 4, 2010. *ECF 5.*[1] Generally, the Consent Decree required McAdam to bring himself into compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act"). The Court "retain[ed] jurisdiction [] for the purpose of enforcing or modifying [the Consent] Decree and

[1]"ECF" refers to the document as numbered in the Court's Electronic Case Files. *See The Bluebook, A Uniform System of Citation, § 10.8.3.*

for the purpose of granting such additional relief as may be necessary or appropriate." *ECF 5 at 18.*

In February 2013, the United States filed the following documents: (1) "Petition for an Order to Show Cause Why Defendant Toby McAdam Should Not be Held in Civil Contempt" (*ECF 18*) and (2) "Motion for Liquidated Damages" (*ECF 19*). After the Court granted McAdam extensions of time to respond (*see ECF 21, 28, 31)*, it held a hearing on these motions on September 25, 2013. Despite adequate notice of the hearing, McAdam failed to appear. The United States presented the testimony of Lisa Altha, FDA Compliance Officer, regarding the FDA investigations of McAdam's activities.

On September 25, 2013, the Court issued a Show Cause Order, giving McAdam another opportunity to appear and show cause why he should not be held in contempt and sanctioned for violating the Consent Decree. *ECF 34.* This show-cause hearing was held on October 21, 2013. The Court heard testimony from McAdam and further testimony from Lisa Althar. In addition, the United States was given time to file its "Motion for Attorney Fees" (*ECF 45*). McAdam responded with a "Motion to Vacate Fines and Response" (*ECF 46*).

Having considered the oral testimony, written motions, and arguments of the parties, the Court enters the following Findings and Recommendations.

II. Background Facts

A. Events Leading to Consent Decree

In 2006, the Food and Drug Administration ("FDA") issued Defendant Greta Armstrong a Warning Letter that Risingsun was advertising unapproved cancer remedies on the websites www.risingsunhealth.com and www.bloodrootproducts.com, and warned her that selling unapproved products for use in the cure, mitigation, treatment, and prevention of disease violated the Act. The FDA also advised that the products advertised on the website were misbranded under the Act and did not contain adequate directions for usage. McAdam then informed the FDA by telephone that he was the owner of Risingsun and he would remove the offending drug claims from the websites. McAdam sent a letter to the FDA shortly thereafter confirming that he would remove the offending drug claims.

The following year, in November 2007, FDA investigators inspected Risingsun and discovered that McAdam's violations of the Act

continued. McAdam wrote two more letters promising that he would cease illegal activity. Despite this, on April 4 and 10, 2009, FDA investigators noted that Risingsun's websites and many of their product labels still contained illegal drug claims that its products could cure, mitigate, treat, or prevent disease.

In May and June 2010, the FDA made numerous undercover purchases of Risingsun's products and found that McAdam continued to sell illegal unapproved new drugs which the FDA had previously informed McAdam were in violation of 21 U.S.C. §§ 352(f)(1) and 355(a). These purchases were shipped from Montana to undercover investigators located in Maryland, Arizona, and Washington State.

On October 13, 2010, the United States filed its Complaint herein invoking the injunction provisions of the Act, 21 U.S.C. § 332(a). The Complaint alleged, among other things, that McAdam regularly sold unapproved drugs in interstate commerce to treat serious diseases such as cancer, anemia, asthma, ADD/ADHD, arthritis, epilepsy, and intestinal parasites. These drugs were alleged to be "new drugs," as defined by 21 U.S.C. § 321(p)(1), in that they were not generally recognized, among experts qualified by scientific training and

experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. *See ECF 1*. The Complaint also alleged:

> (1) that McAdam violated 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce such unapproved drugs in violation of 21 U.S.C. § 355;
>
> (2) that McAdam sold new animal drugs, as defined by 21 U.S.C. § 321(v)(1), that were unapproved by the FDA, and which were "unsafe" within the meaning of 21 U.S.C. § 360b(a), and "adulterated" within the meaning of 21 U.S.C. § 351(a)(5); and
>
> (3) that McAdam's drug products were "misbranded" within the meaning of 21 U.S.C. § 353(b)(1) because they were prescription drugs, the distribution of which without a prescription resulted in the drug being "misbranded" while held for sale, and within the meaning of 21 U.S.C. § 352(f)(1), because the labeling failed to bear adequate directions for use.

B. <u>Consent Decree</u>

The parties negotiated the Consent Decree. McAdam was represented by counsel throughout those negotiations.

The Consent Decree enjoins McAdam from introducing into interstate commerce, holding for sale after shipment in interstate commerce, and manufacturing, processing, packaging, labeling, holding, selling, and distributing a broad range of products, including, *inter alia*, (a) any topically-applied product for human or animal use containing extracts or components of the Bloodroot or Graviola plants, (b) any "new drug," (c) any "new animal drug," and (d) any dietary supplement, unless and until (i) the FDA approves a new drug application or abbreviated new drug application for the product pursuant to 21 U.S.C. § 355, or (ii) the FDA approves an investigational new drug application for the product pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. § 312, or (iii) the FDA approves a new animal drug application or abbreviated new animal drug application for the product pursuant to 21 U.S.C. § 360b(b) or such product meets the requirements for the investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j).

Second, the Consent Decree requires that McAdam demonstrate to the FDA that the new drug is the subject of a valid FDA approval before manufacturing or distributing any new drug.

Third, the Consent Decree requires McAdam to retain a labeling expert.

Fourth, the Consent Decree generally enjoins McAdam from introducing unapproved, misbranded, and/or adulterated human and animal drugs into interstate commerce, or causing the adulteration or misbranding of such products held for sale after shipment in interstate commerce.

The Consent Decree also states that if McAdam violates the Consent Decree, the Act, or the FDA's regulations, the "FDA may, as and when it deems necessary in its sole discretion, direct [McAdam], in writing, and order [McAdam] to take appropriate corrective action. . . ." *ECF 5 at 13.* Such corrective action may include an order to "[c]ease manufacturing, processing, packaging, labeling, holding, selling, and/or distributing any or all drugs and/or dietary supplements," or "any other corrective action(s) as FDA deems necessary to protect the public health or to bring [McAdam] and [his] products into compliance with the Act, applicable regulations, and this [Consent] Decree." *Id*. at 13-14.

In addition, the Consent Decree orders that McAdam will pay monetary damages if he violates the Consent Decree, attorney's fees in a contempt action, and the costs of "all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in [the Consent Decree] or that FDA deems necessary to evaluate [McAdam's] compliance" at the standard prevailing rates. *Id. at 17-18.*

The Consent Decree provides that "[a]ll decisions specified in this [Consent] Decree shall be vested in the discretion of FDA and shall be final and [McAdam] shall abide by the decisions of FDA." *Id. at 18.* If contested, the Consent Decree provides that the FDA's decisions "shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A)." *Id.*

On February 14, 2012, McAdam filed a "Request to Set Aside Consent Decree and Preliminary Injunction." *See ECF 8.* McAdam's request alleged that he had been coerced and intimidated into signing the Consent Decree, that he should not be required to hire a labeling expert because "there is no criteria nor certification procedures for a person to become a label specialist," and that the Consent Decree

violates his rights to equal protection. On March 8, 2012, Judge Cebull denied McAdam's motion in full. *See ECF 12.*

On September 11, 2012, McAdam filed a motion entitled "Request for Hearing to Compel [the Government] to Specify Criteria as to What is Not a Medical Claim and to Clarify Criteria Standards Set for So-Called Label Specialist and For this Court to Review and Determine If [McAdam] Has Infect (sic) Complied With Decree." *See ECF 13.* Judge Cebull denied this "Request," concluding that "[e]ach of the arguments advanced in Defendant's motion have already been rejected by this Court." *ECF 16 at 1.*

C. Alleged Violations of Consent Decree

On September 15, 2011, the FDA notified McAdam that Risingun was in violation in the Consent Decree and ordered McAdam to cease operations until he could demonstrate compliance with the Consent Decree. On February 14, 15, and 16, 2012, the FDA conducted an inspection at Risingsun. The FDA's inspection revealed that, notwithstanding the FDA's September 15, 2011 notification of non-compliance, McAdam continued to sell products in violation of the Consent Decree.

Following the February 2012 inspection, McAdam faxed to the FDA a letter dated March 5, 2012, which indicated that he would soon address the observed deficiencies. McAdam, however, did not follow up on this assurance and did not submit a corrective action plan that was later requested by the FDA. Furthermore, on March 29, 2012, the FDA sent an invoice of $1,524.39, pursuant to Paragraph 12 of the Consent Decree, to reimburse the Agency for the cost of the February 2012 inspection. McAdam did not pay this invoice.

The FDA sent McAdam another letter on April 20, 2012, notifying him that he was continuing to violate the Consent Decree and pointing out that the FDA had observed several additional violations of the Consent Decree. McAdam did not respond. The FDA sent him yet another letter on July 27, 2012, requesting that he pay liquidated damages in the amount of $80,000 because of his clear and ongoing violations of the Consent Decree and the Act. McAdam did not pay the liquidated damages request.

On October 17, 2012, the FDA conducted an inspection of Gesunheit! Nutrition Center in Bozeman, Montana, and found further evidence that McAdam was in violation of the Consent Decree.

On October 31, 2012, the FDA's Office of the Chief Counsel informed McAdam via letter that McAdam's case had been referred back to his office to consider whether to bring further court proceedings, and that, in the absence of immediate compliance with the Consent Decree, the FDA would refer this case back to the Department of Justice to file a motion with the Court seeking an award of liquidated damages under Paragraph 7 of the Consent Decree. In response, McAdam filed a sworn affidavit dated November 8, 2012, stating that he "will cease operations." *See ECF 17.*

III. Standard of Review

Federal courts have inherent power to force entities to comply with their lawful orders through actions for civil contempt. *Spallone v. United States*, 493 U.S. 265, 276 (1990); *Shillitani v. United States*, 384 U.S. 364, 370 (1966). Federal courts have the authority to issue contempt sanctions for violations of judicial orders, including consent decrees. *F.T.C. v. EDebitPay, LLC*, 695 F.3d 938, 943 (9th Cir. 2012). Sanctions for civil contempt may be imposed to coerce compliance with a court order or to compensate the injured party for losses sustained. *Koninklijke Philips Elecs., N.V. v. KXD Tech., Inc.*, 539 F.3d 1039, 1044

(9th Cir. 2008); *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)).

The Supreme Court has consistently recognized that a consent decree entered by the court reflects "an agreement that the parties desire and expect will be reflected in, and be enforceable as, a judicial decree that is subject to the rules generally applicable to other judgments and decrees." *Rufo v. Inmates of Suffolk Cnty Jail*, 502 U.S. 367, 378 (1992). A party who fails to comply with the terms of a court-ordered consent decree is subject to the court's contempt power. *See Nehmer v. U.S. Dept. of Veterans Affairs*, 494 F.3d 846, 860 (9th Cir. 2007) ("It is well established that the district court has the inherent authority to enforce compliance with a consent decree that it has entered in an order, to hold parties in contempt for violating the terms therein . . . ." (citing *Rufo*, 502 U.S. at 381 & n.6)).

Civil contempt "consists of a party's disobedience to a specific and definite court order by failure to take all reasonable steps within the party's power to comply." *Reno Air Racing Ass'n v. McCord*, 452 F.3d

1126, 1130 (9th Cir. 2006) (quoting *In re Dual–Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir. 1993)).

To justify civil contempt, the moving party must establish "(1) that [the alleged contemnor] 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) (quoting *Labor/Cmty. Strategy Ctr. v. L.A. Cnty Metro. Trans. Auth.*, 564 F.3d 1115, 1123 (9th Cir. 2009)); *see also F.T.C. v. Affordable Media*, 179 F.3d 1228, 1239 (9th Cir. 1999) ("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 moving party meets this initial four-part test, the burden then shifts to the alleged contemnor to demonstrate why it was unable to comply. *Affordable Media*, LLC, 179 F.3d at 1239; *Stone v. City & Cnty. of San Francisco*, 968 F.2d 850, 856 n. 9 (9th Cir. 1992). In other words, the accused party must "show [that it] took every reasonable step to comply." *Stone*, 968 F.2d at 856 n. 9 (citation omitted).

IV. Analysis

The Court finds that the United States has presented clear and convincing evidence that McAdam has failed to comply with several requirements of the Consent Decree.

First, McAdam has violated Paragraph 3.A.1, which prohibits the sale of topically-applied products containing extracts or components of the Bloodroot plant. *See ECF 5 at 4.* Second, McAdam has violated Paragraphs 4 and 5 of the Consent Decree by continuing to sell products that are intended to be used topically or ingested by humans, without submitting certifications by an expert that the products comply with the law. *Id. at 6-10.* Finally, McAdam has repeatedly failed to comply with the FDA's order, issued pursuant to Paragraph 10 of the Consent Decree, that Risingsun cease manufacturing, processing, packaging, labeling, holding, selling, and/or distributing all products intended to be ingested by, or applied topically to, humans or animals, including, without limitation, any drugs and/or dietary supplements. *Id. at 13-14.*

The United States' Exhibit A shows that on September 12, 2013, McAdam was sharing information and advertising for the sale of his

Bloodroot products on his Risingsun Herbal Health Facebook page, including a link to the website where the Bloodroot products can be purchased. *Government's Exhibit A at 2*; *Tr. 33.*

McAdam's own testimony and the exhibits he offered at the hearing confirm his violations. McAdam testified that he had been selling Black Salve in order to pay for his hip surgery. *Tr. 29, 3-7; 31 16-19; 43, 4-7.* McAdam's Exhibit 1, entitled "Batch Record," indicates McAdam produced "Bloodroot Immune Capsules" on April 16, 2012. McAdam also testified that he did not have proof that a labeling expert had submitted proposed labels for FDA inspection. *Tr. 45, 14-16.*

McAdam's conduct has demonstrated an attitude of defiance toward the FDA and the Court's order. By failing to comply with the Consent Decree, McAdam continues to expose the public to unapproved drugs that have not been demonstrated to be safe or effective, as well as dietary supplements that are not manufactured in compliance with the Current Good Manufacturing Practices ("cGMPs") regulations. *See generally 21 C.F.R. Parts 210-211.*

Further, the United States has devoted significant time and resources negotiating the terms of the Consent Decree, investigating

whether McAdam has complied with the Consent Decree, and documenting McAdam's non-compliance.

Civil sanctions are necessary to force McAdam to comply with the Consent Decree and the FDA's order. McAdam should be required to immediately cease all manufacturing, processing, packaging, labeling, holding, selling, and/or distributing all products intended to be ingested by, or applied topically to, humans or animals, including, without limitation, any drugs and/or dietary supplements. McAdam must immediately shut down his website and the Risingsun Herbal Health Facebook page, remove all products from Amazon.com, and remove any related telephone listings from phone books. This must be done unless and until the FDA in writing certifies compliance and permits McAdam to resume operations.

V. Damages and Fees

Given McAdam's repeated failures to comply with the terms of the Consent Decree, despite repeated warnings from the FDA and multiple opportunities to comply, the Court must consider the issues of liquidated damages and attorney fees.

Paragraph 17 of the Consent Decree provides as follows:

> If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the Plaintiff, Defendants shall pay to the United States of America: one thousand dollars ($1,000.00) in liquidated damages, and an additional sum of one thousand dollars ($1,000.00) in liquidated damages for each day the violation of the Act, its implementing regulations, and/or this Decree continues.

Under this provision, the amount of liquidated damages imposed may not exceed "eighty thousand dollars ($80,000) per defendant in any calendar year." *ECF 5 at 17.*

The United States has, as required by the Decree, "specif[ied] the noncompliance giving rise to the motion." *See ECF 18, 19 and attachments).* The United States has demonstrated through an affidavit (*ECF 33*) and in testimony at the hearing that McAdam has been noncompliant with the Consent Decree since it was entered, and has ignored the FDA's order to cease operations dated September 15, 2011. McAdam's testimony at the hearing confirmed his noncompliance.

Although it argues that the Consent Decree may permit a request for additional liquidated damages, the United States is seeking a total

of eighty thousand dollars ($80,000.00) in such damages. McAdam should be required to pay to the United States liquidated damages in the amount of eighty thousand dollars ($80,000.00) pursuant to Paragraph 17 of the Consent Decree. *See ECF 5.*

The United States also seeks an award of fees and costs as an additional sanction related to McAdam's conduct. *ECF 45.* In support of this motion, the United States filed a declaration of Rodney Veenstra, a Supervisory Budget Analyst, Budget Execution Branch of the Civil Division, Department of Justice. *ECF 45-1.* Mr. Veenstra calculates the DOJ attorney's hourly rate as $149.34. *Id. at 4-5.* The Court finds this rate to be reasonable. In addition, the United States presents the Declaration of DOJ counsel David Sullivan, documenting the expenditure of 228.65 hours between February 14, 2012, and September 30, 2013. *ECF 45-3 at 1-2.* Although this would yield an award of $34,146.59, the United States seeks only $3,584.16, or about 10 percent of the larger sum. Travel costs are documented to be $1,352.32. *Id. at* 3.

In response to this request for fees and costs, McAdam primarily presents arguments that Judge Cebull has heretofore rejected. *See*

ECF 46. He cites no authority to support his remaining objections and, even liberally construed, they are without merit.

VI. Conclusion

Based upon the foregoing, IT IS RECOMMENDED that:

1. Plaintiff's Petition for a judgment of civil contempt against McAdam for violations of the Consent Decree (*ECF 18 at 4*) be GRANTED. McAdam should be required to immediately cease all manufacturing, processing, packaging, labeling, holding, selling, and/or distributing all products intended to be ingested by, or applied topically to, humans or animals, including, without limitation, any drugs and/or dietary supplements. McAdam should be required to immediately shut down his website and the Risingsun Herbal Health Facebook page, remove all products from Amazon.com, and remove any related telephone listings from phone books. This should be done unless and until the FDA in writing certifies compliance and permits the resumption of operations.

2. Plaintiff's Motion for Liquidated Damages (*ECF 19*) be GRANTED. McAdam should be directed to pay to the United States liquidated damages in the amount of eighty thousand dollars ($80,000.00) pursuant to Paragraph 17 of the Consent Decree of Permanent Injunction. *See ECF 5*.

3. The United States Motion for Attorney Fees and Costs (*ECF 45*) should be GRANTED, and the United States should be awarded the total sum of $4,936.48.

4. McAdam's Motion to Vacate Fines (*ECF 46*) should be DENIED.

NOW, THEREFORE, IT IS ORDERED that the Clerk of Court shall serve a copy of the Findings and Recommendations of United States Magistrate Judge upon the parties. The parties are advised that pursuant to 28 U.S.C. § 636, any objections to the Findings and Recommendations must be filed with the Clerk of Court and copies served on opposing counsel within fourteen (14) days after service hereof, or objection is waived.

DATED this 12th day of November, 2013.

/s/ Carolyn S. Ostby
United States Magistrate Judge