IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
Plaintiff	:	**CIVIL ACTION**
	:	
v.	:	
	:	
DANIEL L. ALLGYER.	:	**No. 11-02651**
Defendant	:	

M E M O R A N D U M

Stengel, J. **February 2, 2012**

The United States brought this action on behalf of the Food and Drug Administration ("FDA") under the Public Health Services Act ("PHSA"), 42 U.S.C. §§ 264[1] and 271,[2] and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a),[3] 343(e)(1) and (i)(1),[4] against Mr. Daniel Allgyer, an individual doing business as

[1] The relevant language of § 264 states:

> (a) Promulgation and enforcement by Surgeon General. The Surgeon General, with the approval of the Administrator [Secretary], is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

[2] § 271 of the PHSA concerns appropriate penalties for any violation of the quarantine laws.

[3] § 331 state that "[t]he following acts and the causing thereof are hereby prohibited: (a) [t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

[4] 21 U.S.C. § 343(e)(1) and (i)(1) states that:

> (e) … If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count ….
>
> (i) … Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such

Rainbow Acres Farm for the sale and distribution of unpasteurized (or "raw") milk. On December 6, 2011, the government filed this motion for summary judgment. For the reasons stated below, I will grant the motion.

I. Background[5]

On April 19, 2011, the United States filed its Complaint alleging that Mr. Allgyer is the owner and operator of a dairy farm located in Kinzers, Pennsylvania known as Rainbow Acres Farm. Government's Statement of Undisputed Facts at ¶ 3 ("Doc. #22-2") citing Declaration of Kirk D. Sooter, District Director, Philadelphia District Office, FDA ("Sooter Decl.") ¶¶ 5, 15; Exhibit F; Answer to Complaint for Permanent Injunction ("Answer"). As the owner, Mr. Allgyer has authority over all of the manufacturing and distributing done by Rainbow Acres Farm and has engaged in, and continues to engage in, the milking, packaging, labeling, selling, and distributing of unpasteurized cow milk

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> ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 721(c) [21 USCS § 379e(c)][,] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary

[5] I have viewed the facts in the light most favorable to the defendant, as the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). However, defendant's Answer fails to specifically deny the allegations of the Complaint for Permanent Injunction. Because the defendant is unrepresented by counsel, I will not view all allegations in the Complaint as deemed admitted pursuant to Fed. R. Civ. P. 8. However, defendant's Answer and Motion in Opposition to the Government's Motion for Summary Judgment corroborate many of the statements of fact enumerated in the Government's Statement of Undisputed Facts. Where the facts are not disputed or are clearly supported by the record, I cite the paragraphs from the plaintiff's Statement of Undisputed Material Facts after my careful examination of the record.

in interstate commerce for human consumption in violation of the PHSA and FDCA. Id. citing Sooter Decl. ¶¶ 4, 6, 11-12, 15-17, 20, 23-24; Exhibit E[6]; Answer ¶ 3.

From 2009 through 2011, the FDA conducted a two-year undercover investigation into Mr. Allgyer's operations. Id. The bulk of this investigation consisted of placing orders for Rainbow Acres' raw milk online through a *Yahoo!* group named "grassfedonthehill." Doc. #22-2 at ¶ 4 citing Sooter Decl. ¶ 11; Exhibit E. Buyers were required to join grassfedonthehill to purchase products from defendant. Id. citing Sooter Decl. ¶¶ 6-7; Exhibit A. The grassfedonthehill website describes grassfedonthehill as a "group . . . created to support and organize the delivery of grass fed (no antibiotics or hormones) Raw Dairy and Meat to the Greater Washington, DC area." Doc. #22-2 at ¶ 4 citing Sooter Decl. ¶¶ 6-7; Exhibit A. The website also listed delivery locations in Maryland and the greater D.C. area, and warned members to "not share information" about the group with government agencies or doctors. Id. The website identified Mr. Allgyer as grassfedonthehill's farmer. Customers must sign agreements to join the Communities Alliance for Responsible Eco-farming ("CARE") group "in order to protect [the] farm … from the ongoing harassment" by the Pennsylvania Department of Agriculture.[7] Id.

[6] Exhibit E consists of computer printouts of receipts for the FDA's raw milk purchase. The copies illustrate that payment is to be made to Dan Allgyer and sent to Rainbow Acres. The order confirmations span the time frame during which the FDA conducted its investigation.

[7] The agreement describes the CARE group as a private contractual buying group or alliance. In the contract, the customers acknowledge the dangers of raw milk and agree to waive the protection offered by government regulations. The CARE Contract further provides that the parties "retain[] the right to enter into a cow share, lease or other agreement" with defendant. Doc. #22 at 4 citing Sooter Decl. ¶ 8; Exhibit B; Exhibit C.

Mr. Allgyer states that he is the not owner or in control of the organization grassfedonthehill. Defendant's Response to the Motion for Summary Judgment at 1 ("Response"). However, Rainbow Acres Farm sold its raw milk online through that organization for $6 per gallon and $3.25 per half-gallon. Doc. #22-2 at ¶ 5 citing Sooter Decl. ¶¶ 6-7; Exhibit A; see also Answer at ¶ 3. Mr. Allgyer also states that he is not the owner or in control of the CARE organization. Response at 1. But Mr. Allgyer signed the CARE Membership Agreement, Sooter Decl. ¶ 8; Exhibit B; Exhibit C, as well as the CARE Membership Contract, Sooter Decl. ¶ 9; Exhibit D, which provide that Mr. Allgyer will enter into a cow share or lease agreement. Farmer Member and Community Member Private Contract at ¶ 5 ("CARE Contract").

Following the purchasing and pick-up instructions on the Rainbow Acres Farm website, the FDA purchased and paid for 23 gallon and half-gallon containers of raw milk, which were tested at an independent laboratory and confirmed to be unpasteurized.[8] Doc. # 22-2 at ¶¶ 4-5 citing Sooter Decl. ¶¶ 11-12; Exhibit E. After securing a warrant, the FDA inspected Rainbow Acres Farm and collected evidence that Mr. Allgyer was engaged in milking cows and packaging the unpasteurized milk in unlabeled containers for delivery out of state.[9] Id. citing Sooter Decl. ¶¶ 14-16; Exhibit F.[10] Following the inspection, the FDA sent Mr. Allgyer a warning letter dated April 20, 2010, which

[8] The containers of raw milk delivered to the "drop site" in Maryland were unlabeled. (Doc. #22 at 4-5).

[9] FDA investigators photographed 17 coolers, labeled with names of locations in Maryland, lined up on defendant's driveway containing milk in unlabeled gallon and half-gallon containers.

[10] Exhibit F contains a number of photographs depicting coolers filled with unlabeled gallon and half gallon milk containers with names like "Bowie" and "Highland" to designate specific drop offs.

informed Mr. Allgyer of his various violations enforced by federal law and the possible legal repercussions for failing to adhere to those laws. Doc. #22-2 at ¶ 14; see also Answer at ¶ 2; Response at 5-6.

After receiving the warning letter, Mr. Allgyer posted on the Farm's website stating that the government was trying to "shut [him] down," but that he was going to continue selling raw milk by "leasing" his cows through a private organization.[11] Doc. #22-2 at ¶¶ 16-17 citing Sooter Decl. ¶ 20; Exhibit H. On May 6, 2010, grassfedonthehill emailed its members a message stating that, with the change over to the Rawsome Club, Mr. Allgyer was making deliveries on Monday and Thursday by 4:00 p.m. Doc. #22-2 at ¶ 18 citing Sooter Decl. ¶ 22; Exhibit J.

On September 28, 2011, FDA investigators accessed the Rainbow Acres Farm website and found that Mr. Allgyer continues to offer unpasteurized milk for direct human consumption to out-of-state consumers under the name "Rainbow Valley Farms."[12] Doc. #22-2 at ¶ 20 citing Sooter Decl. ¶ 24; Exhibit K.

Regulation of Raw Milk

From 1974 to 1982, the FDA collected and evaluated scientific and medical information and data to determine if the outbreak of certain diseases was associated with the consumption of raw milk. The FDA worked closely with the Centers for Disease

[11] The organization required a $25.00 membership fee and was called "The Right to Choose Healthy Food's Rawsome Club" ("Rawsome Club"). Mr. Allgyer states that he does not own or have any control over this organization. Response at 1.

[12] There is some argument as to the correct name of Mr. Allgyer's operations as of today. Mr. Allgyer contends the government's position that Rainbow Acres Farm became Rainbow Valley Farm is incorrect. Mr. Allgyer argues that "Rainbow Valley" does exist and is a "1st and 14th private membership association" that does not deal with the public.

Control and Prevention ("CDC"), a branch of Health and Human Services ("HHS"), and encouraged the states to test milk and milk products for bacteria or microorganisms and to report outbreaks of milk-borne disease to the CDC. See Public Citizen v. Heckler, 653 F. Supp. 1229, 1232 (D.D.C. 1986); Oyarzo v. Md. Dep't of Health & Mental Hygiene, 187 Md. App. 264, 278 (Md. Ct. Spec. App. 2009); Consumers Union v. Alta-Dena Certified Dairy, 4 Cal. App. 4th 963, 6 Cal. Rptr. 2d 193 (1st App. Dist. 1992).

On August 10, 1987, the FDA's final rule on the debate over the regulation of raw milk became effective, codified at 21 C.F.R. § 1240.6. The Rule provides:

> No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized.

21 C.F.R. § 1240.61(a). However, the regulation of intrastate sale of raw milk is a matter of state law and Pennsylvania permits such sales.[13]

After the 1987 debates, the FDA ultimately concluded that the consumption of unpasteurized milk and unpasteurized milk products was linked to the outbreak of serious disease. See 52 Fed. Reg. 29509, 29510-12; Public Citizen v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986) ("It is undisputed that all types of raw milk are unsafe for human consumption and pose a significant health risk. . . . There is no longer any question of fact as to whether the consumption of raw milk is unsafe.").

[13] The government does not seek to enjoin defendant's sale of these products to consumers in Pennsylvania.

The United States seeks a permanent injunction preventing Mr. Allgyer from selling raw milk and milk products in interstate commerce and from introducing into interstate commerce food that is misbranded pursuant to the FDCA. For the reasons stated below, I will grant the government's motion for summary judgment.

II. Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" when "a reasonable jury could return a verdict for the nonmoving party" based on the evidence in the record. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is "material" when it "might affect the outcome of the suit under the governing law." Id.

A party seeking summary judgment initially bears responsibility for informing the court of the basis for its motion and identifying those portions of the record that "it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial Celotex burden can be met simply by demonstrating to the district court that "there is an absence of evidence to support the non-moving party's case." Celotex, 477 U.S. at 325. After the moving party has met its initial burden, the adverse party's response "must--by affidavits or as otherwise provided in this rule--set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2). Summary judgment is therefore appropriate when the non-moving party fails to rebut by making a factual showing that is "sufficient to establish the

existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

Under Rule 56 of the Federal Rules of Civil Procedure, the court must draw "all justifiable inferences" in favor of the non-moving party. Anderson, 477 U.S. at 255. The court must decide "not whether . . . the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." Id. at 252. If the non-moving party has produced more than a "mere scintilla of evidence" demonstrating a genuine issue of material fact, then the court may not credit the moving party's "version of events against the opponent, even if the quantity of the [moving party's] evidence far outweighs that of its opponent." Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

III. Discussion

The main issue in this case is whether Daniel Allgyer is in violation of federal law. According to the United States, defendant's history of distributing raw milk and raw milk products across state lines, or in interstate commerce,[14] establishes that defendant

[14] A provision of the FDCA, 21 U.S.C. § 321(b), defines "interstate commerce" to mean "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body." Courts have interpreted the purpose behind the FDCA's interstate commerce regulation to be to "safeguard the consumer from the time the food is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer." United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 92 (1964).

Thus, the purchase of raw milk by one who traveled between states to obtain it, or traveled between states before consuming it or sharing it with friends or family members, implicates "commerce between any State . . . and any place outside thereof," see 21 U.S.C. § 321(b), "introduction of [raw milk] into the channels of interstate commerce" before delivery to an ultimate consumer, see Wiesenfeld Warehouse Co., 376 U.S. at 92, and "the interstate flow of goods" prior to delivery to an ultimate consumer, see United States v. Sullivan, 332 U.S. 689, 696 (1948). Such conduct plausibly involves "causing [raw milk] to be delivered into interstate commerce." 21 C.F.R. § 1240.61.

violated 21 U.S.C. § 331(a) and 42 U.S.C. § 264. The United States also contends that the defendant's mislabeling of the gallon jugs violates 21 U.S.C. § 343(e)(1) and (i)(1).

Section 332(a) of Title 21 of the United States Code empowers district courts to enjoin violations of § 331. 21 U.S.C. § 332(a). To be entitled to an injunction the government must establish that the defendant violated § 331(a) of the FDCA and that there is a cognizable danger of recurrent violations. See United States v. Lane Labs-USA, Inc., 324 F. Supp. 2d 547, 573 (D.N.J. 2004); United States v. Odessa Union Warehouse Co-op, 833 F.2d 172, 176 (9th Cir. 1987); United States v. Diapulse Corp. of Am., 457 F.2d 25, 28 (2d Cir. 1972) ("The passage of the [Food, Drug, and Cosmetic Act] is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained.").

In his response, Mr. Allgyer claims that summary judgment should not be granted for five reasons. Primarily, Mr. Allgyer contends that his involvement in a private membership cow sharing organization precludes FDA involvement.[15] Mr. Allgyer also argues that this action is not a civil action, but instead is a quasi-criminal action due to the sanctions that could be imposed and, therefore, requires probable cause and an official complaint. Response at 3. He contends that the FDA illegally sent him warning letters[16]

[15] The contract between Mr. Allgyer and persons entering into a cow share agreement is merely a subterfuge to create a transaction disguised as a sale of raw milk to consumers. The practical result of the arrangement is that consumers pay money to Mr. Allgyer and receive raw milk, which is transported across state lines and left at a "drop point." As such, despite any artful language, the agreement involves the transfer of raw milk for consideration, which constitutes a sale and is lawfully regulated by the FDA.

[16] The FDA frequently sends warning letters as a way to "communicate[] the agency's position on a matter, but it does not commit FDA to taking enforcement action." FDA, REGULATORY PROCEDURES MANUAL § 4-1-1 (Mar. 2010). Moreover, the FDA policy is clear: Warning Letters are informal, advisory, and not intended to serve as final agency action. Id. ("Warning Letter is informal and advisory. . . . FDA does not consider Warning Letters to be final agency action on which it can be sued.").

and failed to answer the mandatory Privacy Act Questions required by the Privacy Act of 1974.[17] Id. at 2. Finally, Mr. Allgyer states that summary judgment cannot be granted because he has not received the agents "Oaths of Office." Id.

Mr. Allgyer has failed to meet his Celotex burden of making a factual showing that there is a genuine issue for trial. Celotex, 477 U.S. at 322. He has provided no record evidence, and he raises no disputed issues of material fact. Here, the evidence shows that Mr. Allgyer violated the FDCA by distributing misbranded raw milk. As of September 28, 2011, the investigators from the FDA found that Mr. Allgyer continued to sell raw milk across state lines. Mr. Allgyer's answer to the Complaint and his response to the motion for summary judgment corroborate these allegations. Therefore, the government has established that defendant violated §§ 331(a) and 343(e)(1) and (i)(1) of the FDCA.

In FDCA cases, injunctive relief must be used sparingly, to prevent future harm, and not to punish past violations. See SEC v. Bonastia, 614 F.2d 908, 912 (3d Cir. 1980); United States v. Barr Laboratories, Inc., 812 F. Supp. 458, 487-88 (D.N.J. 1993). A court should review the totality of the circumstances surrounding both the statutory violation and the violators in order to determine whether the government can show the

[17] Mr. Allgyer argues that the FDA did not comply with the Privacy Act of 1974 when it investigated and inspected Rainbow Acre Farms' practice of selling raw milk. I disagree. The Privacy Act simply does not apply under these circumstances. The purpose of Privacy Act (5 USCS § 552a) is to protect privacy of individuals identified in computerized information systems maintained by federal agencies by enabling individuals to obtain their personal records and permitting the agency to retain information relevant to a specific and legal purpose. Pub.L. 93-597, 88 Stat.1896, codified at 5 U.S.C. § 552a (Supp. V 1975). The Senate Report to the Privacy Act states that the Act is intended to "distinguish between the rights which are given to the citizen as an individual under this Act and the rights of proprietorships, businesses and corporations which are not intended to be covered by this Act. This distinction was to insure that the bill leaves untouched the Federal Government's information activities for such purposes as economic regulations." S.Rep. No. 1183, 93d Cong., 2d Sess. 79 (1974).

need for a permanent injunction.[18] States v. Toys "R" Us, Inc., 754 F. Supp. 1050, 1059 (D.N.J. 1991). The probability of future violations may be inferred from past unlawful conduct. Lane Labs-USA, Inc., 324 F. Supp. 2d at 573; Odessa Union, 833 F.2d at 176; United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 50 (E.D.N.Y. 2001). Defendant's violative conduct has continued despite notices from the FDA and this action. Moreover, the defendant maintains the attitude that his participation in private membership associations, which sell raw milk in interstate commerce, cannot be regulated by the FDA, and he fails to recognize the wrongfulness of his conduct. Because of Mr. Allgyer's history, I find that he is likely to continue to violate the FDCA and injunctive relief is warranted.

However, I find the government's proposed injunction to be overly burdensome on the defendant.[19] A district court has considerable discretion in granting injunctive relief

[18] Factors to consider when determining whether there is a reasonable chance of future infractions by a defendant include:

> (1) the degree of scienter involved on the part of the defendant; (2) the isolated or recurrent nature of the infraction; (3) the defendant's recognition of the wrongful nature of his conduct; (4) the sincerity of defendant's assurances against future violations; and (5) the nature of defendant's occupation. It is deemed important to consider as well the defendant's voluntary cessation of challenged practice, the genuineness of the defendant's efforts to conform to the law, the defendant's progress toward improvement and the defendant's compliance with any recommendations made by the government.

Barr Labs, 812 F. Supp. at 486 (citing Toys "R" Us, 754 F. Supp. at 1058-59).

[19] Specifically, paragraphs 9 and 10 of the government's proposed injunction state:

> 9. Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect defendant's facilities and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted prompt access to buildings, equipment, raw materials, in-process and finished articles, containers, labeling, promotional materials, and other documents and things therein; to take photographs and make video recordings; to take samples of defendant's raw materials, in-process and finished articles, containers, labeling, and packaging material; and to examine and copy all records related to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all of defendant's products. The inspections shall be permitted upon presentation of a copy of this Order

and in tailoring injunctive relief, but the relief must not be overly broad in light of the conduct of the enjoined party. See generally Lane Labs-USA, Inc., 324 F. Supp. 2d at 571 (stating that the court retains discretion to grant or deny equitable relief and it must determine whether the injunctive relief requested is needed to remedy the threatened violations); Odessa Union, 833 F.2d at 177 (same). The terms of the permanent injunction must comport with principles of equity and be "in harmony with the overall objectives of the legislation [the FDCA]." Commodity Futures Trading Comm'n v. Hunt, 591 F.2d 1211, 1219 (7th Cir. 1979).

In United States v. Organic Pastures Dairy Co., 708 F. Supp. 2d 1005, 1016 (E.D. Cal. 2010), the defendants mislabeled, misbranded, and shipped raw milk and raw milk products across state lines in violation of the FDCA. The court compared the defendants' actions to food contamination cases and stated that "[o]n these facts, the suggestion that government should have the access and control normally associated with contamination/adulteration cases is unpersuasive ….This is not a 21 U.S.C. § 342 case."

Like Organic Pastures Dairy Co., I find that the proposed injunction submitted by the government in this case is overly broad. This is not a 21 U.S.C. § 342 case, and the

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and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to conduct inspections under the FDCA, 21 U.S.C. § 374.

10. Defendant shall pay all costs of FDA's inspections, investigations, supervision, review, examinations, analyses, and other work that FDA deems necessary to evaluate defendant's compliance with this Order at the standard rates prevailing at the time that the costs are incurred. As of the date of this Order, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour and fraction thereof per representative for analytical or review work; $0.51 per mile for travel by automobile; the government rate or equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

difference in the harm threatened suggests that government should not have the access and control associated with § 342 cases. See Organic Pastures Dairy Co., 708 F. Supp. 2d at 1016. Further, Mr. Allgyer is not prohibited, under state law, from selling raw milk in Pennsylvania, and his operations are permitted to continue in that vein. Therefore, I do not find that all of the provisions in the government's proposed injunctive relief are needed to remedy the threatened violations.

IV. Conclusion

Defendant has failed to meet his burden in opposing summary judgment. The government has demonstrated that defendant violated the PHSA and FDCA and has established a likelihood of additional FDCA violations. Therefore, the government's motion for summary judgment is GRANTED and defendant shall be permanently enjoined from such distribution.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff	: :	CIVIL ACTION
v.	:	
DANIEL L. ALLGYER. Defendant	: :	No. 11-02651

ORDER OF PERMANENT INJUNCTION

AND NOW, this 2nd day of February, 2012, upon consideration of Plaintiff's Motion for Summary Judgment (Doc. # 22) and Defendant's response thereto (Doc. # 24), it is hereby ordered that Plaintiff's motion is GRANTED.

It is FURTHER ORDERED that:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendant under the PHSA, 42 U.S.C. §§ 201 et seq., and the FDCA, 21 U.S.C. §§ 301-399a.

3. Defendant violates the PHSA, 42 U.S.C. § 264(a), and its implementing regulation, 21 C.F.R. § 1240.61(a), by engaging in conduct that endangers the public health and safety by distributing in interstate commerce unpasteurized milk ("raw milk") and milk products in final package form for direct human consumption.

4. Defendant violates the FDCA, 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into

interstate commerce, misbranded food within the meaning of 21 U.S.C. § 343(e)(1) and (i)(1), respectively, in that the unlabeled containers in which Defendant's unpasteurized milk is delivered lack Defendant's name and place of business and the common or usual name of the product.

5. Upon entry of this Order, Defendant, any company or assumed name through which Defendant operates, and each and all his directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive notice of this Order are permanently restrained and enjoined from directly and/or indirectly doing or causing to be done any act that:

a. Violates 42 U.S.C. § 264(a), by distributing in interstate commerce unpasteurized milk and unpasteurized milk products in final package form for human consumption in violation of 21 C.F.R. § 1240.61; and

b. Violates 21 U.S.C. § 331(a), by introducing and delivering for introduction in interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(e)(1) or (i)(1).

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.

6. Upon entry of this Order, Defendant shall continuously display the statement:

> Daniel L. Allgyer and Rainbow Acres Farm [and/or any other entity or name by or through which Daniel L. Allgyer operates] will no longer introduce or deliver for introduction, or cause to be introduced and

> delivered for introduction, into interstate commerce, any unpasteurized milk or unpasteurized milk products. Selling or distributing Rainbow Acres Farm's unpasteurized milk and unpasteurized milk products outside the state of Pennsylvania is prohibited by federal law.

on:

a. All product labels, labeling, brochures, and other promotional materials, retail invoices, and packing slips for Defendant's unpasteurized milk and unpasteurized milk products; and

b. All websites that Defendant owns, controls, or uses, directly or indirectly, to promote or make available for purchase his unpasteurized milk and unpasteurized milk products. For each website, the statement shall be posted on the website's home page and on all web pages that make Defendant's unpasteurized milk or unpasteurized milk products available for purchase (e.g., by email, online, or telephone).

7. Defendant shall maintain complete records of the sale and distribution of all his unpasteurized milk and unpasteurized milk products that shall include, but not be limited to, the name and address of persons and entities to whom products are sold or distributed, the date of sale or distribution, the product type, and the amount or quantity. Defendant shall also maintain at least one copy of the following documentation with respect to his unpasteurized milk and unpasteurized milk products:

a. All label(s) affixed to the products;

b. All labeling affixed to shipping containers; and

c. All labeling, brochures, website pages, and other materials used to promote, describe, or refer to the products.

Upon request, FDA shall have immediate access to all of the records described in this paragraph.

8. This order does not in any way limit the FDA's ability under generally applicable federal laws and regulations to regulate, monitor, inspect, and supervise Defendant or any business operated, directly or indirectly, by Defendant. This order also does not in any way relieve Defendant of his obligations to comply with generally applicable federal laws and regulations.

9. If at any time after entry of this Order, FDA determines, based on the results of any inspection, analysis, or any other information, that Defendant is not in compliance with this Order, FDA may, as and when it deems necessary, inform Defendant, in writing, of his noncompliance and require Defendant to take immediate action, including but not limited to one or more of the following actions:

a. Cease manufacturing, processing, packing, labeling, holding, and/or distributing in interstate commerce unpasteurized milk and unpasteurized milk products intended for human consumption;

b. Submit additional reports or information to FDA;

c. Submit samples of Defendant's products for analytical testing; and/or

d. Recall at Defendant's expense any unpasteurized milk and unpasteurized milk products intended for human consumption delivered into interstate commerce.

Upon receipt of such written directive, Defendant shall immediately and fully comply with its terms. Any cessation of operations ordered by FDA as described above shall continue until:

I. Defendant receives written notification from FDA that Defendant appears to be in compliance with the terms of the written directive, the PHSA, the FDCA, and applicable regulations, and may resume operations; or

II. The written directive to cease operations has been modified or reversed by this Court.

10. Defendant shall provide notice of this Order in the following manner:

a. Within ten (10) calendar days after entry of this Order, Defendant shall: (1) provide a copy of the Order, by personal service or by certified mail, return receipt requested, to each and all of Defendant's representatives, officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them; and (2) explain the terms of the Order to each employee.

b. Within 20 calendar days after entry of this Order, Defendant shall provide to FDA an affidavit from a person with personal knowledge of the facts therein, stating the fact and manner of Defendant's compliance with and identifying the names and positions of all persons who were notified pursuant to paragraph 12(a).

c. After entry of this Order, Defendant shall, within 5 calendar days after hiring any new employee:

I. Provide a copy of the Order, by personal service or by certified mail, return receipt requested, to such employee; and

II. Explain the terms of the Order to the employee.

11. Defendant shall notify FDA, in writing, at least thirty (30) calendar days before any change in ownership, name, or character of its business that occurs after the entry of

this Order, such as reorganization, relocation, assignment, or sale of the business that may affect compliance with this Order. Defendant shall provide a copy of this Order to any prospective successor or assignee at least thirty (30) calendar days prior to any sale or change of business, and shall furnish to FDA an affidavit of compliance with this paragraph within fifteen (15) calendar days prior to such sale or change of business.

12. If Defendant violates this Order and is found in civil or criminal contempt thereof, Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigational and analytical expenses, and any other costs or fees relating to the contempt proceedings.

13. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

14. No sooner than sixty (60) months after entry of this Order, Defendant may petition this Court to dissolve this Order. If Defendant has maintained, to FDA's satisfaction, a state of continuance compliance with this Order, the FDCA, the PHSA, and all applicable regulations during the sixty (60) months preceding Defendant's petition, the United States will not oppose such petition.

15. All notifications, correspondence, and communications to FDA required by this Order shall be submitted to the Director, Philadelphia District Office, U.S. Food and Drug Administration, U.S. Custom House - 200 Chestnut Street, Philadelphia, Pennsylvania 19106.

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

BY THE COURT:

/s/LAWRENCE F. STENGEL
LAWRENCE F. STENGEL, J.