Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 16 2011

Gary Cox, Esq.
4240 Kendale Road
Columbus, Ohio 43220

Re: Initial Administrative Determination
Pursuant to 21 C.F.R. §§ 10.25(c) and 10.60

Dear Mr. Cox:

This letter constitutes the initial administrative determination pursuant to 21 C.F.R. §§ 10.25(c) and 10.60 that the Food and Drug Administration ("FDA" or "Agency") agreed to render in connection with *Farm to Consumer Legal Defense Fund v. FDA, et al.* (the "Litigation"), which is pending in the United States District Court for the Northern District of Iowa (the "Court").

On August 18, 2010, the Court issued a Memorandum and Order that, among other things, stayed the Litigation to provide your clients with an opportunity to file a Citizen Petition with the Agency pursuant to 21 C.F.R. § 10.30 in order to raise three specific questions. Your clients declined the opportunity provided by the Court to file a Citizen Petition. Following subsequent discussions involving you, the Agency, and the Department of Justice, the parties to the Litigation agreed instead that FDA would accept the referral of the three questions posed by the Court in accordance with the doctrine of primary jurisdiction and the procedures contemplated by 21 C.F.R. §§ 10.25(c) and 10.60. On September 17, 2010, the parties jointly proposed this plan to the Court, which the Court accepted and reduced to an order dated September 17, 2010.

The questions referred by the Court and accepted by FDA pursuant to the order dated September 17, 2010, are as follows:

> "Whether 21 C.F.R. § 1240.61 applies to and proscribes the conduct of the following persons:
>
> (A) persons who travel from one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members; or
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> (B) a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and deliver it to the principal in the principal's home state, where sales of raw milk are not permitted, where the principal then consumes the raw milk or gives it to the principal's friends or family members; or

(C) a producer of raw milk who sells raw milk in a state where it is legal to do so in an intrastate transaction to persons that he knows are from out of state?"

(September 17, 2010, Order, at 2-3). In responding to these questions, we have considered the Public Health Service Act, 42 U.S.C. § 264(a) ("PHSA"), 21 C.F.R. § 1240.61 (the "Regulation"), the proposed and final rules related to the issuance of 21 C.F.R. § 1240.61, a review of the Agency's history of enforcement discretion in connection with raw milk since the promulgation of 21 C.F.R. § 1240.61, and the materials cited herein.

I. Background

A. The Risks of Raw, Unpasteurized Milk.

Raw, unpasteurized milk[1] can contain a wide variety of harmful bacteria, including *Listeria monocytogenes, Escherichia coli* O157:H7, *Salmonella, Campylobacter, Yersinia, Mycobacterium bovis*, *Tuberculosis*, and *Brucella,* all of which can cause illness and possibly death.[2] In pregnant women, *Listeria monocytogenes*-caused illness can result in miscarriage, fetal death, or the illness or death of a newborn infant. *E.coli* O157:H7 infection has been linked to hemolytic uremic syndrome ("HUS"), a condition that can cause kidney failure and death.[3] Young children are particularly susceptible to contracting HUS, as recent experience in the United States has demonstrated.[4] As reported by the Centers for Disease Control and Prevention ("CDC"), between 1998 and 2008, 86 outbreaks of human infections resulting from the consumption of raw milk dairy products were reported. These outbreaks included a total of 1,676 reported illnesses, 191 hospitalizations, and two deaths.[5] Because not all cases of foodborne illnesses are recognized and reported, the actual number of illnesses associated with raw milk likely is greater.

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[1] The terms "raw milk" and "unpasteurized milk" are used interchangeably herein.

[2] *See* "Questions and Answers, Raw Milk," available at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm122062.htm; "The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk," FDA publication available at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm 079516.htm. *See also* Hayes, M. C. and K. J. Boor. 2001, Raw milk and fluid milk products, p. 59-76, In J. L. Steele and E. H. Marth (ed.), Applied Dairy Microbiology, Marcel Decker, Inc., New York, NY; Jayarao, B. M. and D. R. Henning, 2001, Prevalence of foodborne pathogens in bulk tank milk, Journal of Dairy Science, 84:2157-2162; Oliver, S. P., B. M. Jayarao, and R. A. Almeida, 2005, Foodborne pathogens in milk and the dairy farm environment: food safety and public health implications, Foodborne Pathogens and Disease, 2:115-119; Oliver, S. P., K. J. Boor, S. C. Murphy, and S. E. Murinda, 2009, Food safety hazards associated with consumption of raw milk, Foodborne Pathogens and Disease, 6: 793-806; and Van Kessel, J. S., J. S. Karns, L. Gorski, B. J. McCluskey, and M. L. Perdue, 2004, Prevalence of Salmonellae, Listeria monocytogenes, and fecal coliforms in bulk tank milk on US dairies, Journal of Dairy Science, 87:2822-2830.

[3] *Id.*

[4] *See* Centers for Disease Control Morbidity and Mortality Weekly Report (MMWR) dated June 13, 2008, "Escherichia coli 0157:H7 Infections in Children Associated with Raw Milk and Raw Colostrum From Cows --- California, 2006," *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a2.htm .

[5] This information has been compiled by the CDC from the information available in the National Outbreak Response System ("NORS"), *available at* http://www.cdc.gov/outbreaknet/nors/.

B. The Promulgation of 21 C.F.R. § 1240.61.

In 1985, after FDA had spent thirteen years studying the health risks of raw, unpasteurized milk, the Agency was sued by a public health advocacy group in the United States District Court for the District of Columbia for failing to take regulatory action to halt the distribution of raw milk. After considering the administrative record, the court found that there was "overwhelming evidence of the risks associated with the consumption of raw milk," and that it was "undisputed that all types of raw milk are unsafe for human consumption and pose a significant health risk." *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1238, 1241 (D.D.C. 1986) ("*Public Citizen*"); *see also id.* at 1232-33 n.3. According to the court, "[t]here [was] no longer any question of fact as to whether the consumption of raw milk is unsafe." *Id.* at 1241. Having found that the evidence had "conclusively" shown that raw milk was unsafe, the court ordered FDA to propose a rule "banning the interstate sale of all raw milk and raw milk products." *Id.*

Following the court's order in *Public Citizen,* FDA published a proposed rule to ban the interstate sale of unpasteurized milk. *See* Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 Fed. Reg. 22340 (June 11, 1987) ("Proposed Rule"). The Proposed Rule received many comments, only three of which were negative. *See* Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 Fed. Reg. 29509, 29511 (August 10, 1987). As reported in the Federal Register, the remaining comments "favored the proposed rule on the basis that the risks associated with consuming raw milk, including certified raw milk,[6] outweigh any benefits from its consumption. Commenters favoring the proposed rule include[d] the American Academy of Pediatrics, the National Milk Producers, the National Association of State Departments of Agriculture, the Centers for Disease Control, and numerous State departments of health." *Id.*

In considering whether to finalize the Proposed Rule, FDA found that the record "demonstrate[d] an association between the consumption of raw milk and the outbreak of disease." *See* 52 Fed. Reg. 29511. FDA's finding paralleled the conclusions of a study published in the Journal of the American Medical Association that "the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly." *Id.* Particularly persuasive to FDA were the results of a study performed by the California Department of Health Services ("CDHS") on the incidence of *Salmonella dublin* ("*S. dublin*") infections. *Id.* at 29511-12. FDA summarized that study as follows:

> [CDHS] has reported that 50 percent of all the S. dublin infection cases reported in California in 1984 involved the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though S. dublin is host adapted to cattle, only a small percent (15 percent or less) of cases

[6] The *Public Citizen* court described "certified raw milk" as unpasteurized milk produced by methods that comported with the standards established by the American Association of Medical Milk Commissions, a private trade organization comprising two major producers of certified raw milk in the United States in 1987. *Public Citizen*, 653 F. Supp. at 1231, n.2.

> report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting S. dublin is *158 times* greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk. CDHS considered this relative risk 'extremely large and among the largest obtained in any epidemiologic investigation.'

Id. (emphasis added).

Based on these and other findings,[7] FDA concluded that a final rule requiring the pasteurization of all raw milk and raw milk products in interstate commerce should issue. 52 Fed. Reg. 29513. Pursuant to its authority under the PHSA to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from one state to another,[8] FDA issued the final rule ("Final Rule"), which was codified as 21 C.F.R. § 1240.61 and which became effective on August 10, 1987. As set forth in the Final Rule in direct and unequivocal language:

> [n]o 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).[9]

The scope of the Regulation is limited by two important exceptions. First, by its terms, 21 C.F.R. § 1240.61 does not apply to purely intrastate sales of raw milk. *See also* 52 Fed. Reg. 29509 ("The final regulation does not apply to . . . raw milk products in intrastate commerce.") Second, the Regulation "does not apply to the interstate transportation of raw (unpasteurized) milk to dairy processing plants for pasteurization . . . ." *Id.*[10]

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[7] For instance, FDA concluded that "certification" programs could not provide a reliable index showing whether raw milk or milk products are contaminated with pathogenic bacteria. 52 Fed. Reg. 29512. FDA also concluded that pasteurization effectively eliminated harmful microorganisms in milk and that pasteurization did not significantly change the nutritive or immunologic value of milk. *Id.* at 29512-13.

[8] Under the PHSA, the Secretary of the Department of Health and Human Services is authorized to make and enforce regulations such as 21 C.F.R. § 1240.61 to prevent the introduction, transmission, or spread of communicable diseases from one state to another. *See, e.g., State of Louisiana v. Matthews*, 427 F. Supp. 174 (E.D. La. 1977) (holding that a ban on the inter- and intrastate sale of small turtles was authorized by 42 U.S.C. § 264(a) and was clearly reasonable to prevent interstate spread of disease).

[9] "Milk products" are defined in 21 C.F.R. § 1240.3(j) as "[f]ood products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals." "Pasteurized" and "pasteurization" are defined in 21 C.F.R. § 1240.61(b).

[10] The Regulation also notes the availability of alternative procedures to pasteurization, none of which are relevant here. 21 C.F.R. § 1240.61(a).

C. The Applicability of 21 C.F.R. § 1240.61 to Milk Products in Interstate Commerce.

The interstate distribution of raw milk to consumers is prohibited by 21 C.F.R. § 1240.61 because such milk is necessarily delivered into interstate commerce. An article is in interstate commerce if it is transported across state lines, but the concept of interstate commerce includes more than the act of carrying an article across state lines. Interstate commerce "includes the whole transaction for which such transporting is a part . . . ." *Barnes v. United States*, 142 F.2d 648, 650 (9th Cir. 1944); *see also Bruhn's Freezer Meats of Chicago, Inc. v. U.S. Dept. of Agriculture*, 438 F.2d 1332, 1339 (8th Cir. 1971) ("It is settled doctrine that where one purchases goods in one state for transportation to another, the interstate commerce transaction includes the purchase as well as the transportation.").

Because the entirety of a transaction is considered when establishing whether a product is in interstate commerce, a product that is "destined for sale in a state other than the place from which [it was] shipped" is therefore in interstate commerce. *See United States v. Food, 2,998 Cases . . . First Phoenix Group, Ltd.*, 64 F.3d 984, 988 (5th Cir. 1995). This was the holding, for instance, in *United States v. Vidal-Cruz*, where milk was deemed to have been delivered in interstate commerce because it had been "delivered . . . to a purchaser who [the seller] knew or intended would subsequently introduce the adulterated milk into the interstate market." 67 F. Supp. 2d 35, 41 (D.P.R. 1999).

Moreover, it has been settled law for nearly a century that an article that is purchased by a consumer and transported across state lines for his or her personal consumption is in interstate commerce. *See, e.g., United States v. Simpson*, 252 U.S. 465, 466-67 (1920) (fact that "liquor was intended for the personal use of the person transporting it is not material" to conclusion that the liquor was "transported in interstate commerce"); *Drown v. United States*, 198 F.2d 999 (9th Cir. 1952), *cert denied*, 344 U.S. 920 (1953) (sale to consumers who intended to transport product out of state constituted delivery into interstate commerce); *United States v. Sanders*, 196 F.2d 895 (10th Cir. 1952) (same); *see also Munson v. Richfield Oil Corp.*, 91 F. Supp. 171, 173 (S.D. Cal. 1950) ("gasoline purchased in one state and transported by its owner in his own automobile into another state for his own personal use" was in interstate commerce). *Cf. United States vs. Bongiorino*, 106 F.3d 1027, 1031 (1st Cir. 1997) ("The term 'commerce' in the Commerce Clause context is a term of art, and the Court consistently has interpreted it to include transactions that might strike lay persons as 'noncommercial.'").

In light of the foregoing case law, it is apparent that the sale of unpasteurized milk to a customer who intends to transport it out-of-state, either directly or through an intermediary, constitutes delivery into interstate commerce. Not only do direct shipments across state lines to consumers constitute interstate commerce, but under the above case law, a person who purchases unpasteurized milk in one state with the intent to take it to another state (either for personal use or to distribute to others) is engaging in interstate commerce.

Moreover, a person who has directly shipped unpasteurized milk to another state has likely "cause[d] to be delivered" the milk into interstate commerce in violation of the Regulation. This same conclusion holds with respect to a person who purchases raw milk with the intent to

carry it out of state for distribution to others or for his own personal consumption. In each case, the solicitation of the purchase has likely "cause[d]" the delivery of the milk into interstate commerce. Moreover, the person who carries raw milk across state lines and distributes it to others would likely be deemed to have either "sold" or "otherwise distributed" raw milk after shipment in interstate commerce in violation of the Regulation.

D. FDA's Exercise of Enforcement Discretion with Respect to Raw Milk.

Despite this clear and broad regulatory authority over the introduction of raw milk into interstate commerce, the Agency has consistently exercised its enforcement discretion with respect to consumers. In so doing, FDA has *never* sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption. Among other reasons, it would not constitute an efficient use of Agency resources to focus on end-users and consumers. This is true not only with respect to raw milk, but generally also with other products regulated by FDA. To the extent that the introduction of a food, drug, or medical device violates the law and constitutes a public health threat, it is almost always prudent for the Agency to focus its limited enforcement resources on the producers and distributors of such products.[11]

Producers and distributors of raw milk in interstate commerce, therefore, have been the object of the Agency's enforcement efforts. This focus is amply justified and warranted by epidemiological data demonstrating that the consumption of raw milk continues to pose a significant threat to public health. FDA believes that its efforts to enforce the law by preventing the interstate delivery and distribution of raw milk by producers and distributors materially improves the public health by preventing numerous illnesses, hospitalizations, and deaths.

A review of past raw milk-related enforcement actions by FDA reflects this regulatory strategy. Although FDA has not sought an enforcement action[12] against any individual consumers of raw milk, FDA has attempted to stop the interstate delivery of raw milk by producers and distributors. For instance, in 2010, at the government's request, the United States District Court for the Eastern District of California enjoined, under the PHSA and 21 C.F.R. § 1240.61, Organic Pastures Dairy Company, a California farm that was actively distributing its products to several other states and labeling its raw milk as "pet food" in an attempt to avoid regulatory scrutiny.

The Agency's advisory actions reflect the same focus. In 2007, FDA sent a warning letter to Forest Grove Dairy in Indiana, informing it that its flagrant interstate distribution of raw milk was illegal and must cease.[13] The dairy ignored FDA's warning and its products caused an

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[11] It is therefore no accident, for instance, that in the *Sanders* and *Drown* cases, *supra*, the Agency did not pursue remedies against the consumers of the unlawful products.

[12] Note that FDA does not have independent litigating authority and its enforcement cases are generally brought through the Department of Justice, which must agree independently to bring a case.

[13] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076271.htm .

outbreak of campylobacteriosis in Michigan in March, 2010.[14] Dee Creek Farm in Woodland, Washington, was the source of an *E. Coli* outbreak in 2005, and received a warning letter in 2006.[15] Similar warning letters have been sent to Rainbow Acres Farm in Pennsylvania,[16] Milky Way Farm in South Carolina,[17] Nature's Sunlight Farm in Pennsylvania,[18] Portage Prairie Pastured Poultry in Michigan,[19] Double O Farms in Kentucky,[20] and White Egret Farm in Texas.[21] It is noteworthy that *none* of these actions has involved isolated sales to out-of-state consumers. Rather, in *each* case, a producer of raw milk was found to have distributed raw milk into interstate commerce frequently and intentionally.

In the future, as in the past, FDA will make judgments about how best to protect the public health in light of the applicable law, competing health priorities, and Agency resources. Although enforcement priorities could possibly change, FDA has no present intent to alter significantly its raw milk-related enforcement activities. Producers and distributors of raw milk will remain subject to regulatory action, but it is highly unlikely that FDA would ever bring an enforcement action directly against a person who carried raw milk across state lines solely for his or her personal consumption. In any given case, of course, FDA's approach towards a consumer might change if he or she were found to frequently distribute raw milk to others, such that the "consumer" would be more aptly described as a "distributor."

II. FDA's Response to the Referred Questions.

Turning to the questions referred by the Court to FDA for initial administrative determination, each of the questions can be answered through the application of the principles set forth above.

Question A: "*Whether 21 C.F.R. § 1240.61 applies to and proscribes the conduct of . . . persons who travel from one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members.*"

Answer: As set forth above in Section I.D., FDA has never sought to bring an enforcement action against a person because he or she crossed a state boundary to purchase and return with raw milk solely for his or her own use, and FDA has no present intent to bring an action against such a person in the future. Nevertheless, as set forth above in Section I.C., by engaging in such activity, the hypothetical interstate traveler in this example would have "cause[d]" raw milk "to be delivered into interstate commerce" in violation of 21 C.F.R. § 1240.61.

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[14] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm206311.htm .
[15] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075889.htm .
[16] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm209276.htm .
[17] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm212541.htm .
[18] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076470.htm .
[19] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076284.htm .
[20] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075939.htm .
[21] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146711.htm .

Likewise, although the distribution of raw milk following its shipment in interstate commerce is proscribed by 21 C.F.R. § 1240.61, FDA has never requested an enforcement action against such persons on the ground that they have given raw milk from out-of-state to friends or family members, and FDA has no present intent to seek such an enforcement action in the future. Nevertheless, to the extent that the hypothetical interstate traveler in this example were to dispense significant volumes of raw milk to others on a regular basis, FDA cannot rule out the possibility that such a person would attract the scrutiny of FDA on the ground that he or she is more aptly described as a distributor of raw milk.

Question B: "*Whether 21 C.F.R. § 1240.61 applies to and proscribes the conduct of . . . a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and deliver it to the principal in the principal's home state, where sales of raw milk are not permitted, where the principal then consumes the raw milk or gives it to the principal's friends or family members.*"

Answer: In this question, a hypothetical agent is purchasing raw milk for delivery to persons in other states. As described above in Section I.C., the purchase of a product in one state for delivery into another state constitutes interstate commerce. The hypothetical agent in this question violates 21 C.F.R. § 1240.61, first by causing raw milk to be delivered into interstate commerce, and second by "distributing" the raw milk to another after shipment in interstate commerce.

Whether FDA would consider an enforcement action against the hypothetical agent in this case would depend on the nature and extent of his or her actions. If the agent were simply to purchase and make a single delivery of milk to an out of state consumer, FDA would not likely bring an enforcement action, consistent with past practices and current intentions. To the extent, however, that the agent is engaged in the organized distribution of raw milk to multiple consumers across state lines, this type of activity would be far more likely to attract regulatory scrutiny.

Question C: "*Whether 21 C.F.R. § 1240.61 applies to and proscribes the conduct of . . . a producer of raw milk who sells raw milk in a state where it is legal to do so in an intrastate transaction to persons that he knows are from out of state?*"

Answer: In this question, the hypothetical producer is knowingly selling raw milk to out of state customers. Assuming that the hypothetical customer intends to transport the raw milk to another state,[22] as set forth above in Section I.C., the sale of the raw milk would constitute delivery into interstate commerce. Based on the holdings in the *Simpson*, *Sanders*, and *Drown* cases, *supra*, this conclusion would hold regardless of whether the purchaser claimed that he or she intended to consume the raw milk personally.

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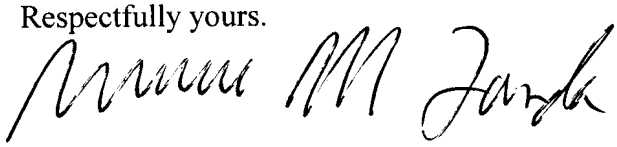
[22] For purposes of this response, FDA has not considered whether the purchase of raw milk by an interstate traveler for consumption *within the state of purchase* would constitute interstate commerce. Although there is ample authority that such a purchase could constitute interstate commerce (*see, e.g., Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 256 (1964)), FDA does not interpret the Court's referral to raise this specific issue.

Whether or not FDA would consider an enforcement action against the hypothetical seller in this question would turn on many other facts not presented. For instance, to the extent that the producer solicits interstate sales and/or regularly sells raw milk that is ultimately transported across state lines, FDA would review the facts for possible regulatory action.

III. Conclusion

As set forth above, FDA and recognized health authorities consider the interstate distribution of raw, unpasteurized milk to constitute a significant threat to public health; accordingly, applying the foregoing considerations, FDA will seek to enforce the law as it becomes aware of potential violations of the PHSA and 21 C.F.R. § 1240.61. FDA, however, intends to continue to direct its limited resources to enforcement actions against those who produce and/or distribute raw, unpasteurized milk in interstate commerce. FDA has not brought enforcement actions against individual consumers in the past and, subject to the considerations described above, has no present intent to do so in the future. Similarly, if a producer solicits interstate sales and/or regularly sells raw milk that is ultimately transported across state lines, FDA would review the facts for possible regulatory action.

Respectfully yours.



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