IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	No. C 10-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

DEFENDANTS' APPENDIX IN RESISTANCE TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Exhibit A

BEFORE THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

Farm-to-Consumer Legal Defense Fund, et al.	:	**Case No. 5:10-cv-04018**
Plaintiffs	:	**Judge Mark W. Bennett**
v.	:	
Kathleen Sebelius, et al.	:	
Defendants	:	

PLAINTIFFS' FIRST AMENDED COMPLAINT FOR DECLARATORY, PRELIMINARY AND OTHER INJUNCTIVE RELIEF

Pursuant to Fed. Rule Civ. P. 57 and 65(a), Plaintiffs hereby file their Complaint seeking declaratory, preliminary and other injunctive relief. Plaintiffs allege as follows:

GENERAL ALLEGATIONS

Nature of the Action

1. This is an action brought by Plaintiffs Farm-to-Consumer Legal Defense Fund (the "Fund" or "FTCLDF") and several of its members under, in part, the Constitutional Right to Travel; the Constitutional Right of Privacy; the substantive due process clause of the Fifth Amendment of the United States Constitution; Article 1, Section 1 of the United States Constitution (the Separation of Powers/Non-delegation doctrine); and the Administrative Procedure Act ("APA"), 5 U.S.C. 701, *et seq.*

2. Plaintiffs seek to enjoin the enforcement of 21 CFR 1240.61 (hereinafter "1240.61") and 21 CFR 131.110 (hereinafter "131.110") against them by the Food and Drug Administration ("FDA") and also seek a declaration that 1240.61 and 131.110 are

unconstitutional as applied against them. The legislative authority for and the specific language of these agency regulations are addressed below in Count One of this complaint.

3. A preliminary injunction is necessary at the appropriate time because Plaintiffs will suffer irreparable, actual harm if enforcement of 1240.61 and 131.110 is not enjoined. Specifically, the individual Plaintiffs have already decided that complying with 1240.61 and 131.110 violates their liberties including but not limited to their constitutional right to travel and their constitutional right of privacy, and also violates their rights to substantive due process.

The Parties

4. Plaintiff Fund is a non-profit organization organized under the laws of the State of Ohio. The Fund's principal place of business is located at 8116 Arlington Boulevard, Suite 263, Falls Church, Virginia 22042.

5. As of January 1, 2010, the Fund consisted of over 1,900 members from 49 different States.

6. Plaintiff Laurie Donnelly resides at 427 8th Street, Sloan, Woodbury County, Iowa.

7. It is illegal to sell raw milk in the State of Iowa even though it is legal to consume raw milk and raw dairy products in Iowa. However, it is legal to sell raw milk and cream in the State of Nebraska as long as the sale takes place at a dairy farm.[1]

8. On more than one occasion in 2009, Plaintiff Donnelly drove from Iowa into Nebraska and legally purchased and obtained raw milk in final package form.

[1] Some States allow the sale of raw milk and/or raw milk products (such as kefir, yogurt, butter, etc.); others prohibit the sale of raw milk and/or raw milk products. As of the filing of this Complaint, at least 28 States allow the *sale* of raw milk. However, the *consumption* of raw milk is legal in all 50 States.

9. After legally purchasing raw milk from a dairy farm in Nebraska, Plaintiff Donnelly traveled back into Iowa in possession of the raw milk where she and her family then consumed the milk. This activity continues to this day.

10. Plaintiff Jennifer Allen resides at 3603 Ramelle Drive, Council Bluffs, Iowa.

11. It is illegal to sell raw milk and cream in the State of Iowa even though it is legal to consume raw milk and raw dairy products in Iowa. However, it is legal to sell raw milk and cream in the State of Nebraska as long as the sale takes place at a dairy farm.

12. On more than one occasion in 2009, Plaintiff Allen drove from Iowa into Nebraska and legally purchased and obtained raw milk and cream in final package form.

13. After legally purchasing raw milk and cream from a dairy farm in Nebraska, Plaintiff Allen traveled back into Iowa in possession of the raw milk and cream where she and her family then consumed the milk and cream. This activity continues to this day.

14. Plaintiff Dr. Joseph Heckman is a member of the Fund and resides at 19 Forman Avenue, Monroe, New Jersey.

15. It is illegal to sell raw milk in the State of New Jersey even though it is legal to consume raw milk and raw dairy products in New Jersey. However, it is legal to sell raw milk in the State of Pennsylvania as long as the seller is either a licensed dairy farm or a licensed retail store.

16. On more than one occasion in 2009, Plaintiff Heckman drove from New Jersey into Pennsylvania and legally purchased and obtained raw milk in final package form from a licensed dairy farm.

17. After legally purchasing raw milk from a licensed farm in Pennsylvania, Plaintiff Heckman traveled back into New Jersey in possession of the raw milk where he and his family then consumed the milk. This activity continues to this day.

18. Plaintiff Dane Miller resides at 198 Slater Road Reading, Pennsylvania and has relatives are located in the State of Virginia.

19. It is illegal to sell raw milk in the State of Virginia even though it is legal to consume raw milk and raw dairy products in Virginia. However, it is legal to sell raw milk in the State of Pennsylvania as long as the seller is either a licensed dairy farm or a licensed retail store.

20. On more than one occasion in 2009, Plaintiff Miller drove from Virginia to Pennsylvania and legally purchased and obtained raw milk in final package form from a licensed dairy farm in Pennsylvania.

21. After legally purchasing raw milk from a licensed farm in Pennsylvania, Plaintiff Miller traveled from Pennsylvania into Virginia in possession of the raw milk, where he and his relatives then consumed the milk. This activity continues to this day.

22. Plaintiff Cynthia Lee Rose resides at 415 North Main Avenue, Maiden, North Carolina.

23. It is illegal to sell raw milk in the State of North Carolina even though it is legal to consume raw milk and raw dairy products in North Carolina. However, it is legal

to sell raw milk in the State of South Carolina as long as the seller is a licensed dairy farm or a licensed retail store.

24. On more than one occasion in 2009, Plaintiff Rose drove from North Carolina into South Carolina and legally purchased and obtained raw milk in final package form.

25. After legally purchasing raw milk from a licensed farm in South Carolina, Plaintiff Rose traveled back into North Carolina in possession of the raw milk where she and her family then consumed the milk. This activity continues to this day.

26. Plaintiff Eric Wagoner is a member of the Fund and resides at 310 Woody Road, Royston, Georgia 30662.

27. It is illegal to sell raw milk for human consumption in the State of Georgia even though it is legal to consume raw milk and raw dairy products in Georgia. However, it is legal to sell raw milk in the State of South Carolina as long as the seller is either a licensed dairy farm or a licensed retail store.

28. On more than one occasion in 2009, Plaintiff Wagoner drove from Georgia to South Carolina and legally purchased and obtained raw milk in final package form.

29. After legally purchasing raw milk from a licensed farm in South Carolina, Plaintiff Wagoner traveled back into Georgia in possession of the raw milk where he and his family then consumed the milk. This activity continues to this day.

30. Plaintiff Wagoner is also the owner of an internet-based virtual farmers' market known as "Athens Locally Grown." Individuals can become members of Athens Locally Grown ("ALG") by paying an annual membership fee of $25 per household.

31. Plaintiff Anne Cooper is a member of ALG and resides at 1104 Mill Pointe, Bogart, GA 30622.

32. Plaintiff Wagoner manages and owns ALG, which operates in this fashion:

(i) Approximately 100 different farms/farmers list their agricultural products with ALG;

(ii) Some of the 100 different farms/farmers are located in Georgia while some are located in South Carolina;

(iii) Approximately 2,000 members peruse the ALG list and place orders for the products that are listed there by the 100 farmers;

(iv) Orders are placed once a week and deliveries are made on Thursdays at a location in Georgia, and this practice continues to this day;

(v) Some of the ALG members, including Plaintiffs Wagoner and Cooper, order raw milk in final package form for personal consumption from three dairies located in South Carolina who list their dairy products with ALG;

(vi) Plaintiff Wagoner drives to South Carolina to pick up the raw dairy products and returns with them to Georgia for distribution to the ALG members and to Plaintiffs Wagoner and Cooper;

(vii) ALG members pay the farmers for the price of the products listed on ALG.

33. On October 15, 2009, Plaintiff Wagoner was driving from South Carolina into Georgia with about 110 gallons of raw milk in final package form. Upon reaching Georgia, Plaintiff Wagoner's truck was searched and seized by officials from Georgia

without a warrant. The raw milk in Wagoner's truck was embargoed by officials from Georgia without a warrant.

34. On October 19, 2009, the 110 gallons of raw milk, including milk owned by Plaintiffs Wagoner and Cooper, were destroyed at the order of the Georgia officials and the FDA without a warrant or other legal process.

35. Plaintiff Cooper has an agency relationship with Plaintiff Wagoner, whereby Wagoner, as the agent for Cooper, picks up the raw milk in South Carolina that was legally purchased and is owned by Cooper and delivers that raw milk to Cooper in Georgia.

36. Plaintiff Buck is a member of the Fund and resides at 175 Dairy Lane, Saluda, South Carolina.

37. Plaintiff Buck owns and operates a dairy farm known as Butter Patch Jerseys that is located at 175 Dairy Lane, Saluda, South Carolina. The dairy farm includes approximately 30 dairy cows and a retail store located on the farm.

38. Plaintiff Buck has held a Grade A dairy license from the State of South Carolina since 1987 and has held a retail raw milk license from the State of South Carolina since 2006.

39. It is legal to sell raw milk in South Carolina as long as the seller is either a licensed dairy farm or a licensed retail store.

40. Approximately 25% of the milk produced by Plaintiff Buck's dairy cows is sold in South Carolina as retail raw milk.

41. Plaintiff Buck sells only raw milk and no other raw dairy products, and sells his raw milk on his farm; to a retail store located in Sumter, South Carolina; to a retail

store located in Aiken, South Carolina; and to two retail stores located in Columbia, South Carolina.

42. Plaintiff Buck has personal knowledge that people from North Carolina and Georgia, where it is illegal to sell raw milk for human consumption, purchase raw milk at his farm and at the Sumter store, and that people from Georgia purchase raw milk at the Aiken store.

43. Plaintiff Buck has never had any sanctions or penalties levied against his dairy; he has never had to dump even a single load of milk since he has been in business; and, as far as he knows, there has never been any illness caused by the consumption of raw milk produced at his dairy.

44. Defendant Kathleen Sebelius is the current Secretary of the United States Department of Health and Human Services ("HHS"), Defendant Sebelius is being named a party in her official capacity as Secretary of HHS.

45. Defendant HHS is the executive department having jurisdiction over the Food and Drug Administration ("FDA").

46. Defendant Margaret Hamburg is the current Commissioner of FDA. As Commissioner, Ms. Hamburg is responsible for the direction and supervision of all operations and activities of the FDA. Defendant Hamburg is being named a party in her official capacity as Commissioner of FDA.

47. Defendant FDA is the administrative agency granted authority by Congress to regulate the interstate sale of food in the United States.

57. All of the individual Plaintiffs are, have been, and will be damaged and have suffered, are suffering and will suffer an injury in fact by the prohibitions contained in 1240.61 and 131.110. Specifically, all Plaintiffs are being deprived their fundamental and inalienable rights of (a) traveling across State lines with raw dairy products legally obtained and possessed; (b) providing for the care and well being of themselves and their families, including their children; and (c) producing, obtaining and consuming the foods of choice for themselves and their families, including their children. Plaintiffs are also suffering injury from the promulgation and enforcement of regulations that are beyond the Defendant's authority and that are arbitrary and capricious.

58. The threat of an enforcement action by FDA guarantees standing to the individual Plaintiffs. *See Houston v. Hill,* 482 U.S. 451, 459, n. 7 (1987); *Steffel v. Thompson,* 415 U.S. 452, 459 (1974); *First Nat. Bank of Boston v. Bellotti,* 435 U.S. 765, 785, n. 21 (1978); *Rosenbloom v. Metromedia, Inc.,* 403 U.S. 29, 52-53 (1971); *New York Times Co. v. Sullivan,* 376 U.S. 254, 278 (1964).

59. A declaratory judgment action is the appropriate action to bring when faced with a Hobson's choice, i.e., either comply with a law that is believed to be illegal, or ignore the illegal law and face the possible consequences of noncompliance. *See Abbott Laboratories v. Gardner*, 386 U.S. 136, 152-153, (1967); *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 172 (1967).

60. A favorable ruling on the claims presented in this Complaint would redress Plaintiffs' injury in fact. Specifically, a ruling that 1240.61 and 131.110 are illegal as applied to Plaintiffs would allow the individual Plaintiffs to travel across State lines with legally obtained raw dairy products in their possession; would allow Plaintiffs to provide

66. More people are killed each year from lightning strikes on golf courses than die from milkborne illnesses.

67. As of July 2009, and based on statistics maintained by the Centers for Disease Control on food borne illnesses and outbreaks, the top ten riskiest foods in the United States that are regulated by the FDA include the following: (1) leafy greens; (2) eggs; (3) tuna; (4) oysters; (5) potatoes; (6) cheese (pasteurized); (7) ice cream (pasteurized); (8) tomatoes; (9) sprouts; and (10) berries.

COUNT ONE
1240.61 AND 131.110 EXCEED FDA'S STATUTORY AUTHORITY AND ARE ARBITRARY AND CAPRICIOUS

68. Paragraphs 1 through 67 are incorporated into this Count as if rewritten herein.

69. 5 U.S.C 702 provides, in part, that "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."

70. 5 U.S.C. 706(2) provides, in part, that a Court may "hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."

71. 5 U.S.C. 551(13) provides, in part, that "agency action" includes "the whole or a part of an agency rule, . . . relief, or the equivalent or denial thereof, or failure to act."

milk product has first been "pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized."

78. The way it is written, therefore, 1240.61 makes all raw milk and raw dairy products in final package form that cross state lines, whether or not taken across State lines by a consumer, by an agent of the consumer, or by the producer who legally sells raw milk to a consumer, and which is/are intended for human consumption an "illness" *per se* or a communicable disease *per se*, which is contrary to law.

79. Rather than branding all raw milk and raw dairy products as an "illness" or a "communicable disease," FDA could use a less stringent means of regulating raw milk and raw dairy products.

80. For example, FDA has a regulation at 21 C.F.R. 101.17 that pertains to unpasteurized juices, and provides, in part, that a warning label on a juice container is an acceptable alternative to pasteurizing the juice, to wit: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

81. Such a warning label could be used for raw milk and raw dairy products as a less stringent means than an outright ban.

82. With respect to 131.110, the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. 301 *et seq*., at Section 341 provides, in part, that the FDA may promulgate "standards of identity" and "definitions" for foods in order to "promote honesty and fair dealing in the interest of consumers."

96. There is nothing in the PHSA that authorizes the FDA to find that a product that is legal to sell in more than half the States and where it is legal to consume in all 50 States should be banned as a "communicable disease" or "illness" particularly when there are other foods in the United States that cause more cases of foodborne illness.

97. There is nothing in the FDCA that authorizes FDA to promulgate a "standard of identity" or "definition" for raw milk that requires all milk for human consumption to first be pasteurized before or after it is taken across State lines lest such milk be deemed "misbranded."

98. There is nothing in the FDCA that authorizes FDA to prohibit the interstate movement of goods when the goods are purchased by a consumer in one State and then taken across state lines to another State.

99. 1240.61 and 131.110 exceed the scope of authority Congress has delegated to FDA, for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

COUNT TWO
1240.61 AND 131.110 VIOLATE THE CONSTITUTIONAL RIGHT TO TRAVEL

100. Paragraphs 1 through 99 are incorporated into this Count as if rewritten herein.

101. The United States Constitution recognizes a fundamental right to travel. *U.S. v. Guest*, 383 U.S. 745 (1966).

102. Any law impacting the right to travel must use the least stringent means possible. *Aptheker v. Secretary of State*, 378 U.S. 500 (1964).

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

Farm-to-Consumer Legal Defense Fund, et al.	:	**Case No. 5:10-cv-4018**
Plaintiffs	:	**Judge Mark W. Bennett**
v.	:	
Sebelius, et al.	:	
Defendants	:	

PLAINTIFFS' BRIEF IN SUPPORT OF RESISTANCE TO DEFENDANT'S MOTION TO DISMISS

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allegedly illegal behavior and they are refusing to modify their conduct to satisfy FDA. Instead, all Plaintiffs are willing to be prosecuted by FDA for their conduct because all Plaintiffs believe the "law" that FDA is enforcing is illegal. Thus, all Plaintiffs have Article III standing to bring this action.

1. Under FDA's own interpretation, all Plaintiffs are engaged in conduct that allegedly constitutes a violation 1240.61 and 131.110.

In this case, Plaintiffs have alleged that 1240.61 and 131.110 are unconstitutional as applied to them, that 1240.61 exceeds the authority of FDA as granted to it by the Public Health and Safety Act ("PHSA"), that 131.110 exceeds the authority of FDA as granted to it by the Food, Drug and Cosmetic Act ("FDCA"), and that 1240.61 and 131.110 are arbitrary and capricious. In other words, Plaintiffs believe that 1240.61 and 131.110 are illegal. Consequently, they must either comply with what they believe are illegal laws or they must risk an enforcement action by choosing to ignore them. This gives Plaintiffs standing in the context of a declaratory judgment action.

To demonstrate the likelihood of their probable recovery, this Court may either hold an evidentiary hearing or Plaintiffs may rely "on pleadings and affidavits." *Epps v. Stewart Information Services Corp.*, 327 F. 3d 642, 646 (8th Cir. 2003). *See also Sierra Club v. E.P.A.,* 292 F.3d 895, 900 (D.C. Cir. 2002) (Plaintiffs may establish their standing "by the submission of [their] arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding."); *Citizens Against Ruining The Environment v. E.P.A.*, 535 F.3d 670, 675 (7th Cir. 2008) ("While in many cases a petitioner's standing is self-evident, when it is not, the petitioner must supplement the record to the extent necessary to establish her entitlement to judicial review at the first appropriate point in the proceeding."). Since FDA has not asked for an

evidentiary hearing, Plaintiffs have submitted affidavits in support of their standing. As explained in the affidavits attached hereto, Plaintiffs have more than adequately pled facts to raise a reasonable expectation that they will prevail on their claims if the laws of the United States are construed in a manner that is consistent with their arguments.

The affidavit of Plaintiff Eric Wagoner, a Georgia resident, demonstrates that he was told by an FDA employee to dump out some milk that had been obtained in South Carolina by his agent. *See* Wagoner Affidavit, attached hereto as Exhibit A. Specifically, Wagoner allowed his agent to drive his truck to South Carolina, 110 gallons of raw milk were purchased from a farm in South Carolina (where it is legal to purchase raw dairy products), two gallons of which were owned by Wagoner, and then the agent drove back into Georgia. Wagoner lost the use of his property because he was forced to dump out his raw milk at the order of FDA. A two part video of this activity can be viewed at the You Tube website, part 1 accessible at www.youtube.com/watch?v=EMfQXxVAPgk and part 2 at http://www.youtube.com/watch?v=wPey52Ybp0U. FDA's actions have clearly caused an injury to Wagoner.

The other individual Plaintiffs[7] who drive into neighboring States to legally obtain raw dairy products are similarly "breaking the law" as interpreted by FDA, i.e., if Wagoner was violating 1240.61 by his conduct, so too are all of the other individual Plaintiffs when they drive into neighboring States to legally purchase raw dairy products and then drive back into their State of residence to consume the milk. In other words, the individual Plaintiffs must either refrain from engaging in what they believe is lawful

[7] Laurie Donnelly, Jennifer Allen, Dr. Joseph Heckman, Dane Miller, Cynthia Lee Rose, Anne Cooper.

conduct or they can keep engaging in the conduct that FDA deems unlawful and risk an enforcement action by the FDA. This creates an Article III injury. *See Minnesota Citizens Concerned for Life v. Federal Election Com'n*., 113 F.3d 129, 131 (8th Cir. 1997) (when a party "must either make significant changes to [their conduct] to obey [a challenged law], or risk a criminal [or civil] enforcement action by disobeying the regulation," this Hobson's choice confers Article III standing.). Therefore, all of the individual consumer Plaintiffs have suffered or are suffering an injury- in-fact at the expense of FDA.

With respect to the single farmer Plaintiff in this case, Michael Buck sells raw dairy products in the State of South Carolina where it is legal to do so. *See* Complaint, pars. 40, 41. However, some of his customers are from out of state, for example, Georgia and North Carolina, to which they take their raw dairy products after purchasing them from Buck. *See* Complaint, par. 42. In addition, Plaintiff Buck sells some of his raw dairy, legally, to a store in South Carolina, some of whose customers are out-of-state residents. *Id*. As demonstrated by the affidavits of Pete Kennedy and Steve Bemis, attached hereto as Exhibits B and C, FDA considers this a violation of 1240.61 because Buck would allegedly be "causing to be delivered in interstate commerce" raw dairy products.

Specifically, Kennedy's affidavit shows that dairy farmers in the State of Washington, Michael and Anita Puckett of Dee Creek Farm, were the subjects of a criminal action brought by the United States Department of Justice at the request of the FDA. In the Dee Creek case, residents from Oregon traveled to the Puckett's farm in Washington to obtain raw dairy products. The Pucketts made raw dairy products

available to their shareholders through a herdshare[8], the legitimacy of which was challenged by the Washington authorities.

The Oregon residents obtained raw dairy products from the Pucketts in Washington and then returned to Oregon to consume their milk. The Pucketts were aware their shareholders were Oregon residents. Even though the Pucketts themselves did not ship any milk across state lines, the FDA sent the Pucketts a warning letter informing them they were violating 1240.61. Ultimately, the Pucketts were criminally charged with a misdemeanor for distributing adulterated food in interstate commerce and were sentenced by the Honorable United States Magistrate Judge Karen L. Strombom in October 2008. *See* Case No. 3:08-cr-05424, W.D. Wash.

Moreover, Kennedy's affidavit also shows that FDA has alleged that a dairy farmer in South Carolina, where it is legal to sell raw milk, is also in violation of 1240.61. FDA is claiming that residents in Georgia are operating a "cooperative" and that this cooperative obtains its raw dairy products from the farmer in South Carolina. Specifically, FDA is alleging that this dairy farmer's "raw milk is sold through" the co-op in Georgia. Thus, FDA is alleging this South Carolina dairy farmer has "caused to be delivered in interstate commerce" raw dairy products because he is allegedly causing to be delivered raw dairy products to a state other than South Carolina.

In this case, Plaintiff Buck is doing the same thing as the South Carolina and Washington farmers did, i.e., he is making raw milk available to consumers that includes

[8] A herdshare is an operation where a group of individuals purchase an undivided ownership interest in a herd of cows and the shareholders then board their herd at a dairy farm. This type of arrangement is historically known as an Agistment agreement. Because of their ownership interest in the herd, the shareholders also have an ownership interest in the raw milk and raw dairy products produced by their herd.

out-of-state residents. Consequently, Buck can either continue his conduct and subject himself to a criminal action or he can stop his conduct and comply with what he believes is an illegal regulation. Thus, according to the Eighth Circuit, Buck has standing to bring this action because he "must either make significant changes to [his conduct] to obey [a challenged law], or risk a criminal [or civil] enforcement action by disobeying the regulation." *See Minnesota Citizens Concerned for Life v. Federal Election Com'n*., 113 F.3d 129, 131 (8th Cir. 1997). Consequently, Buck has Article III standing.

Bemis' affidavit demonstrates that FDA has taken the same position in Michigan and in Illinois. Bemis' affidavit shows that Michigan and Illinois residents lease a herd of cows located in Indiana, and that the Indiana farmer tends to, manages and takes care of the herd leased by the Illinois and Michigan residents. Bemis' affidavit also shows that the Indiana farmer would make the raw dairy products produced by the herd available to the Illinois and Michigan residents. FDA informed the Indiana farmer that he was in violation of 1240.61 and 131.110 because he was "delivering in interstate commerce" raw dairy products. Thus, even when a farmer makes raw dairy products available across state lines to individuals who have a leasehold interest in the raw dairy products, FDA takes the position that this conduct violates 1240.61 and 131.110. Moreover, FDA takes this position even though the farmer himself, like Plaintiff Buck in this case, never crosses state lines.

Therefore, all of the Plaintiffs have standing and FDA's motion to dismiss should be denied.

B. Plaintiffs' declaratory judgment action is ripe for review and Ewing is not on point.

FDA makes a curious three-part argument that Plaintiffs lack standing.

unfit for judicial review." FDA then cites to *National Right to Life Political Action Committee v. Connor*, 323 F.3d 684 (8th Cir. 2003), *Texas v. U.S.* 523 U.S. 296, 118 S.Ct. 1257 (1998), *BBK Tobacco & Foods, LLP v. U.S. Food and Drug Admin*., 672 F.Supp.2d 969 (D. Ariz. 2009) and *Paraquad, Inc. v. St. Louis Housing Authority*, 259 F.3d 956 (8th Cir. 2001) to suggest that because "contingent future events" may or "may not occur at all," Plaintiffs' action is not ripe.

As has already been addressed in Section III. A., FDA's argument is a red herring and lacks merit. Specifically, FDA's regulations force Plaintiffs to choose between two bad options – abandoning their rights or risking enforcement actions – and that is enough to confer Article III standing in a declaratory judgment action. Furthermore, Plaintiffs' allegations must be construed as true, not as a hypothetical. Moreover, and as evidenced by the affidavits of Wagoner, Bemis and Kennedy, FDA has already evinced its interpretation of 1240.61 and 131.110, i.e., Plaintiffs' conduct constitutes a violation of law. Thus, there is nothing "hypothetical" about this case.

Because the Plaintiffs' allegations are based on final regulations adopted by FDA, which is clear "final agency action" for purposes of the APA, causing actual existing injury to the Plaintiffs, the instant case is distinguishable from those cited by FDA. For example, *National Right to Life* dealt with a situation where it was unclear whether or not a fee would be imposed on out-of-state political action committees. "The district court correctly pointed out that '[h]ow the MEC would handle the 'fee' for failing to file prior to the 30 day window would have a significant impact' on our constitutional scrutiny of section 130.011(10).'" *National Right to Life Political Action Committee v. Connor*, 323 F.3d at 693 (8th Cir. 2003). Thus, the case was dismissed for not being ripe because there

specific attempt at enforcement….

Id. at 163. Thus, Plaintiffs do not need to "wait" for FDA to "enforce" the law for this Court to declare whether 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs' conduct.

Finally, FDA argues on pages 16 and 17 that under *Ewing* and its progeny, including *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980) and *Parke, Davis & Co. v. Califano*, 564 F.2d 1200 (6th Cir. 1977), FDA has the "discretion under the FDCA to initiate a seizure or injunction." While that may be so, this is not a *Ewing*-type situation where Plaintiffs are asking this Court to enjoin FDA from "seizing" their raw milk that they take with them across state lines. Instead, Plaintiffs are asking this Court to declare whether 1240.61 and 131.110, regulations that have been in existence for over 20 years, are unconstitutional as applied to their conduct.

Moreover, the court in *Southeastern Minerals* expressly stated that "[n]o final agency action of the type presented to the Supreme Court in *Abbott Laboratories* is present in the instant case" and thus it was improper to enjoin FDA from seizing product that was regulated by the Food, Drug and Cosmetic Act. *Id*. at 764. In addition, the *Parke, Davis* court expressly stated the following: "In short, this case is controlled by *Ewing v. Mytinger & Casselberry* rather than *Abbott Laboratories v. Gardner*." *Id*. at 1206. Thus, neither *Southeastern Minerals* nor *Parke, Davis* apply to this case.

Consequently, this Court has subject matter jurisdiction over Plaintiffs' claims. Therefore, FDA's argument is not well taken and its motion on the issue of lack of standing should be denied.

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

Farm-to-Consumer Legal Defense Fund, et al.	:	**Case No. 5:10-cv-4018**
Plaintiffs	:	**Judge Mark W. Bennett**
v.	:	
Sebelius, et al.	:	**AFFIDAVIT OF ERIC WAGONER**
Defendants	:	

STATE OF GEORGIA :
COUNTY OF FRANKLIN :

I, Eric Wagoner, being duly sworn, hereby make the following statements based on my personal knowledge, understanding and belief:

1 I am a Plaintiff in this case and at all time relevant to this case have been a member of the Plaintiff Farm-to-Consumer Legal Defense Fund.

2. I reside at 310 Woody Road, Royston, Georgia 30662 and have resided at this location at all times relevant to this case

3. I am the owner as well as a member of an internet-based virtual farmers' market known as "Athens Locally Grown." Individuals can become members of Athens Locally Grown ("ALG") by paying an annual membership fee of $25 per household.

4. Plaintiff Anne Cooper is also a member of ALG and resides at 1104 Mill Pointe, Bogart, GA 30622

5 I manage and own ALG, which operated in this fashion until October 19, 2009:

a. Approximately 100 different farms/farmers listed their agricultural products with ALG;

b. Some of the 100 different farms/farmers are located in Georgia while some are located in South Carolina;

c. Approximately 2,000 members of ALG perused the ALG list and placed orders for the products that were listed there by the 100 farmers;

d. Orders were placed once a week and deliveries were made on Thursdays at a location in Georgia;

e. Some of the ALG members, including myself and Anne Cooper, ordered raw milk in final package form for personal consumption from three dairies located in South Carolina who listed their dairy products with ALG;

f. I drove to South Carolina to pick up the raw dairy products and returned with them to Georgia for distribution to the ALG members, including to myself and Ms. Cooper;

g. ALG members paid the farmers for the price of the products listed on ALG's website

6. On October 15, 2009, an ALG volunteer was driving my delivery truck from South Carolina into Georgia with about 110 gallons of raw milk in final package form that had been ordered and purchased by members of ALG. Not only was the volunteer delivering my own milk in my own truck, she was acting as the agent of the other ALG members, including Ms Cooper, who had purchased raw milk from the South Carolina farmers.

7 Of the 110 gallons of raw milk the volunteer was delivering, I owned 2 gallons and Ms Cooper owned 1 gallon.

8. Upon reaching Georgia, my truck was searched and seized by officials from Georgia without a warrant. Officials from Georgia embargoed the raw milk in my truck without a search warrant.

9. I was allowed to drive my truck and its contents to my home where it was parked until October 19th.

10. On October 19, 2009, the 110 gallons of raw milk, including milk owned by Ms. Cooper and I, were destroyed at the order of the Georgia officials and of the FDA without a warrant or other legal process.

11. The FDA agent who ordered me to destroy the 110 gallons of raw milk was Marybeth Willis from FDA's Atlanta office.

12. The destruction of the raw milk was video taped by my wife, Christina Wagoner.

13. A copy of this video is on the internet website You Tube, located in two parts at http://www.youtube.com/watch?v=EMfQXxVAPgk.

14. The destruction of the raw milk was also video taped by a film crew hired by Ms. Kristin Canty, who I understand is also supplying an affidavit in opposition to FDA's motion to dismiss

15. During the destruction process, I questioned Ms Willis about FDA's interpretation of 21 C F R 1240 61, which I understand prohibits the interstate distribution or transport of dairy products in final package form for human consumption that are not pasteurized.

16. During the destruction process, Ms Willis stated it is a federal crime to bring raw milk or raw dairy products across state lines for any reason. She specifically said that if you go to the dairy yourself, buy a gallon for your own use, and bring it back to your own home in Georgia, you would be a federal criminal.

17 Ms Cooper and I have been injured by FDA's actions because we have not been allowed to keep our raw milk but instead had to destroy it at FDA's direction.

18. In addition, all other ALG members for whom I acted as their agent have been injured by FDA's actions because they too have been deprived the use of their raw milk at the direction of FDA.

FURTHER AFFIANT SAYETH NAUGHT

Eric Wagoner

Sworn and subscribed before me this 8 day of June, 2010.

Notary public

JIMMY WALL NOTARY PUBLIC CLARKE COUNTY, GA EXP. AUG. 2, 2013

CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2010, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

MARTHA A. FAGG
Assistant United States Attorney
600 4th Street, Suite 670
Sioux City, IA 51101
712-255-6011
712-252-2034 (fax)
martha.fagg@usdoj.gov
usao.ian-civ-dc-sc@usdoj.gov

ROGER GURAL
Trial Attorney
Office of Consumer Litigation
Department of Justice
Civil Division
P.O Box 386
Washington, D.C. 20044
202-307-0174
202-514-8742 (fax)
roger.gural@usdoj.gov

/s/ David G. Cox
David G. Cox

Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	**No. C 10-4018-MWB**
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

DECLARATION OF MARYBETH WILLIS

I, Marybeth Willis, hereby declare as follows:

1. I am a Regional Milk Specialist in the Food and Drug Administration's ("FDA") Southeast Regional Office, in Atlanta, Georgia. The statements made in this declaration are based upon my own personal knowledge and upon my review of records within the custody and control of FDA.

2. I am generally familiar with a regulatory action taken by the State of Georgia against Eric Wagoner and his business "Athens Locally Grown," which occurred in the vicinity of Athens, Georgia.

3. On Friday, October 16th, 2009, the FDA received a telephone call from Peggy Gates, Director for the Dairy Division at the Georgia Department of Agriculture. Ms. Gates informed FDA that a meat compliance officer from the Georgia Department of Agriculture had placed an embargo on 110 gallons of raw milk intended for human consumption at the Athens Free Market (a local farmer's market). FDA was informed that the meat inspector had been at the market to inspect meat for sale, and had come across the raw milk unexpectedly.

4. At no time on Friday or over the following weekend did anyone from FDA have contact with the Mr. Wagoner, who had possession of the embargoed the raw milk. Neither did FDA have any contact with anyone else associated with Mr. Wagoner or Athens Locally Grown.

5. In a discussion with Peggy Gates, I was informed that Mr. Wagoner had agreed to destroy voluntarily the embargoed 110 gallons of raw milk. I was informed that the destruction would take place on the afternoon of Monday, October 19, 2009, at Mr. Wagoner's residence. I was informed that the destruction was to take placed at this location because Mr. Wagoner had requested and received permission, to move the milk from the farmer's market to his residence.

6. I accompanied Ms. Gates and another state inspector to observe the destruction. This was to observe and collect information on behalf of FDA. I met Ms. Gates and her colleague at approximately 1:00 pm on October 19th, and we then proceeded to Mr. Wagoner's home.

7. Upon arrival at Mr. Wagoner's home, we were told that the embargoed milk was in a truck at the bottom of a long driveway. We proceeded to walk down the driveway and, as we approached the truck, I noticed a gathering of about 30 to 50 people, many of whom carried video cameras.

8. Mr. Wagoner proceeded to voluntarily dump all of the embargoed raw milk on the ground. I am not aware of any attempt by Mr. Wagoner (or anyone else) to petition a court to lift the embargo before the milk was dumped.

9. At no time did I, or anyone else from FDA, order or otherwise direct Mr. Wagoner to destroy the embargoed raw milk or take any other action. While at Mr. Wagoner's residence I did my best to politely answer questions that were directed to me by those congregated on Mr. Wagoner's property. If asked about the requirements of federal law with respect to raw milk, I would have responded that federal regulations prohibit the delivery of raw milk into interstate commerce. I did not, however, issue any order or direction to anyone on this or any other basis.

10. In addition, I would have had no authority to order Mr. Wagoner to destroy the embargoed raw milk. If FDA were to have taken an action to seize and destroy the embargoed milk, this would have involved a multistep process beginning with a recommendation from FDA's Atlanta District Office to FDA's Center for Food Safety and Nutrition ("CFSAN") in College Park, Maryland. If CFSAN concurred with the District Office's recommendation, the matter would be referred to the FDA's Office of Chief Counsel ("OCC"). Subject to OCC's approval, the matter would be referred to the United States Department of Justice. These procedures are laid out in detail in the Chapter 6 of the FDA's Regulatory Procedures Manual, available on the internet at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm . (*See, e.g.,* Section 6-1-9 ("Action on Seizure Recommendations"), and Section 6-1-10 ("Seizure Accomplishment and Close-Out Documentation")). Only DOJ has the authority to initiate a judicial proceeding that could result in a seizure, and, to my

knowledge, no such proceeding was ever initiated with respect to the embargoed raw milk in Mr. Wagoner's possession.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on May 10, 2011.

Marybeth Willis

Marybeth Willis

Exhibit E

DECLARATION OF PEGGY GATES

I, Peggy Gates, hereby declare as follows:

1. I am the Program Manager of the Dairy Division with the Georgia Department of Agriculture ("GDA"). The statements made in this declaration are based upon my own personal knowledge and upon my review of records within the custody and control of the GDA.

2. As described below, in October, 2009, GDA embargoed 110 gallons of unpasteurized milk in the possession of Eric Wagoner. GDA became aware of the unpasteurized milk when a GDA investigator was conducting an investigation of illegal meat sales at Athens Free Market, a farmer's market in Athens, Georgia.

3. On the afternoon of Thursday, October 15, 2009, the GDA investigator arrived at the farmer's market to investigate the allegation of illegal meat sales. While conducting this investigation, GDA inspector noticed Mr. Wagoner, unloading gallon jugs of milk from coolers that were on Mr. Wagoner's truck. The investigator inspected the milk jugs, and determined that they contained unpasteurized milk from South Carolina.

4. All of the unpasteurized milk (the "Embargoed Milk") on Mr. Wagoner's truck, (totaling 110 gallons) was placed under a Stop Sale Order (embargo) and Mr. Wagoner was advised that it is illegal under Georgia law to sell unpasteurized milk for human consumption in the State of Georgia.

5. Mr. Wagoner was advised that the Embargoed Milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Mr. Wagoner agreed to voluntarily destroy the Embargoed Milk. Because a place to destroy the Embargoed Milk could not be found, Mr. Wagoner asked that he be allowed to transport it to his home for destruction on the following Monday. This permission was granted.

6. At the time the Embargoed Milk was placed under embargo, a Stop Sale notice was given to Mr. Wagoner and tags placed on each cooler. A photograph of one of Mr. Wagoner's coolers with a tag is attached hereto as Attachment A. Because the tag in Attachment A is difficult to read, Attachment B contains a blank form of the tag for reference.

7. On Monday, October 19, 2009, I and a GDA investigator drove to Mr. Wagoner's residence. We were accompanied by Marybeth Willis of the U.S. Food and Drug Administration ("FDA"), who was there in an observational capacity. After our arrival, Mr. Wagoner voluntarily dumped the Embargoed Milk on the ground.

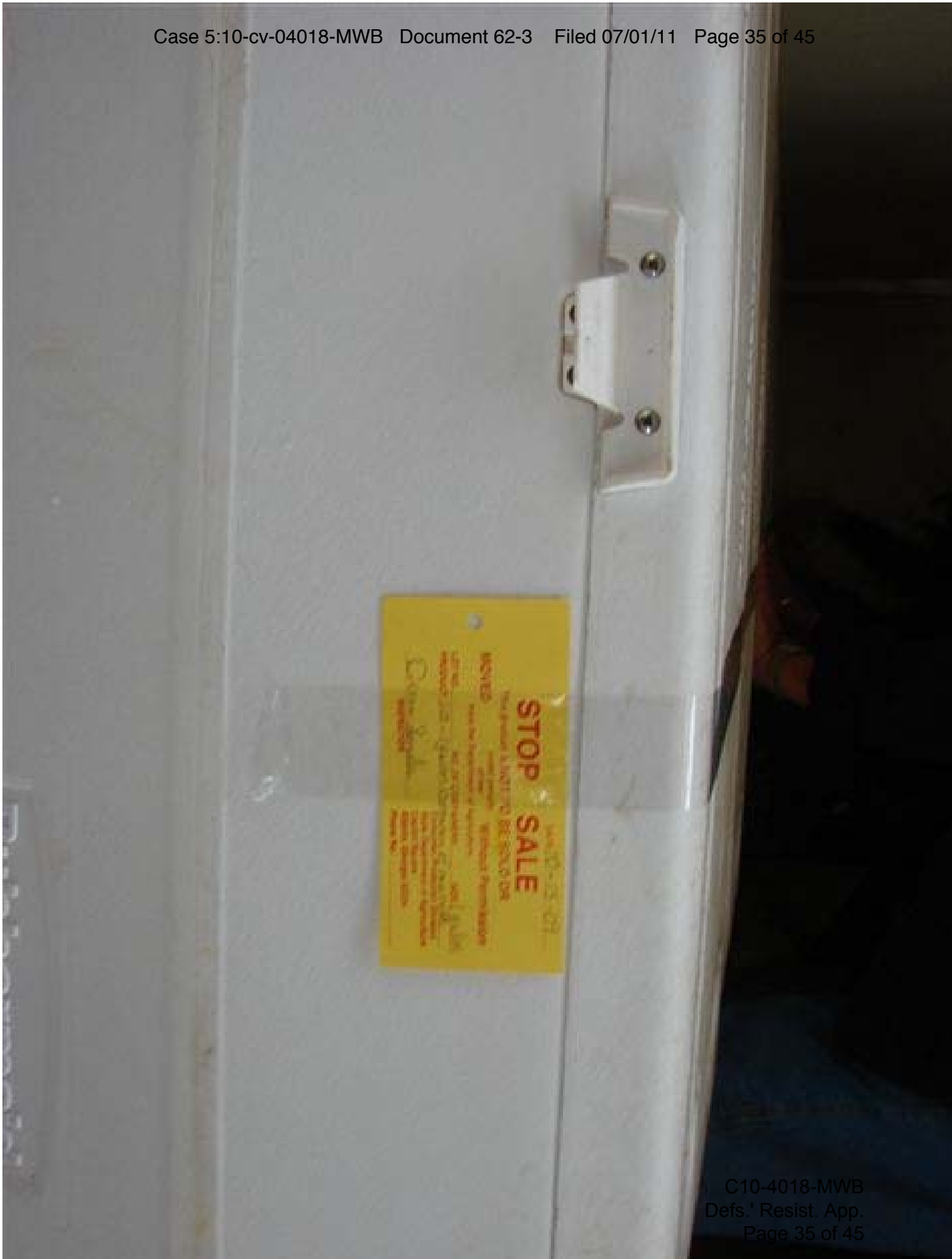
8. The embargo described above was carried out entirely by GDA under the authority of Georgia law. Mr. Wagoner did not challenge the embargo in court, as was his right under Georgia law. As also described above, Mr. Wagoner destroyed the Embargoed Milk voluntarily. FDA played no role in the embargo of the Embargoed Milk and/or the discussions with Mr. Wagoner leading up to his decision to voluntarily destroy the Embargoed Milk.

9. Furthermore, the regulatory action described above was undertaken entirely under Georgia law. It is illegal to sell unpasteurized milk for human consumption in the State of Georgia (*see* GEORGIA CODE. ANN § 26-2-242), and it is also illegal to ship unpasteurized milk for human consumption into Georgia from another state. *See* GEORGIA CODE. ANN. § 26-2-244(a).

Pursuant to 28 U.S.C. Section 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on May 10, 2011.

Peggy Estes

Attachment A


STOP SALE

Attachment B

STOP SALE

This product is NOT TO BE SOLD OR

MOVED under penalty of law Without Permission

from the Department of Agriculture

LOT NO._____ NO. OF CONTAINERS_____ SIZE_____

PRODUCT_____

_____

INSPECTOR

Consumer Protection Division
State Department of Agriculture
Capitol Square
Atlanta, Georgia 30334
Phone No.:_____

Exhibit F

delegated to the Commissioner (21 CFR 2.120): *It is ordered*, that Part 18 be revised to read as follows:

Sec.
18.1 Definitions.
18.2 Milk; identity.
18.10 Lowfat milk; identity.
18.20 Skim milk; identity.
18.30 Half-and-half; identity.
18.501 Light cream; identity.
18.511 Light whipping cream; identity.
18.515 Heavy cream; identity.
18.520 Evaporated milk; identity.
18.525 Concentrated milk; identity.
18.530 Sweetened condensed milk; identity.
18.540 Nonfat dry milk; identity.
18.545 Nonfat dry milk fortified with vitamins A and D; identity.

AUTHORITY.—Secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).

§ 18.1 Definitions.

(a) "Cream" means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) "Pasteurized" when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature:	*Time*
145°F[1]	30 minutes
161°F[1]	15 seconds
191°F	1 second
204°F	0.05 second
212°F	0.01 second

[1] If the dairy ingredient has a fat content of 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F.

(c) "Ultra-pasteurized" when used to describe a dairy product means that such product shall have been thermally processed at or above 280°F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

§ 18.2 Milk; identity.

(a) *Description.* Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) *Vitamin addition* (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milk fat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.[2]

(2) Milk solids not fat content—Calculated by subtracting the milk fat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.[2]

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.[2]

(e) *Nonmenclature.* The name of the food is "milk". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) If vitamins are added, the phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamin A and D" or "vitamins A and D added", as is appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) *Label declaration.* When used in the food, each of the ingredients specified in paragraphs (b) and (c) (2) of this section shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 18.10 Lowfat milk; identity.

(a) *Description.* Lowfat milk is milk from which sufficient milkfat has been removed to produce a food having, within limits of good manufacturing practice, one of the following milkfat contents: ½, 1, 1½, or 2 percent. Lowfat milk is pasteurized or ultra-pasteurized, contains added vitamin A as prescribed by paragraph (b) of this section, and contains not less than 8¼ percent milk solids not fat. Lowfat milk may be homogenized.

(b) *Vitamin addition.* (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c) (2) of this section are used, emulsifiers, stabilizers, or both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.[2]

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.[2]

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.[2]

(e) *Nomenclature.* The name of the food is "Lowfat milk". The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 1.12 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

See footnote at end of document.

Exhibit G

to the public interest to grant such exemption.

Issued in Washington, DC on August 4, 1987, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 87-18046 Filed 8-7-87; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 81N-204C]

Milk, Lowfat Milk, and Skim Milk, Pasteurization Requirements for Fluid Milk Products for Consumer Use

AGENCY: Food and Drug Administration.

ACTION: Final rule; termination of stay.

SUMAMRY: The Food and Drug Administration (FDA) is announcing that the stay of that portion of the standard of identity for milk, lowfat milk, and skim milk products that concern the requirement that certified fluid milk products for consumer use be pasteurized is terminated. Elsewhere in this issue of the **Federal Register** under 21 CFR Part 1240—Control of Communicable Diseases, FDA is taking action to require that milk and milk products, certified and noncertified, in final package form for human consumption in interstate commerce be pasteurized.

EFFECTIVE DATE: September 9, 1987.

FOR FURTHER INFORMARTION CONTACT: Robert J. Lahan, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0162.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1972 (37 FR 18392), FDA, under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341), proposed to revise existing standards of identity and to establish new standards of identity for certain milk and cream products. This notice included an FDA proposal to require that each of the listed milk and cream products be pasteurized.

In the **Federal Register** of October 10, 1973 (38 FR 27924), FDA published a final rule which included the requirement that milk products moving in interstate commerce be pasteurized. In deciding upon the pasteurization requirement, FDA reasoned that pasteurization was the only way to assure the destruction of pathogenic microorganisms that might be present.

Following publication of the final rule, FDA received one request for a hearing and an accompanying set of objections on the pasteurization requirement for certified raw milk. The procedures used in producing certified raw milk are significantly different from those used in producing raw milk in general in that they must comport with the methods and standards established by the American Association of Medical Milk Commissions, a private organization that provides to its members guidelines for the production of certified raw milk. Only dairies that employ the Association's techniques have the right to use the term "certified" on their products. The objections, which pertained only to certified raw milk, were based on two premises: (1) Certified raw milk is a safe product, and (2) section 401 of the Act (21 U.S.C. 341) does not provide authority to establish a standard of identity solely for health reasons.

In the preamble of the **Federal Register** of December 5, 1974, (39 FR 42351), FDA announced that the objections raised a substantial issue of fact with regard to whether pasteurization is needed for certified raw milk and that a hearing would be conducted. Accordingly, FDA stayed this requirement for certified raw milk.

This stayed requirement for certified raw milk has been rendered moot by the agency's issuance elsewhere in this issue of the **Federal Register** of a final rule requiring that all milk and milk products, certified and noncertified, in final package form for human consumption in interstate commerce be pasteurized. This fianl rule was issued in response to a decision by the United States District Court for the District of Columbia ordering "that the Food and Drug Administration and the Secretary of Health and Human Services publish in the **Federal Register**, a proposed rule banning the interstate sale of all raw milk and raw milk products, both certified and non-certified, pursuant to the provisions of 5 U.S.C. section 553 and complete all rulemaking proceedings in accordance with this Court's opinion within one hundred eighty (180) days." *Public Citizen* v. *Heckler*, 653 F. Supp. 1229, 1242 (D.D.C. 1986). The proposal was published in the **Federal Register** of June 11, 1987 (52 FR 22340).

Therefore, consistent with the court decision, the agency is announcing that the stay of that portion of the standards of identity for milk, lowfat milk, and skim milk products that concern the requirement that certified fluid milk products for consumer use be pasteurized is hereby terminated.

List of Subjects in 21 CFR Part 131

Cream, Food standards, Milk, Yogurt.

PART 131—MILK AND CREAM

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10); *It is ordered* that the stay announced in the preamble of the **Federal Register** of December 5, 1974 (39 FR 42351) is terminated.

Dated: August 5, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-18191 Filed 8-6-87; 3:14 pm]

BILLING CODE 4160-01-M

21 CFR Part 1240

[Docket No. 81N-204C]

Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation requiring that milk and milk products in final package form for human consumption in interstate commerce be pasteurized. The final regulation does not apply to the interstate transportation of raw (unpasteurized) milk to dairy processing plants for pasteurization or to raw milk products in intrastate commerce. The final regulation also does not apply to milk and milk products for which an alternative to pasteurization is established in a standard of identity regulation.

EFFECTIVE DATE: September 9, 1987.

FOR FURTHER INFORMATION CONTACT: Robert J. Lenahan, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0162.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 11, 1987 (52 FR 22340), FDA issued a notice of proposed rulemaking in response to a decision by the United States District Court for the District of Columbia ordering "that the Food and Drug Administration and the Secretary of Health and Human Services publish in the **Federal Register**, a

Exhibit H

BEFORE THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

Farm-to-Consumer	:	
Legal Defense Fund	:	**Case No.**
8116 Arlington Blvd, Suite 263	:	
Falls Church, VA 22042	:	
	:	**Judge**
and	:	
	:	
Laurie Donnelly	:	
427 8th Street	:	
Sloan, IA 51055	:	
	:	
and	:	
	:	
Jennifer Allen	:	
3603 Ramelle Dr.	:	
Council Bluffs, IA 51501	:	
	:	
and	:	
	:	
Dr. Joseph Heckman	:	
19 Forman Ave.	:	
Monroe, NJ 08831	:	
	:	
and	:	
	:	
Dane Miller	:	
198 Slater Rd.	:	
Reading, PA 19605	:	
	:	
and	:	
	:	
Cynthea Lee Rose	:	
415 N. Main Ave.	:	
Maiden, NC 28650	:	
	:	
and	:	
	:	
Eric Wagoner	:	
310 Woody Rd.	:	

Royston, GA 30662 :
:
and :
:
Anne Cooper :
1104 Mill Pointe :
Bogart, GA 30622 :
:
and :
:
Michael Buck :
d/b/a Butter Patch Jerseys :
175 Dairy Lane :
Saluda, SC 29138 :
:
Plaintiffs :
:
v. :
:
Kathleen Sebelius, :
in her official capacity as Secretary, :
United States Department of Health :
and Human Services, :
200 Independence Avenue, S.W., :
Sixth Floor, :
Washington, D.C. 20201 :
:
and :
:
United States Department of :
Health And Human Services, :
200 Independence Avenue, S.W. :
Washington, D.C. 20201 :
:
and :
:
Margaret Hamburg, :
in her official capacity as :
Commissioner, United States :
Food and Drug Administration :
10903 New Hampshire Ave. :
Silver Spring, MD 20993-0002 :
:
Defendants :

PLAINTIFFS' COMPLAINT FOR DECLARATORY, PRELIMINARY AND OTHER INJUNCTIVE RELIEF

Pursuant to Fed. Rule Civ. P. 57 and 65(a), Plaintiffs hereby file their Complaint seeking declaratory, preliminary and other injunctive relief. Plaintiffs allege as follows:

GENERAL ALLEGATIONS

Nature of the Action

1. This is an action brought by Plaintiffs Farm-to-Consumer Legal Defense Fund (the "Fund" or "FTCLDF") and several of its members under, in part, the Constitutional Right to Travel; the Constitutional Right of Privacy; the substantive due process clause of the Fifth Amendment of the United States Constitution; Article 1, Section 1 of the United States Constitution (the Separation of Powers/Non-delegation doctrine); and the Administrative Procedure Act ("APA"), 5 U.S.C. 701, *et seq.*

2. Plaintiffs seek to enjoin the enforcement of 21 CFR 1240.61 (hereinafter "1240.61") and 21 CFR 131.110 (hereinafter "131.110") against them by the Food and Drug Administration ("FDA") and also seek a declaration that 1240.61 and 131.110 are unconstitutional as applied against them. The legislative authority for and the specific language of these agency regulations are addressed below in Count One of this complaint.

3. A preliminary injunction is necessary at the appropriate time because Plaintiffs will suffer irreparable, actual harm if enforcement of 1240.61 and 131.110 is not enjoined. Specifically, the individual Plaintiffs have already decided that complying with 1240.61 and 131.110 violates their liberties including but not limited to their constitutional right to travel and their constitutional right of privacy, and also violates their rights to substantive due process.