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Living Foods For Life

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May 31st 2013

Division of Dockets Management
FDA, Department of HHS
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket: FDA-2009-P-0003, Citizens Petition

To Whom It May Concern:

On December 22, 2008, I submitted a Citizen's Petition on behalf of Organic Pastures Dairy Company ("Organic Pastures") seeking an amendment to 21 C.F.R. 1240.61. On July 17, 2009, FDA sent me a letter acknowledging receipt of that 2008 petition. On February 26, 2013, FDA denied the petition ("denial").

Pursuant to 21 C.F.R. 10.25, 10.30, 10.30(j) and 10.45(f), I hereby submit this Citizen's Petition on behalf of Organic Pastures as a supplement to the 2008 petition and seek additional administrative action in the form of a modification to FDA's denial dated February 26, 2013 ("Petition to Modify"). Pursuant to 21 C.F.R. 10.20(c), all material submitted in support of the 2008 petition shall hereby be incorporated in this Petition to Modify. Moreover, all material submitted in support of this Petition to Modify shall hereby be incorporated in the 2008 petition.

A. Action Requested

Organic Pastures requests that the Commissioner review the information in support of the 2008 petition and the additional information in support of this Petition to Modify and take additional administrative action in the form of a modification to the February 26th 2013 denial. The modification would allow the interstate delivery or sale or distribution of raw milk and raw dairy products from the seller's state to the destination state. For purposes of this Petition to Modify, references to raw milk include references to raw dairy products.

B. Statement of Grounds

1. Access to Raw Milk is in the Public's Interest Because It Promotes a Healthy Diversity of Gut Bacteria that is Essential for Human Health.

In its denial, FDA claims that the original 2008 petition was not "in the public interest." However, as explained below, access to raw milk *is* in the public's interest.

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The National Institutes of Health has initiated a new project called the Human Microbiome Project ("HMP"). ***See Exhibit* 1**. The HMP recognizes that bacteria in, throughout and on our bodies (including our guts) outnumber our human cells by ten to one. NIH concedes that this community of gut bacteria "remains largely unstudied, leaving their influence upon human development, physiology, immunity and nutrition almost entirely unknown." Thus, the HMP was established with the purpose of analyzing the role of bacteria "in human health and disease."

In order to understand the role of bacteria in human health and disease, the HMP has funded 15 projects. ***See Exhibit* 2**. These 15 projects include, but are not limited to, such topics as "Diet, Genetic Factors, and the Gut Microbiome in Crohn's Disease;" "The Role of the Gut Microbiota in Ulcerative Colitis;" "The Role of the gut Microbiota in Obesity in the Amish;" and "Foregut microbiome in development of esophageal adenocarcinoma." The HMP has also concluded that "future study" is needed that will "help to unravel" how a healthy gut affects our health. ***See Exhibit* 3**, pg. 6. Thus, while one branch of the federal government (NIH) understands the importance that a diverse gut bacteria plays in human health, another branch of the federal government (FDA) refuses to recognize this issue. Organic Pastures asks that FDA join NIH in recognizing the importance of bacteria to human health.

Dr. Bonnie Bassler is a Professor at Princeton University and worked on the Human Genome Project. Her TED talk explains the role of these bacteria in human health. ***See Exhibit* 4**. To summarize Dr. Bassler, humans are driven by bacterial genetics and sharing of bacteria DNA. Ninety-eight percent (98%) of what makes us human is genetically bacterial. Bacteria are critical to how we function. When our bacteria are missing we get sick. This defines the condition classified as "autoimmune diseases." Other disorders, such as diabetes, asthma, allergies and arthritis, are associated with low immunity and lack of biodiversity in the gut. In the modern American diet there is virtually no bacteria. Improving access to raw milk can remedy this defect and improve the health of society.

A Yale study of lab rats showed that when bacteria were removed from the gastrointestinal tract of a group of rats, those rats began to present with diabetes. ***See Exhibit* 5**. When common gut bacteria were introduced and supported in lab rats, however, those rats did not suffer diabetes. The study concluded that non-obese diabetic mice "exposed to harmless bacteria normally found in the human intestine were significantly less likely to develop diabetes." *Id.* Consequently, the public interest is best served when disease is prevented and immunity is improved to avoid and protect against disease and infection, including diabetes.

In addition to providing good bacteria necessary for human health, raw milk has been found to help the body build immunity to certain bad bacteria. For example, *Campylobacter* is the most common food borne pathogen in America. Yet, it was discovered as long ago as 1987 that the more one consumes raw milk, the greater the likelihood of developing immunity to *Campylobacter*. In one study, raw milk consumers were found to have immunity and a positive titer to *Campylobacter*. ***See Exhibit* 6**.

Intriguing findings from the University of California, Davis International Milk Genomics Consortium (IMGC) strongly suggest that raw milk (from whatever mammalian species) is not a

simple food. Instead, it is a highly complex multiple mission baby support system that builds immunity, is complete and ready for digestion, assists in colonization of the gut with essential bacteria required for enzyme creation, and protects against pathogen invasion. Raw milk is a complex bioactive food that is not simply some fat, some protein and some sugar as suggested by FDA-approved nutrient labels. The FDA claims that pasteurization has little or no effect on the nutritive value of milk. The attached "Splash Newsletters" written by the IMGC staff and their contents, however, strongly contradict FDA's policy position:[1]

1. April 2012 issue of Splash Newsletter: (***See Exhibit* 7**)
    a. the role of lactoferrin and bacteria in the development and protection of a newborn baby's immune system;
    b. how the consumption of raw cheese decreases blood sugar levels and fat tissue in obese/diabetic mice;
    c. how two proteins in raw milk help a baby's brain grow and develop;
2. June 2012 Splash Newsletter: (***See Exhibit* 8**)
    a. specialized sugars in raw milk do not feed the baby, they instead feed the bacteria inside the baby;
    b. essential gut bacteria are found in the mother's milk and become part of the babies biome and essential gut flora;
    c. the critical role of bacteria and specialized sugars to "close the leaky gut gaps of newborns;"
    d. raw milk reduces severe GI tract disorders and its relationship to beneficial bacteria;
3. September 2012 Splash Newsletter: (***See Exhibit* 9**)
    a. breast milk contains bacteria;
    b. essential role of fats in milk for brain development, etc.;
4. October 2012 Splash Newsletter: (***See Exhibit* 10a**)
    a. pasteurization destroys beneficial, heat sensitive parts of raw milk;
    b. GABRIELA study noted;
    c. benefits of raw milk for allergies and asthma;
    d. AMISH study, PASTURE Cohort and GABRIELA studies all given support and acclaim;
    e. strong evidence that raw milk benefits children;
5. November 2012 Splash Newsletter: (***See Exhibit* 11**)
    a. the secret to managing allergies and asthma lies in raw milk;
    b. microbes and gut bacteria rule the world;

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[1] Based on understanding and belief, FDA demanded in 2012 that IMGC immediately remove the October 2012 article "The evidence around raw milk" and its findings from public view and access. *See* Affidavit of Mark McAfee, attached hereto. FDA's demand is implied by the "editor's note," "clarification" and "disclaimer" noted in a modified article which makes it clear that at one time the article was removed yet then allowed to be re-published on the condition that the note, clarification and disclaimer be included. ***See* Exhibit 10b**. It is clear that the FDA knows the connection between raw milk and its prevention or alleviation of allergies and asthma and immune enhancing properties and FDA should consider this connection when acting upon this Petition to Modify.

19. These intestinal problems and severe allergies are not a mystery. As recognized by the NIH and its HMP, bacteria play a critical and increased role in our immune system and our health.

However, internationally published articles and studies on raw milk state as their primary finding that raw fresh milk is associated with reduction of allergies and prevention of asthma. *See, e.g.*, PARSIFAL Study (***Exhibit* 20**); GABRIELA Study (***Exhibit* 21**); Amish Study (***Exhibit* 22**). No study to-date contradicts these studies. To the contrary, a recent study confirms the findings of the PARSIFAL, GABRIELA and AMISH studies. *See, e.g.*, "Prenatal and early-life exposures alter expression of innate immunity genes: the PASTURE cohort study," Loss G., et al., *J Allergy Clin Immunol*. 2012 Aug; 130(2):523-30. ***See Exhibit* 23**. The PASTURE study found that pregnant mothers drinking raw farm milk enhance newborns' immunity during their first year of life. Thus, while pasteurized milk is the most allergenic food in America, raw milk intended for human consumption is not and instead promotes a strong immune system.

FDA may claim that the PARSIFAL study "is about farm milk, not raw milk." However, the authors of the PARSIFAL study found that the two most likely explanations for the reduced risk of asthma and rhinoconjunctivitis associated with drinking it were (1) much of the "farm milk" was raw, and (2) the milk tended to be from grass-fed cows. The PARSIFAL study also found that "half of the parents indicated that they usually did not boil the milk before consumption." In any event, the GABRIELA study confirmed the PARSIFAL results because the GABRIEL study found that asthma and allergies were *inversely associated* with raw farm milk but was not inversely associated from boiled farm milk.

FDA may also argue that the GABRIELA study does not recommend raw milk consumption because it "might contain" pathogens. However, the GABRIELA study was not designed to measure risk, i.e., nowhere in the GABRIELA study was there any analysis of the dose-response relationship, the dynamics of pathogen prevalence, dose-response, host factors, storage, the risk per serving, risk per consumer, rate of morbidity-hospitalization-mortality, and risk by demographic and/or immunologically susceptible groups. To the contrary, GABRIELA was designed to measure the effects of raw milk consumption on allergies and asthma. Consequently, FDA cannot compare the GABRIELA study to the other, more recent QMRAs conducted in Europe to suggest that GABRIELA supports the notion that raw dairy products constitute a "high risk" food group. ***See*** Section 3 below, ***Exhibits* 39, 40, 41**.

Not only is raw milk in the public's best interest as an alternative to a known allergen that causes death, the public has displayed huge support for raw milk. At least 3% of the United States population, or more than 9 million people, consume raw milk regularly. ***See Exhibit* 24**, pg. 14/29. In addition, hundreds of people have held demonstrations in front of the FDA offices in Maryland and other locations demanding that the FDA allow raw milk to be shipped over state lines. ***See Exhibits* 25, 26, 27**. FDA's position that raw milk is not in the public's interest is in conflict with the scientific information and consumer experience to the contrary. At the same time that demand for raw milk increases, pasteurized milk sales fall every year. Indeed, from 1960 to 2011 the total decline in consumption of plain whole milk has fallen 81%. ***See Exhibit* 28**.

Increasing access to raw milk is also being espoused by farming organizations. In March 2013, The National Farmers Union (NFU), one of the oldest farmers organization in America (formed in 1902), voted and passed policies in support of:

- Universal access to raw milk for all Americans
- Responsible standards for raw milk production.
- Single source raw milk bottling. No outsourcing of raw milk, "One bottle-One farmer".
- Interstate transport of raw milk for human consumption.

***See Exhibit* 29**, page 9/9.

This action by the delegates of the NFU signals a bell weather event. Lobbyists in Washington that are now working on the farm bill will use the NFU policy manual to determine the basis of farm policy. Organic Pastures, and certainly the NFU, hope that the FDA will be in front of this issue, meeting with farmers to develop standards and policies for this high demand and high value food, especially in light of the declining demand for fluid pasteurized milk.

Given the known nutritional qualities of milk, providing an alternative to pasteurized milk is in the public's interest. Given the proven health benefits of raw milk and the increased public demand for this food, it is undoubtedly in the public's interest for FDA to foster and promote the availability of clean, responsibly produced raw milk.

3. A Comprehesive Look at the Data Shows that Responsibly Produced Raw Milk is Safe and Should Not Be Treated Differently From Other Foods in Interstate Commerce.

In its denial of February 26th, the FDA referred to data that supported its position but ignored its own data that conflicted with its position. Specifically, the FDA failed to consider the number of illnesses and deaths caused by human consumption of *pasteurized* milk and other foods.

For example, the FDA failed to cite to the more than 1600 illnesses and 7 hospitalizations that occurred from CDFA inspected pasteurized milk in July of 2006. ***See Exhibit* 30**. Nor did it refer to the 8,385 people who got sick from eating greens-based salad; the 3,084 people who got sick from eating eggs; the 3,081 who got sick from eating tomatoes; or the 1,900 who got sick from eating lettuce. ***See Exhibit* 31**, Table 5. In addition, in 2012 spinach and leafy greens laden with *E. coli.* continue to sicken and hospitalize people in multiple states but are free to be shipped all over America. ***See Exhibit* 32**. None of these foods are banned from interstate commerce and none of these foods must be pasteurized or sterilized before being eaten.

FDA also failed to cite to the fourteen people who *died* from consuming pasteurized milk in Massachusetts in 1983. ***See Exhibit* 33**, pg. 4/8. The FDA also omitted three *deaths* from consuming pasteurized milk in 2007 that occurred at Whittier Farms in Massachusetts. ***See Exhibit* 34**. FDA also failed to refer to the 4 *deaths*, which included one fetal death, and 20 hospitalizations that resulted from consuming cheese made from pasteurized milk in 2012. ***See Exhibit* 35**, pg. 2/4.

By way of comparison with other foods permitted in interstate commerce, FDA estimates that oysters *kill* an average of 16 people per year and admits that cantaloupe *killed* at least 36 people in 2011 and 2012. ***See Exhibit* 36** (pg. 6/66) and ***Exhibit* 37**. FDA failed to address this data in its denial as well. Yet cantaloupe and oysters can be shipped across America without prohibition.

The FDA has pointed to *Listeria* as a food-borne pathogen associated with raw milk and the alleged dangers of *Listeria* and raw milk on pregnant women. ***See Exhibit* 38**. In reality, CDC has few, if any, incidences of miscarriages from *Listeria* and raw milk that instead relate to thermalized cheeses or pasteurized milk.

To the contrary, several recent European scientists have performed "Quantitative Microbial Risk Assessments" (QMRAs) on the alleged risks of consuming raw milk. *See, e.g., Quantitative Risk Assessment of Verocytotoxin-Producing Escherichia coli* 0157 and *Campylobacter jejuni* related to consumption of raw milk in a province in Northern Italy, *J Food Prot.* 75:2031-2038 (Giacometti *et al* 2012) (***Exhibit* 39**); Quantitative risk assessment of *listeriosis* due to consumption of raw milk, *J Food Prot.* 74:1268-1281 (Latoree *et al* 2011) (***Exhibit* 40**); Quantitative microbial risk assessment for *Staphylococcus aureus* and *Staphylococcus* enterotoxin A in raw milk, *J Food Prot.* 88:1219-1221 (Heidinger *et al* 2009) (***Exhibit* 41**). These QMRAs have utilized standard food safety measures employed by FDA, the United Nations and the European Union, including analyzing the dynamics of pathogen prevalence, dose-response, host factors, storage, etc. These QMRAs then take these data to establish the risk per serving, risk per consumer, rate of morbidity-hospitalization-mortality, and risk by demographic and/or immunologically susceptible groups.

All of these QMRAs found that raw milk presents either a "very low" or a "low risk" food against *Campylobacter*, *Listeria*, and *Staphylococcus aureus*. Moreover, these QMRAs found a "low risk" of Hemolytic uremic syndrome (HUS) from *E. coli* 0157 and that *Listeria* is *not* associated with the consumption of raw milk or miscarriages. Significantly, there is no current QMRA for *Salmonella*. These QMRAs all contradict long-standing public health perspectives, including FDA's, and undermine the basis of prohibiting the interstate distribution of raw dairy products.

FDA also claimed in its denial that in September 2006 three children in California were possibly made ill from drinking raw milk. However, FDA failed to recognize there was a national spinach outbreak involving 26 States at the same time that caused illnesses. In fact, FDA failed to report the 205 people that got sick from eating spinach at the exact time that the California raw milk recall occurred. ***See Exhibit* 42**.

Finally, relying on data from the California Department of Health Services collected from before 1987, FDA argued in its denial that raw milk is unsafe. Those pre-1987 data present *Salmonella* outbreaks and its apparent association with "Certified Raw Milk" during the 1980s. However, the number of outbreaks associated with *Salmonella* in raw milk has all but disappeared since then. Specifically, at no time in the last 15 years has the California Department of Health Services or any other branch of California government collected any data

showing a single instance of *Salmonella* illness in California associated with the consumption of Grade A raw milk. Indeed, of the two California state Grade A authorized raw milk producers, no *Salmonella* has ever been found in any environmental sample or in any product samples taken from those two authorized raw milk producers. One of those dairies, Claravale, has been in operation since 1927. The other, Organic Pastures, has been in operation since 1999. Neither dairy has ever produced any milk for human consumption that has had *Salmonella* in it. *See* McAfee Affidavit.

In denying Organic Pasture's 2008 petition, the FDA failed to take a comprehensive look at food safety data. With this Petition to Modify, Organic Pastures respectfully requests that FDA now do so.

4. No Food Can Be Guaranteed Safe and Raw Milk and Raw Dairy Products Should Be Treated Like All Other Foods.

In its denial of Organic Pasture's original petition, FDA found that "there is no reliable method available to guarantee that raw milk from a state-regulated farm or raw milk manufacturer is or will be free of pathogens, or that raw milk from any such farm or manufacturer will not cause disease." However, no food is "guaranteed" to be 100% safe.

FDA states in one of its videos that pasteurization "kills disease causing bacteria," suggesting that pasteurized milk is guaranteed to be safe. *See* http://www.fda.gov/Food/ResourcesForYou/consumers/ucm079516.htm#video. This suggestion, however, is misleading. In fact, 14 people *died* from consuming pasteurized milk in 1983, three *deaths* occurred from consuming pasteurized milk in 2007, and 4 *deaths* (which included one fetal death) resulted from consuming cheese made from pasteurized milk in 2012. ***See Exhibits* 33, 34, 35**. Consequently, "pasteurization" is no guarantee of food safety.

On that same website FDA suggests that ice cream made from raw milk is an "unsafe" food to eat. However, FDA admits that raw eggs (not raw milk) may actually be the cause of illness in homemade ice cream. Yet there is no FDA prohibition against the transport or sale of raw eggs over state lines.

FDA's denial also references "49 deaths from raw milk" in its data. However, this data was from a Jalisco Cheese product that was labeled as a *pasteurized*, not raw, product. In fact, it was reported that the *Listeria* causing the 49 deaths did not come from the dairy farm itself; instead, it was "found in abundance" at the cheese processing plant "where unlicensed employees were being allowed to pasteurize milk." Jalisco Cheese sued its milk supplier but the milk supplier was found not liable because *Listeria* was never found in its milk or herds. ***See Exhibit* 43**. FDA's citation to this data to support its denial of Organic Pasture's original petition is therefore improper and disingenuous.

Essentially, there are no absolute guarantees for food safety with *any* food. All foods can potentially be dangerous to certain consumers with certain health conditions. Pasteurized milk is no exception; 14 people *died* from consuming pasteurized milk in 1983 (***Exhibit* 33**), three *deaths* occurred from consuming pasteurized milk in 2007 (***Exhibit* 34**), and 4 *deaths*, which

included one fetal death, resulted from consuming cheese made from pasteurized milk in 2012 (***Exhibit* 35**). Moreover, an average of 16 people per year die from eating oysters (***Exhibit* 36**) and thirty-six people died in 2011 and 2012 from consuming cantaloupe (***Exhibit* 37**). Thus, for FDA to require a "guarantee" of safety from raw milk and raw dairy products when not requiring the same from other foods is, in part, arbitrary and capricious.

Although there is no "guarantee" of safety for any food, the associated risks are generally outweighed by the need and desire of the American consumer to have access to whole, healthy, nutrient dense foods. With respect to raw milk produced under State regulations, the risks are clearly outweighed by the benefits such that interstate access to raw milk is in the public's interest. Indeed, at least 28 States allow the sale of raw milk and raw dairy products in one form or another. Some of those States, and their respective citations to regulatory authority creating a comprehensive regulatory program over raw milk, are identified below:

1. Arizona, A.R.S. 3-601 *et seq.*, Ariz. Admin. Code R3-2-801 *et seq.*;
2. California, Cal. Food and Agric. Code 35891 *et seq.*, Cal. Admin. Code, Title 3, §400 *et seq.*;
3. Connecticut, C.G.S.A. 22-127 *et seq.*, Regs. Conn. State Agencies, §22-203c-6 *et seq.*;
4. Maine, M.R.S.A. 2900 *et seq.*, 01-001 CMR Ch. 329, §1 *et seq.*;
5. New Hampshire, N.H. Rev. Stat §184.30-c, *et seq.*, N.H. Code Admin. R. Mil 301.01 *et seq.*;
6. Pennsylvania, 31 P.S. §645 *et seq.*, 7 Pa. Code §59a.401 *et seq.*

Thus, the presence and existence of a State regulatory program is the best evidence that raw milk and raw dairy products are safe. Otherwise, FDA's regulatory program is not a guarantee that *any* of the foods it regulates is safe.

FDA may argue that State testing requirements are not required for "each shipment" of raw milk. FDA may also argue that State testing requirements "do not provide any information as to the presence or absence of harmful bacteria." Thus, argues FDA, no State requires tests for raw milk in a manner that "ensures safety." However, Organic Pastures is not aware of *any* FDA requirement for *any* food that requires testing for "each shipment" of that food, nor of *any* FDA requirement that *any* food must be tested to determine "the presence of absence of harmful bacteria" for each shipment of food. Indeed, and as already demonstrated above, pasteurization itself is no guarantee that milk is free from harmful pathogens, given the 70 deaths that have occurred from consuming pasteurized dairy products since 1983 (14 deaths in 1983, 3 deaths in 2007, 4 deaths in 2012, and 49 Jalisco Cheese deaths in 1985). Significantly, FDA routinely relies on its "adulteration" provisions of 21 U.S.C. §342 to protect public safety and it should do so with raw milk and raw dairy products as well.

In addition to State regulations to ensure safety, the Raw Milk Institute (RAWMI) (www.rawmilkinstitute.org) has published voluntary food safety standards, voluntary food safety plans, and voluntary testing protocols that address the concerns of the FDA. ***See Exhibit* 44**. Farmers in multiple states use these voluntary standards and they have been shown to be very effective. *See* McAfee Affidavit. So far no illnesses or pathogens have been found at any of the operations listed at RAWMI. *Id.* RAWMI Risk Assessment Management Plans (RAMP) are developed not only by Ph.D. experts from all over the world but also with assistance from experienced raw milk producers that produce under the highest standards and very tough regulatory environments. *Id.* These voluntary standards demonstrate the low risk associated with the production of raw milk for human consumption. When a farm adopts very strict standards from grass to glass, the resulting raw milk is very safe. It is clear that when coliforms rarely reach above 5 and conditions are correct pathogens are simply not present or do not contain enough concentrations to be detected or cause illness.

The presence of one pathogen will not necessarily cause illness. By the same token, pasteurization does not always works effectively to kill all pathogens. I personally attended the April 2009 National Conference on Interstate Milk Shipments (NCIMS) convention in Florida. During that convention, a conference attendee recommended that because some pathogens had become heat resistant to pasteurization temperatures, post-pasteurization pathogen testing should be initiated. The FDA staff expert in attendance blurted out immediately "Lord no...we might find a pathogen, then what would we do?" *See* McAfee Affidavit.

The idea that all raw milk must be perfectly sterile or guaranteed safe is unreasonable. Many other foods do not require testing yet they are commonly uncooked and consumed raw. These foods include:

- Sushi
- Eggs
- Vegetables
- Fresh squeezed raw juices
- Raw oysters
- Sprouts

Unlike raw milk, however, these foods are not subject to a ban in interstate commerce.

Thus, for FDA to require a "guarantee" of safety from raw milk and raw dairy products is, in part, arbitrary and capricious.

5. Advances in Technology and Testing Make Raw Milk Safe and it Should Not Be Treated the Same as Raw Milk Intended For Pasteurization.

FDA claims in its denial to Organic Pasture's original petition that it is "unaware of any advancements in the understanding of microbiology which would ensure the safety of raw milk." Therefore, Organic Pastures hereby submits the following information for FDA's consideration.

A study conducted in 2000 by *Pitt, et al.*, "Investigation of the antimicrobial activity of raw milk against several foodborne pathogens," *Milchwissenschalt*, 55 (5) 2000, p. 249-252, concludes that raw milk kills all *Listeria monocytogenes* after 56 hours of inoculation. ***See Exhibit* 45.**

FDA claims in its denial that it is "unaware of any scientific data" which contradicts its 1987 conclusion that pasteurization "does not significantly change the nutritive or immunologic value of milk." Every month the UC Davis IMGC "Splash Newsletter" exposes new information about how pasteurization and homogenization changes raw milk. Science proves that when milk is pasteurized, it becomes non-digestible, very allergenic, there are fat changes, enzymatic changes, and anti-body changes, and its protein becomes denatured. ***See Exhibits* 7-15.** To quote from one Splash Newsletter: "will store bought milk provide the desired benefits? The answer to that question is unfortunately NO." Without justification, however, FDA has demanded that the Splash Newsletter be suppressed and removed from public view. Again, Organic Pastures hereby requests that FDA reconsider the information presented in the Splash Newsletters.

In its denial, FDA suggests that 11% of "raw milk samples taken from farm bulk tanks" showed the presence of *Salmonella*. However, FDA misstates and missapplies the data from the van Kessel, *et al.* study.

In the study by van Kessel, *et al.*, the bulk tanks that were sampled were not located on farms that produced raw milk intended for human consumption. Instead, bulk tanks in the van Kessel study were located on farms whose raw milk was intended for pasteurization. Moreover, the van Kessel study concluded that "inappropriate handling of raw milk" could result in pathogen growth, suggesting that "appropriate" handling minimizes the growth of pathogens. As required by State regulations and pursuant to RAWMI's voluntary standards, a farm that produces raw milk that is intended for human consumption is operated completely differently from a farm that produces raw milk intended for pasteurization, i.e., it handles raw milk appropriately. *See* McAfee Affidavit. Thus, the FDA's reliance on the van Kessel data to support its denial is improper.

In addition, current milk filter tests are 3 to 10 times more pathogen-sensitive than previously used milk sample tests. Moreover, detection rates of pathogens have recently been enhanced, allowing mitigation of any perceived risk associated with production of raw dairy products.

Organic Pastures attempted to produce raw milk safety data to the FDA at the April 2009 NCIMS convention held at Orlando, Florida. The data was about 5 inches thick and documented pathogen tests performed over a seven-year period in California by State certified laboratories of raw milk that was intended for human consumption. The results of the analysis of these data is clear: no *Salmonella*, no E.coli and no *Listeria* were detected in any samples during this 7 year period of time of raw milk that was intended for human consumption. Unfortunately, FDA staff refused to receive or review these data. *See* McAfee Affidavit. The FDA further refused to receive the PARSIFAL study of 14,900 children in EU showing dramatically lower rates of asthma and allergies when consuming raw milk. *See* McAfee Affidavit.

Organic Pastures hereby requests that the FDA divide raw milk into two clear and distinct food categories; one that is intended for human consumption and one that is intended for pasteurization. Each should be measured and regulated separately with the appropriate respective standards and measures. At least 28 States currently do this. FDA should too.

At this time the FDA has but one rule, which is that all raw milk presents the same level of risk and all raw milk must therefore be pasteurized. However, this is not what has been shown to be true at the State level. FDA's refusal to recognize the difference in standards between raw milk intended for human consumption and raw milk intended for pasteurization is, in part, arbitrary and capricious.

C. Environmental Impact

If raw dairy products were more readily available then there would need to be more dairy farmers engaged in sustainable agricultural practices to meet that demand; conventional agriculture cannot meet that demand because of their filthy operational practices that rely on pasteurization as a cure all. An increase in the number of farmers engaged in sustainable agricultural practices, such as organic practices, leads to an increase in energy efficiency. ***See Exhibit* 46**. An increase in energy efficiency leads to an increase in alternative energy technology, for example, more anaerobic digesters on dairy farms. ***See Exhibit* 47**. Also, sustainable practices conserve natural resources, increase yields, and improve food security. ***See Exhibit* 48**.

Thus, making raw dairy products more available would lead to beneficial environmental benefits such as energy efficiency, alternative energy developments, and conservation of natural resources.

D. Economic Impact

The existence of these food safety standards for the production of raw milk has enabled liability insurance companies to see and appreciate the low risk associated with the production of raw milk. Dairy farmer Charlotte Smith was quoted an insurance premium of $10,000 per year for her raw milk operations in Oregon before she was listed by RAWMI. *See* Affidavit of Charlotte Smith attached hereto. After being listed and posting her written comprehensive food safety plan and her concomitant test results, the quote dropped to $750 per year for the same $1 million in coverage. *Id.* RAWMI listed farmers are low risk and this is a fact reflected by the insurance industry numbers.

The insurance industry knows that tested, properly manufactured raw milk is low risk. The Insurance industry studies risk and it understands how responsibly produced raw milk verses other foods and even pasteurized milk compare on the risk scale. The insurance industry understands that dirty, high bacteria level, raw milk intended for pasteurization needs to be pasteurized, yet clean raw milk intended for human consumption that is tested does not need to be pasteurized to be a low risk food. When the insurance industry makes a risk assessment, it is based on real numbers, real investigations and real risks.

Not only will dairies that produce raw milk intended for human consumption see a decrease in their insurance premiums, they can also expect to see an increase in their sales. For example, prior to December 22, 2008, Organic Pastures sold raw dairy products not only within California but also across State lines. From 2008 to the present, Organic Pastures has been prohibited from selling raw dairy products across State lines because of, in part, the prohibition in 21 C.F.R. 1240.61. Defendants' denial of Organic Pastures' petition has caused economic loss to Organic Pastures in the amount of approximately $650,000 per year. *See* McAfee Affidavit.

Similar economic detriment can be expected of any raw milk producer who intends to sell raw milk for human consumption across State lines. Accordingly, raw milk producers across the country can expect to make millions of dollars in sales if 21 C.F.R. 1240.61 is modified in the manner suggested by Organic Pastures.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition to Modify and the earlier petition of 2008 includes all information and views on which the prior petition and this petition to modify rely and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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5630 FISHERS LANE , ROOM 1061
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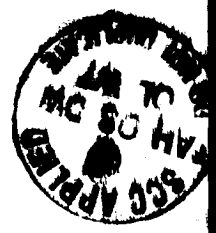

MD 207 9-78

UPS 2ND DAY AIR

TRACKING #: 1Z RV9 885 02 4397 8249

BILLING: P/P

WS 15.0.16 LP2844 39.0A 04/2013