

MICHAEL W. COTTER
United States Attorney

DAVID SULLIVAN
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044
(202) 514-0516
david.sullivan2@usdoj.gov

Attorneys for Plaintiff

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

UNITED STATES OF AMERICA,)
)
Plaintiff,)

Civil No. CV-10-128-BLG-SEH

v.)

**PETITION AND BRIEF
FOR AN ORDER TO
SHOW CAUSE WHY
TOBY MCADAM
SHOULD NOT BE HELD IN
CRIMINAL CONTEMPT**

TOBY MCADAM,)
An Individual,)
d/b/a RISINGSUN HERBAL)
HEALTH CORP.,)
d/b/a RISINGSUN HEALTH,)
d/b/a RISINGSUN)
NUTRITIONAL CORP.,)
d/b/a RISINGSUN)
MINISTRIES,)
d/b/a NUTRITIONAL)
SUPPLEMENTS INC.,)
d/b/a MCADAM HEALTH)
ENTERPRISES CORP.,)
)
Defendant.)

_____)

1. The United States of America, by and through its attorneys, and pursuant to 18 U.S.C. § 401(3) and Fed. R. Crim. P. 42(a), hereby moves this Court for an Order to Show Cause why Defendant Toby McAdam (“McAdam” or “Defendant”) should not be adjudged in criminal contempt of the Consent Decree of Permanent Injunction (“Consent Decree”) entered by this Court on November 5, 2010, and the Order of civil contempt entered by this Court on December 4, 2013. *See United States v. McAdam*, CV 10-128-BLG-SEH (D. Mont. 2010), Civ. DE 5, 49. In support of its petition, the United States respectfully states as follows:

JURISDICTION OF THE COURT

2. This Petition alleges violations by Defendant Toby McAdam of the Consent Decree of Permanent Injunction entered by this Court on November 5, 2010, and the Order of civil contempt entered by this Court on December 4, 2013. This Court has jurisdiction over the Defendant under its inherent power to enforce compliance with its orders and 18 U.S.C. § 401(3).

THE DEFENDANT

3. Toby McAdam operates a sole proprietorship doing business under several names, including Risingsun Herbal Health Corp., Risingsun Health, Risingsun Nutritional Corporation, Risingsun Ministries, Nutritional Supplements Inc. and McAdam Health Enterprises Corporation (hereinafter referred to as “Risingsun”). McAdam is responsible for all business and financial decisions of

Risingsun, including product development, the creation of labeling and promotional materials, the design of product packaging and the development of the content on his internet websites www.bloodrootproducts.com, www.risingsunhealth.com, and www.bloodrootblacksalve.com, as well as the content on the Risingsun Herbal Health Facebook page and Risingsun Herbal Health Amazon.com Storefront. McAdam resides and conducts business in Livingston, Montana.

FACTUAL BACKGROUND

I. Civil Complaint for Permanent Injunction

4. On October 13, 2010, the United States filed a complaint in this Court against McAdam seeking an injunction under the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 332(a). The Complaint alleged, among other things, that McAdam regularly sold unapproved drugs in interstate commerce, purporting them to treat serious diseases such as cancer, anemia, asthma, ADD/ADHD, arthritis, epilepsy, and intestinal parasites. The Complaint also alleged that McAdam violated the Act by introducing or delivering for introduction into interstate commerce such unapproved drugs. Further, the Complaint alleged that McAdam’s drug products were misbranded, per the Act, because they were prescription drugs, and his distribution of such drugs without a prescription resulted in the drugs being misbranded while held for sale. Finally,

McAdam's drug products were misbranded, per the Act, because their labeling failed to bear adequate directions for use.

II. Consent Decree of Permanent Injunction

5. On November 5, 2010, this Court entered the Consent Decree, to which both the United States and McAdam had agreed. Pursuant to the Consent Decree, McAdam agreed to be permanently restrained and enjoined 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 "new drug," as defined by the Act; and
- b) any dietary supplement, as defined by the Act, unless and until:
 - (i) FDA approves a new drug application or abbreviated new drug application for the product, pursuant to the Act;
 - (ii) FDA approves an investigational new drug application for the product, pursuant to the Act; or
 - (iii) any health claims made in the labeling comport with an authorized health claim, pursuant to the Act.

Civ. DE 5, at 3A(1)-(5e).

6. The Consent Decree also prohibited McAdam from introducing or delivering into interstate commerce any drug that is misbranded, as defined in the Act. *Id.* at 3B.

7. Before manufacturing or distributing any product that is not a new drug, but which is intended either to be ingested by humans or animals or topically applied to humans or animals (each such product called an “Other Product”), the Consent Decree requires McAdam to retain a “labeling expert,” defined as:

an independent person or person . . . without any personal or financial ties to [McAdam] and [his] famil[y], and who, by reason of background, training, education, or experience, is qualified to review [McAdam’s] product labeling and determine whether such Other Product(s) comply with the applicable requirements of the Act.

Id. at 5.

8. Before marketing or distributing any Other Product, a labeling expert was required to review the products to “determine whether [McAdam] omitted all claims from their labeling that would cause such Other Product to be a drug and/or, [with respect to a dietary supplement,] that constitute unapproved or unauthorized health claims within the meaning of the Act.” In this regard, before the United States Food and Drug Administration (“FDA”) will consider permitting McAdam to manufacture or distribute any Other Product, the labeling expert “shall submit a written report to FDA analyzing whether McAdam is operating in compliance with

the Act and whether each such Other Product may be manufactured and/or distributed in compliance with the Act.” *Id.*

III. McAdam’s Conduct Post-Consent Decree

9. Immediately following the entry of the November 2010 Consent Decree, McAdam continued the same course of conduct, now in violation of the Consent Decree. For example, McAdam’s website, www.bloodrootproducts.com, made numerous new claims indicating that some of Risingsun’s products were intended to affect the structure or function of the human body, and other products were intended to cure, treat, or prevent various diseases. The sale of such products violated, *inter alia*, Paragraphs 3, 4, and 7(A) of the Consent Decree.

10. On September 15, 2011, pursuant to Paragraph 10 of the Consent Decree, FDA advised McAdam, via letter, that he was in violation of the Consent Decree and ordered him to shut down and cease all manufacturing, processing, packaging, labeling, holding, selling, and distributing all drugs and dietary supplements.

IV. McAdam’s Conduct Following the September 15, 2011 Shutdown Letter

11. FDA conducted an on-site inspection of Risingsun in February 2012. That inspection revealed that McAdam continued to sell products in violation of the Consent Decree.

12. On March 5, 2012, McAdam sent correspondence to FDA, which, among other things, advised that he had either destroyed or given all of his stock of one product to local area ranchers. However, McAdam continued to sell, via his internet websites, other drugs and dietary supplements,

V. Civil Contempt

13. FDA sent correspondence on both April 20 and July 27, 2012, advising McAdam that he was in violation of the Consent Decree due to his continued marketing of adulterated and misbranded drugs and dietary supplements. McAdam did not respond to either letter.

14. On February 22, 2013, the United States filed a petition seeking an order to show cause why McAdam should not be held in civil contempt for violating the terms of the Consent Decree. On October 21, 2013, this Court held a show cause hearing as to why McAdam should not be held in civil contempt. On December 4, 2013, this Court found McAdam in civil contempt, which provided notice to McAdam that his conduct violated the Consent Decree. In a new Order (the “Order of civil contempt”), this Court required McAdam to:

- a) 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;

- b) immediately shut down his website and the Risingsun Herbal Health Facebook page; and
- c) remove all products from Amazon.com.

15. The Order establishes that these requirements shall remain in effect unless and until the FDA, in writing, certifies compliance and permits the resumption of operations. To date, FDA has made not such certification.

VI. Notice To Obey the Order of Civil Contempt

16. On January 9, 2014, FDA sent correspondence to McAdam reiterating the findings in the Order of civil contempt and placing McAdam on notice that violation of the Order could result in the United States Department of Justice filing an action for criminal sanctions against McAdam.

17. On April 7, 2014, FDA sent correspondence to McAdam reaffirming that he was not allowed to conduct business in a manner that violated the Consent Decree or the Order of civil contempt and that McAdam could face an action for criminal sanctions if he failed to comply with those Orders.

ALLEGED VIOLATIONS OF THE COURT'S ORDERS

18. Since the entry of the Consent Decree and Order of civil contempt, McAdam has continued his contumacious conduct, as set forth more fully below:

COUNT I

19. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

20. On or about January 29, 2014, Defendant Toby McAdam sold and distributed in interstate commerce a dietary supplement, to wit, a bottle of Lugol's Iodine, to an undercover FDA employee through Risingsun's Amazon.com store front, and, in doing so, did knowingly and willfully violate clear and definite court orders, specifically paragraphs 3(A)(5) of the Consent Decree and paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT II

21. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

22. On or about April 23, 2015, Defendant Toby McAdam sold and distributed in interstate commerce a dietary supplement, to wit, Bloodroot Immune Support Capsules, to an undercover FDA employee through Risingsun's Amazon.com store front and, in doing so, did knowingly and willfully violate clear and definite court orders, specifically paragraphs 3(A)(5) of the Consent Decree and paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT III

23. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

24. On or about April 23, 2015, Defendant Toby McAdam sold and distributed in interstate commerce a new drug, to wit, a bottle of Lugol's Iodine, to an undercover FDA employee through Risingsun's Amazon.com store front and, in doing so, did knowingly and willfully violate clear and definite court orders, specifically paragraphs 3(A)(3) of the Consent Decree and paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT IV

25. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

26. From at least as early as December 20, 2014, to at least as late as July 29, 2015, Defendant Toby McAdam failed to shut down his website, www.bloodrootproducts.com, and, in failing to do so, did knowingly and willfully violate a clear and definite court order, specifically paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT V

27. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as thought set forth in full.

28. From at least as early as December 20, 2014, to at least as late as July 29, 2015, Defendant Toby McAdam failed to shut down his website, www.risingsunhealth.com, and, in failing to do so, did knowingly and willfully violate a clear and definite court order, specifically paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT VI

29. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

30. From at least as early as December 20, 2014, to at least as late as July 29, 2015, Defendant Toby McAdam failed to shut down his website, www.bloodrootblacksalve.com, and, in failing to do so, did knowingly and willfully violate a clear and definite court order, specifically paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT VII

31. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

32. From at least as early as December 20, 2014, to at least as late as July 29, 2015, Defendant Toby McAdam failed to shut down the Risingsun Herbal Health Amazon.com storefront, and, in failing to do so, did knowingly and willfully violate a clear and definite court order, specifically paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3).

COUNT VIII

33. Paragraphs 1 through 17 of this Petition are realleged and incorporated herein as though set forth in full.

34. From at least as early as December 20, 2014, to at least as late as July 29, 2015, Defendant Toby McAdam failed to shut down the Risingsun Herbal Health Facebook page and, in failing to do so, did knowingly and willfully violate a clear and definite court order, specifically paragraph 1 of the Order of civil contempt.

All in violation of Title 18, United States Code, Section 401(3)

PRAYER FOR RELIEF

35. WHEREFORE, the United States of America respectfully requests that this Court issue an Order requiring Toby McAdam to appear before this Court and to show cause why he should not be adjudged in criminal contempt of the November 5, 2010 Consent Decree of Permanent Injunction and December 4, 2013 Order of civil contempt; and

36. THEREAFTER, issue an Order adjudging Toby McAdam in criminal contempt of this Court's November 5, 2010 Consent Decree of Permanent Injunction and December 4, 2013 Order of civil contempt, and further:

- I. Impose an appropriate term of imprisonment as to Toby McAdam;
- II. Impose an appropriate fine as to Toby McAdam;

Dated: July 29, 2015

Of Counsel:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNA MARIE KEMPIC
Deputy Chief Counsel, Litigation

PERHAM GORJI
Deputy Chief Counsel, Litigation

MICHAEL SHANE
Associate Chief Counsel
for Enforcement
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant
Attorney General

JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL W. COTTER
United States Attorney

MICHAEL S. BLUME
Director
U.S. Department of Justice
Consumer Protection Branch

By: s/ David Sullivan
DAVID SULLIVAN
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20004

CERTIFICATE OF SERVICE

The undersigned hereby acknowledges that the foregoing Petition and Brief for an Order to Show Cause Why Toby McAdam Should Not Be Held in Criminal Contempt and was served on Toby McAdam in the modes used in prior filings: via email and placing into FEDEX, on this 29th day of July, 2015.

/s/ David Sullivan
DAVID SULLIVAN

CERTIFICATE OF COMPLIANCE

The undersigned hereby acknowledges that the foregoing Petition and Brief for an Order to Show Cause Why Toby McAdam Should Not Be Held in Criminal Contempt contains 1,925 words, excluding the caption and certificate of service.

/s/ David Sullivan
DAVID SULLIVAN

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

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Civil No. CV-10-128-BLG-SEH
)	
v.)	
)	
TOBY MCADAM,)	ORDER TO SHOW CAUSE
An Individual,)	WHY TOBY MCADAM
d/b/a RISINGSUN HERBAL)	SHOULD NOT BE HELD IN
HEALTH CORP.,)	CRIMINAL CONTEMPT
d/b/a RISINGSUN HEALTH,)	
d/b/a RISINGSUN)	
NUTRITIONAL CORP.,))	
d/b/a RISINGSUN)	
MINISTRIES,)	
d/b/a NUTRITIONAL)	
SUPPLEMENTS INC.,)	
d/b/a MCADAM HEALTH)	
ENTERPRISES CORP.,)	
)	
Defendant.)	
_____)	

Plaintiff, the United States of America, having filed a petition and brief in support for an order to show cause why Defendant Toby McAdam (hereinafter, “defendant”) should not be held in criminal contempt based on his violations of the Consent Decree of Permanent Injunction (“Consent Decree”) entered by this Court on November 5, 2010, and the Order of civil contempt entered by this Court on

December 4, 2013, and the Court having considered the petition and memorandum, it is hereby ORDERED:

1. Plaintiff's Petition and Brief for an Order to Show Cause Why Defendant Toby McAdam Should Not Be Held in Criminal Contempt is hereby GRANTED;

2. A status call on the Petition to Show Cause will be held on _____, 2015, and thereafter trial on the order shall take place on _____ at _____.

3. The essential facts constituting the alleged criminal contempt are set forth in the Petition and Brief filed by the United States. In sum, the facts alleged as constituting the criminal contempt are that on or about the dates set forth in the Petition and Brief, in connection with the sale and distribution of various dietary supplements and drugs, in the District of Montana and elsewhere, Defendant Toby McAdam knowingly and willfully disobeyed and resisted a lawful order, decree, and command of the United States District Court for the District of Montana, specifically the Consent Decree of Permanent Injunction entered on November 5, 2010, and the Order of civil contempt entered on December 4, 2013, in *United States v. Toby McAdam, et al.*, Civil No. CV-10-128-BLG-SEH (D.MT), in contempt of its authority, by and distributing dietary supplements and drugs in violation of specifically paragraphs 3(A)(3) and 3(A)(5) of the Consent Decree and

paragraph 1 of the Order of civil contempt, and by failing to shut the websites www.bloodrootproducts.com, www.risingsunhealth.com, www.bloodrootblacksalve.com, the Risingsun Herbal Health Amazon.com storefront and Risingsun Herbal Health Facebook page in violation of paragraph 1 of the Order of civil contempt.

Sam E. Haddon
United States District Judge