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

12

13 UNITED STATES OF AMERICA, ) Case No.  
14 )  
15 Plaintiff, ) **COMPLAINT FOR PERMANENT**  
16 ) **INJUNCTION**  
17 v. )  
18 )  
19 ORGANIC PASTURES DAIRY )  
COMPANY LLC, corporation and )  
20 MARK McAFEE, individual. )  
21 )  
22 Defendants. )

21

22 INTRODUCTION

23 Plaintiff, the United States of America, by its undersigned  
24 attorneys, respectfully represents to this Court as follows:

25 1. This statutory injunction proceeding is brought under  
26 the Public Health Service Act (the "PHSA"), 42 U.S.C. §§ 264 and  
27 271, and the Federal Food, Drug, and Cosmetic Act (the "Act"),  
28 21 U.S.C. § 332(a), to enjoin and restrain Organic Pastures Dairy

1 Company LLC, a corporation, and Mark McAfee, an individual  
2 (hereafter collectively, "Defendants"), from violating:

3 A. 42 U.S.C. § 264, by engaging in conduct that may  
4 endanger the public health and safety by contributing to the  
5 introduction, transmission, or spread of communicable diseases  
6 between the states or into the United States. Specifically,  
7 Defendants violate 21 C.F.R. § 1240.61(a), which prohibits the  
8 distribution in interstate commerce of raw (unpasteurized) milk  
9 and raw (unpasteurized) milk products in final package form for  
10 human consumption;

11 B. 21 U.S.C. § 331(a), by introducing or delivering,  
12 and causing to be introduced or delivered, into interstate  
13 commerce food that is misbranded within the meaning of 21 U.S.C.  
14 § 343(a)(1); and

15 C. 21 U.S.C. § 331(d), by introducing or delivering,  
16 and causing to be introduced or delivered, into interstate  
17 commerce new drugs within the meaning of 21 U.S.C. § 321(p) that  
18 are neither approved under 21 U.S.C. § 355(a), nor exempt from  
19 approval pursuant to 21 U.S.C. § 355(i).

20 2. For the purposes of this Complaint, the terms "raw" and  
21 "unpasteurized" have the same meaning and are used  
22 interchangeably.

23 JURISDICTION AND VENUE

24 3. This Court has jurisdiction pursuant to 21 U.S.C.  
25 § 332(a) and 28 U.S.C. §§ 1331 and 1345. This Court also has  
26 jurisdiction under the PHSA, as well as its general equity power  
27 to enjoin conduct that endangers the public health and safety,  
28 such as conduct that violates the PHSA, 42 U.S.C. § 264, and the

1 implementing regulation thereunder, 21 C.F.R. § 1240.61(a).

2 4. Venue in this District is proper pursuant to 28 U.S.C.  
3 § 1391(b) and (c).

4 DEFENDANTS

5 5. Defendant Organic Pastures Dairy Company LLC ("Organic  
6 Pastures") is incorporated under the laws of the state of  
7 California, with its principal place of business located at 7221  
8 South Jameson, Fresno, California.

9 6. Defendant Mark McAfee, an individual, is the co-founder  
10 and managing member of Organic Pastures. Mr. McAfee is the most  
11 responsible individual for the day-to-day operations of Organic  
12 Pastures. Specifically, he is responsible for, and has authority  
13 over, all of Organic Pastures' manufacturing and distribution  
14 operations. Mr. McAfee resides and conducts business in  
15 California, within the jurisdiction of this Court.

16 7. Defendants have been, and are now, engaged in milking  
17 cows and packaging, labeling, selling, and distributing in  
18 interstate commerce raw milk and raw milk products including, but  
19 not limited to, cream, butter, buttermilk and colostrum.

20 HEALTH RISKS ASSOCIATED WITH RAW MILK

21 8. Raw milk and raw milk products contain a wide variety  
22 of harmful bacteria including, but not limited to, listeria  
23 monocytogenes, e. coli, salmonella, campylobacter, and brucella,  
24 all of which may cause illness and possibly death.

25 9. The United States Food and Drug Administration ("FDA")  
26 and other federal and state health agencies have documented a  
27 long history of the risks to human health associated with the  
28 consumption of raw milk and raw milk products. Clinical and

1 epidemiological studies by FDA, state health agencies, and others  
2 have established a direct causal link between the consumption of  
3 raw milk and gastrointestinal disease. See also Public Citizen  
4 v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986) ("[i]t is  
5 undisputed that all types of raw milk are unsafe for human  
6 consumption and pose a significant health risk.").

7 10. Between 2000 and 2005, there were nineteen events of  
8 illness associated with raw milk and raw milk products that  
9 involved 473 persons, many of them children and pregnant women.  
10 These events resulted in seven deaths, including three infant  
11 mortalities.

12 11. FDA, the Centers for Disease Control, the National  
13 Association of State Departments of Agriculture, and others have  
14 expressly advised consumers about the dangers of drinking raw  
15 milk.

16 LEGAL STANDARDS

17 12. The PHSA, 42 U.S.C. § 264(a), authorizes the Secretary  
18 of the Department of Health and Human Services to make and  
19 enforce regulations to prevent the introduction, transmission, or  
20 spread of communicable diseases from one state to another.

21 13. Section 368(a) of the PHSA, 42 U.S.C. § 271(a), makes  
22 any violation of a regulation issued under 42 U.S.C. § 264 a  
23 crime.

24 14. Pursuant to the PHSA, FDA has promulgated the following  
25 ban against the interstate sale of raw milk and raw milk  
26 products: "No person shall cause to be delivered into interstate  
27 commerce or shall sell [or] otherwise distribute . . . any milk  
28 or milk product in final package form for direct human

1 consumption unless the product has been pasteurized or is made  
2 from dairy ingredients (milk and milk products) that have all  
3 been pasteurized . . ." 21 C.F.R. § 1240.61(a).

4 15. "Milk product" is defined as food "made exclusively or  
5 principally from the lacteal secretion obtained from one or more  
6 healthy milk-producing animals . . ." 21 C.F.R. § 1240.3(j).

7 16. The introduction and delivery for introduction into  
8 interstate commerce of misbranded foods violates section 331(a)  
9 of the Act. 21 U.S.C. § 331(a).

10 17. A food is deemed misbranded under the Act if its label  
11 is false or misleading in any particular. 21 U.S.C. § 343(a)(1).

12 18. Any product is a drug if it is "intended for use in the  
13 diagnosis, cure, mitigation, treatment, or prevention of  
14 disease." 21 U.S.C. § 321(g)(1)(B).

15 19. The intended use of a product may be determined from  
16 any relevant source. See 21 C.F.R. § 201.128.

17 20. The Act defines labeling as "all labels and other  
18 written, printed, or graphic matter (1) upon any article or any  
19 of its containers or wrappers, or (2) accompanying such article."  
20 21 U.S.C. § 321(m). The term "accompanying" in the second clause  
21 of § 321(m) is not restricted to labeling that is on or in the  
22 article at issue and that physical attachment is not necessary;  
23 rather, an article "accompanies" another when one supplements or  
24 explains the other such as a committee report of the Congress  
25 "accompanies" a bill.

26 21. Under the Act, a new drug is any drug "the composition  
27 of which is such that such drug is not generally recognized,  
28 among experts qualified by scientific training and experience to

1 evaluate the safety and effectiveness of drugs, as safe and  
2 effective for use under the conditions prescribed, recommended,  
3 or suggested in the labeling thereof . . . " 21 U.S.C.  
4 § 321(p) (1).

5 22. A new drug may not be introduced or delivered for  
6 introduction into interstate commerce unless FDA has approved a  
7 new drug application or an abbreviated new drug application with  
8 respect to the drug, or it qualifies for an exemption as an  
9 investigational new drug. 21 U.S.C. § 355.

10 23. The introduction and delivery for introduction into  
11 interstate commerce of an unapproved new drug violates section  
12 331(d) of the Act. 21 U.S.C. § 331(d).

13 FDA INSPECTIONS/EVIDENCE

14 2007 EVIDENCE REGARDING DEFENDANTS' SALE OF RAW MILK

15 24. In September 2007, Organic Pastures distributed  
16 numerous frozen samples of raw milk and raw milk products in  
17 interstate commerce. The labeling located on the **exterior** of the  
18 shipping container read as follows:

19 "In compliance with FDA regulations and CFR 1240.61,  
20 [Organic Pastures] does not take orders or ship any raw  
21 dairy products for 'human consumption' outside of the State  
22 of California. All out of state product sales are labeled  
23 and intended for: 'Pet Food' consumption only. The quality  
24 and safety of this 'pet food' product is identical to  
25 what is offered to consumers in the California retail  
26 market."

27 (hereafter, referred to as "Defendants' 'pet food'  
28 labeling").

29 Nowhere on the individual retail product is there a label  
30 indicating that the product is to be limited to pet consumption  
31 or identifying the product as pet food. The labels on the  
32 individual retail products bear statements such as "the best milk

1 you'll ever taste," and state that Organic Pastures products "are  
2 highly recommended by . . . thousands of happy healthy people."

3 25. The labels on the individual retail products  
4 distributed by Organic Pastures in September 2007 also contain  
5 the following statement:

6 "Raw (unpasteurized) milk and raw milk dairy products may  
7 contain disease-causing micro-organisms. Persons at  
8 highest risk of disease from these organisms include  
9 newborns and infants; the elderly; pregnant women; those  
10 taking corticosteroids, antibiotics or antacids; and  
11 those having chronic illnesses or other conditions that  
12 weaken their immunity."

13 This statement (hereafter, referred to as "Defendants'  
14 Statement") indicates that Defendants' raw milk and raw milk  
15 products are intended for human consumption.

16 26. During FDA's September 2007 inspection of Organic  
17 Pastures, Defendant McAfee confirmed that, with respect to  
18 Defendants' raw cream, stickers stating "Cat or Dog Food Only" or  
19 "Pet Food consumption only" are placed only on the exterior of  
20 shipping containers for products shipped out of state and not on  
21 the individual retail products.

22 27. In September 2007, an FDA investigator received an  
23 unsolicited email from Organic Pastures regarding raw milk that  
24 read, in part: "Dear raw milk customer; Absolutely! Raw milk can  
25 be shipped via UPS to all US states \*\*\* We would love you to try  
26 raw milk today! \*\*\* Raw milk is known for its ability to re-build  
27 your immune system \*\*\* Remember to tell everyone who has asthma  
28 that they will be cured by raw milk \*\*\*." Nowhere in this email  
does it state that raw milk is intended to be used as pet food.

29 28. In June 2007, Defendant McAfee sent an email to an FDA  
public affairs specialist in which he objected to an FDA

1 presentation regarding the health risks associated with raw milk.  
2 In the email, he states that "when raw milk is tested and labeled  
3 as intended for direct human consumption it is extremely safe,"  
4 and makes numerous statements reflecting his intention that raw  
5 milk be consumed by humans.

6 29. On March 17, 2008, FDA investigators confirmed that  
7 Defendants' website (www.organicpastures.com) (hereafter,  
8 "Defendants' website") provides the following statement to  
9 explain the 'pet food' labeling on some of its products:

10 "FDA law CFR 1240.61 states that it is illegal for anyone to  
11 transport raw dairy products across state lines 'in final  
12 package form for direct human consumption unless that  
13 product has been pasteurized.' In compliance with CFR  
14 1240.61, [Organic Pastures] labels and ships its products  
15 outside of California for 'pet consumption only.'"

16 Defendants have included a similar statement on their website's  
17 ordering page.

18 DEFENDANTS' DRUG CLAIMS

19 30. On March 17 and 25, 2008, FDA investigators confirmed  
20 that Defendants' website contains numerous claims that their raw  
21 milk and raw milk products can cure, mitigate, treat, or prevent  
22 various diseases including, but not limited to, cataracts, ear  
23 infections, sinus infections, arthritis pain, allergy, and  
24 asthma.

25 31. That same month, FDA investigators confirmed that  
26 Defendants' website contains numerous hyperlinks ("hotlinks") to  
27 other websites. Defendants direct customers to these other  
28 websites as follows:

"[Organic Pastures] may not make a medical claim or post  
cures for any disease process relative to any [Organic  
Pastures] product. That is a crime under current FDA law.  
We can recommend that you visit www.realmilk.com,  
www.westonaprice.org, or www.mercola.com, and other websites



1 that will list literally 50 different illnesses that are  
2 directly, naturally, and positively affected by consuming  
3 raw milk. Please see the testimonial past of this website  
for a list of links, testimonial stories of healing and  
recovery. They are dramatic and compelling."

4 32. With respect to at least one of the other websites  
5 referred to above, [www.localforage.com](http://www.localforage.com), customers can  
6 automatically be directed from Defendants' website to a website  
7 that contains numerous claims that raw milk and raw milk products  
8 can cure, mitigate, treat, or prevent various diseases including,  
9 but not limited to, asthma, eczema, psoriasis, constipation,  
10 Crohn's disease, arthritis, and hypertension. Defendants'  
11 products are specifically referred to throughout the  
12 [www.localforage.com](http://www.localforage.com) website.

13 33. As stated in paragraph 27 above, Defendants sent an  
14 unsolicited email to an FDA investigator in September 2007, in  
15 which Defendants claim that their raw milk cures asthma.

16 34. Defendants distribute promotional materials that  
17 contain claims that their raw milk and raw milk products can  
18 cure, mitigate, treat, or prevent various diseases.  
19 Specifically, Defendants' brochure titled "Organic Pastures Raw  
20 Dairy Products" contains various claims that Defendants' products  
21 can cure allergies and asthma.

22 PRIOR EVIDENCE

23 35. FDA's April 2004 inspection revealed that Defendants  
24 distributed raw milk and raw milk products in interstate commerce  
25 for human consumption.

26 36. Between March and November 2004, FDA collected thirteen  
27 raw milk and raw milk product samples from Organic Pastures after  
28 shipment in interstate commerce. None of the products (either on

1 the shipping cartons or the individual products) contained any  
2 statement that they were not for human consumption.

3 37. On March 8, 2005, an FDA investigator confirmed that  
4 Defendants' website contained the following statement in response  
5 to a question about the 'pet food' labeling on products sold  
6 outside of California:

7 "FDA law CFR 1240.61 states that it is illegal for anyone to  
8 transport raw dairy products across state lines 'in final  
9 package form for direct human consumption unless that  
10 product has been pasteurized.' [Organic Pastures] has  
11 creatively labeled its products for sale outside of  
12 California in such a way that it is not illegal under the  
13 law . . . This provides raw food drinkers the freedom to  
14 choose a raw product over a dead product. It is also great  
15 pet food." (emphasis added).

16 38. According to Defendants' "breaking news" page on its  
17 website, reviewed by an FDA investigator in July 2005, "There are  
18 absolutely no safety or quality differences between the Oregon  
19 products and the [Organic Pastures] products sold throughout  
20 California. There are also no requirements to include a  
21 statement which says, 'not for human consumption.'"

22 39. In July 2005, an undercover FDA investigator ordered  
23 numerous raw milk and raw milk products directly from Organic  
24 Pastures by telephone. An Organic Pastures sales representative  
25 completed this order after the FDA investigator informed her that  
26 the milk was intended for herself and her family. When asked  
27 about the 'pet food' labeling, the sales representative stated  
28 that the product was safe for humans and that this statement was  
a legal loophole for the firm to be able to ship the product out  
of state. These products, which were transported to the state of  
Washington, were shipped in a container to which Defendants' 'pet  
food' labeling was affixed. Like the samples collected in

1 September 2007, the individual retail products contained  
2 Defendants' Statement regarding human consumption and were not  
3 labeled for pet food use.

4 40. Also in July 2005, FDA collected samples of Defendants'  
5 raw milk and raw milk products from a retail market in Oregon.  
6 The labels of the individual retail products were identical to  
7 the labels on the products ordered by FDA directly from Organic  
8 Pastures that same month with the exception that a sticker was  
9 affixed to the individual labels that read, "Cat or Dog Food Only  
10 Outside of California."

11 41. Mark McAfee is quoted in the July 8, 2005, issue of the  
12 Portland Tribune as follows: "The neat thing about the law is  
13 that it can be interpreted in many ways. The state of Oregon  
14 understood that there was a loophole by putting a pet sticker on  
15 the product. And there is no regulation that you can't eat pet  
16 food either. I am a revolutionist in this, and I won't overlook  
17 any loophole that will get the milk out there."

18 42. Defendants also distributed numerous samples of raw  
19 milk and raw milk products in interstate commerce in February  
20 2006. Like the products distributed in September 2007, these  
21 products were shipped in containers that contained Defendants'  
22 'pet food' labeling. The individual retail products were not  
23 labeled as limited to pet food use. The individual retail  
24 products contained the "best milk you'll ever taste" statement,  
25 the recommendation of "thousands of happy healthy people," and  
26 Defendants' Statement regarding human consumption.

27 RECALLS

28 43. Over the past two years, Organic Pastures has issued

1 three recalls associated with pathogenic bacteria in its raw milk  
2 and/or raw milk products. On September 21, 2006, the California  
3 Department of Food and Agriculture ("CDFA") ordered Organic  
4 Pastures to recall all of its products (except aged cheese) from  
5 the retail market and placed a quarantine hold on Defendants' raw  
6 milk production after the state epidemiologically linked the  
7 firm's raw milk and raw milk products to four cases of e.coli  
8 bacterial illness. The state lifted the quarantine hold the  
9 following week.

10 44. In September 2007, CDFA ordered Organic Pastures to  
11 withdraw certain lots of its raw cream from the retail market due  
12 to detection of Listeria monocytogenes bacteria.

13 45. On September 11, 2008, CDFA ordered Organic Pastures to  
14 recall one lot of its raw cream from the retail market and placed  
15 a quarantine hold on the product due to detection of  
16 campylobacter bacteria.

17 DEFENDANTS' VIOLATIONS

18 46. Defendants sell raw milk and raw milk products.  
19 Defendants promote their products as "unpasteurized" or "raw,"  
20 and FDA's independent analysis has confirmed that Defendants'  
21 products are raw.

22 47. Defendants distribute raw milk and raw milk products in  
23 interstate commerce. FDA has solicited numerous interstate sales  
24 of Defendants' raw milk and raw milk products. Defendants'  
25 September 5, 2007, unsolicited email sent to the agency and  
26 Defendants' website specifically state that they ship to all  
27 states.

28 48. Defendants sell raw milk and raw milk products in

1 "final package form." Defendants' products are sold directly to  
2 consumers rather than to dairy processing plants for  
3 pasteurization. Consumers are not required to take any  
4 additional steps (other than thawing) in order to consume  
5 Defendants' products. Defendants' website contains directions  
6 for consumers to thaw their products and states that freezing  
7 "has little effect on the important health benefits that raw  
8 dairy products provide."

9 49. Defendants sell raw milk and raw milk products for  
10 "direct human consumption." Despite the inclusion of Defendants'  
11 'pet food' labeling on products sold outside of California, the  
12 evidence establishes that Defendants intend their products to be  
13 consumed by humans.

14 50. Accordingly, Defendants' sale and distribution into  
15 interstate commerce of raw milk and raw milk products in final  
16 package form for human consumption violates the PHSA, 42 U.S.C.  
17 § 264(a), and the implementing regulation codified at 21 C.F.R.  
18 § 1240.61(a).

19 51. Defendants' milk and milk products are food, as defined  
20 by the Act, 21 U.S.C. § 321(f), which is sold in interstate  
21 commerce.

22 52. The evidence establishes that Defendants' 'pet food'  
23 labeling is false and misleading.

24 53. Accordingly, Defendants' food is misbranded under  
25 21 U.S.C. § 343(a)(1), and Defendants' distribution of these  
26 products in interstate commerce violates 21 U.S.C. § 331(a).

27 54. Defendants have been and are now engaged in making  
28 claims that their raw milk and raw milk products can cure,

1 mitigate, treat, or prevent various diseases including, but not  
2 limited to, asthma, allergies, eczema, sinus/ear infections,  
3 arthritis, and hypertension. The claims on Defendants' website,  
4 at least one other website to which Defendants' website has a  
5 "hotlink," as well as Defendants' brochure and other promotional  
6 materials cause Defendants' products to be drugs within the  
7 meaning of the Act, 21 U.S.C. § 321(g) (1) (B).

8 55. Defendants' products are new drugs within the meaning  
9 of 21 U.S.C. § 321(p) (1), because they are not generally  
10 recognized, among experts qualified by scientific training and  
11 experience to evaluate the safety and effectiveness of drugs, as  
12 safe and effective for use under the conditions prescribed,  
13 recommended, or suggested in their labeling.

14 56. There is not now, nor has there ever been, an approved  
15 new drug application or an abbreviated new drug application on  
16 file with the FDA for any of Defendants' products, nor do  
17 Defendants' products qualify for an exemption as investigational  
18 new drugs. Accordingly, Defendants' products are unapproved new  
19 drugs, within the meaning of 21 U.S.C. § 355.

20 HISTORY OF FDA WARNING TO ORGANIC PASTURES

21 57. FDA issued a Warning Letter to Defendant McAfee, on  
22 behalf of Organic Pastures, on February 24, 2005, advising him  
23 that the firm's distribution of raw milk and raw milk products in  
24 interstate commerce in finished form for human consumption  
25 violates the PHSa, 42 U.S.C. §§ 264(a) and 271(a), and the  
26 implementing regulation, 21 C.F.R. § 1240.61(a). The letter  
27 further stated that failure to make corrections could lead to  
28 regulatory action, including seizure, injunction, and/or

1 prosecution.

2 58. Despite FDA's warning, the most recent evidence  
3 confirms that Defendants continue to distribute raw milk and raw  
4 milk products in final form for human consumption in violation of  
5 the PHSA and the Act. Based on Defendants' most recent course of  
6 conduct, it is evident that, unless restrained by order of this  
7 Court, Defendants will continue to distribute raw milk and raw  
8 milk products in violation of the PHSA, 21 U.S.C. §§ 264(a) and  
9 271(a), and the implementing regulation, 21 C.F.R. § 1240.61(a),  
10 distribute misbranded foods in violation of the Act, 21 U.S.C.  
11 § 331(a), and distribute unapproved new drugs in violation of the  
12 Act, 21 U.S.C. § 331(d).

13 WHEREFORE THE PLAINTIFF PRAYS:

14 I. That Defendants, and each and all of their directors,  
15 officers, agents, representatives, employees, attorneys,  
16 successors, assigns, and any and all persons in active concert or  
17 participation with any of them, be permanently restrained and  
18 enjoined from directly and indirectly violating the PHSA,  
19 42 U.S.C. § 264(a), by contributing to the introduction,  
20 transmission, or spread of communicable diseases between the  
21 states or into the United States. The Defendants past conduct  
22 makes clear any lesser remedy would not stop the violations set  
23 forth herein. Specifically, Defendants should be enjoined from  
24 directly and indirectly introducing and delivering for  
25 introduction, and causing to be introduced and delivered for  
26 introduction, into interstate commerce, raw (unpasteurized) milk  
27 and raw (unpasteurized) milk products in any form (e.g. frozen,  
28 partially-frozen, liquid, dry, powdered), including, but not

1 limited to, products labeled for human consumption or pet food  
2 and products with labeling that makes them drugs within the  
3 meaning of the Act; and

4 II. That Plaintiff be granted judgment for its costs  
5 herein, and that this Court grant such other and further relief  
6 as it deems just and proper.

7 DATED this 20<sup>th</sup> day of November, 2008.

8 Respectfully submitted,  
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