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VIA: ELECTRONIC SUBMISSION

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Citizen Petition to Except from 21 C.F.R. § 1240.61(a) Certain Unpasteurized Milk and Milk Products if Properly Labeled

To Whom It May Concern:

In furtherance of the President's Executive Orders (i.e., "Presidential Memorandum Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing," "Presidential Executive Order on Reducing Regulation Controlling Regulatory Costs," and Presidential Executive Order on Enforcing the Regulatory Reform Agenda"), Real Food Consumer Coalition ("RFCC"), by counsel, hereby submits this Citizen Petition pursuant to 21 C.F.R. § 10.30 to request that the Food and Drug Administration ("FDA" or "Agency") exercise its enforcement discretion with respect to certain unpasteurized milk and milk products in interstate commerce to reduce regulatory burdens while maintaining adequate safeguards for the public. We discuss this request in detail below.

A. INTERESTS OF PETITIONER RFCC

RFCC was formed to empower individuals and organizations to develop community-based food production, distribution, and management systems. It provides guidance and training resources to farmers, food clubs, and other interested parties to reduce burdensome and costly government regulation in private and peaceful transactions. RFCC endeavors to create and maintain voluntary production and distribution standards for interested farmers and consumers as well as provide legal and political resources to protect farmer and consumer rights.

RFCC's members include dairy farmers who would like to sell unpasteurized milk and milk products across state lines, and consumers and buying clubs who would like to purchase and consume unpasteurized milk and milk products in interstate commerce.

B. ACTION REQUESTED

Petitioner respectfully requests that the FDA exercise its enforcement discretion to avoid taking, and to cease taking, enforcement action against those who distribute unpasteurized milk and milk products in interstate commerce¹ when the milk products bear labels that include in conspicuous bold face type prominently displayed under the statement of identity for the product: (1) a warning regarding the health risks of unpasteurized milk and milk products; and, when applicable, (2) instructions for safe handling, including self-pasteurization.

In particular, the requested warning and instructions would read as follows for unpasteurized milk and cream (from milk):

WARNING: This raw (unpasteurized) milk [cream] may contain disease-causing organisms. Persons at highest risk of these organisms include newborns and infants; the elderly; pregnant women; those taking corticosteroids, antibiotics or antacids; and those having chronic illnesses or other conditions that weaken their immunity.

SAFE HANDLING INSTRUCTIONS: To prevent foodborne illness, keep this product refrigerated at 45°F or lower and, prior to consumption, follow the pasteurization process identified below.

Pasteurization Process: (1) Heat milk at 145°F [150°F]² for 30 minutes in stainless steel pot; (2) Remove pot of milk from heat and place it in sink or large bowl filled with ice water stirring constantly until milk temperature drops to 40°F; and (3) Store pasteurized milk in a refrigerator at 45°F or lower.

For other unpasteurized milk products, which may be difficult to pasteurize using the above process, such as cheese, the warning would provide:

WARNING: This raw (unpasteurized) milk product may contain disease-causing organisms. Persons at highest risk of these organisms include newborns and infants; the elderly; pregnant women; those taking corticosteroids, antibiotics or

¹ This Citizen Petition applies to unpasteurized milk and milk products in final package form that a person causes to be delivered into interstate commerce or sells, otherwise distributes, or holds for sale or other distribution after shipment in interstate commerce. Although under 21 C.F.R. § 131.110, "milk" means "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows," as used within this Citizen Petition "milk" is not limited to cow's milk; the term "milk" with respect to the requested action includes milk from all lactating animal species, such as milk from sheep, goats, camels, and cows.

²Under 21 C.F.R. 1240.61(b), if the fat content of the milk product is 10 percent or more, or it contains added sweeteners, the temperature must be increased by 5°F.

antacids; and those having chronic illnesses or other conditions that weaken their immunity.

If the milk or milk product is sold in a state that requires a specific warning that differs from the one stated above, the first part of warning will be tailored to that state.

C. STATEMENT OF GROUNDS

1. The Unpasteurized Milk and Milk Product Ban is Unnecessary

To reduce the risk of foodborne illness, pasteurization is required for all milk and milk products in final package form intended for direct human consumption that are delivered into interstate commerce or sold, otherwise distributed, or held for sale or other distribution after shipment in interstate commerce. *See* 42 U.S.C. §§ 264(a) and 271(a); 21 C.F.R. § 1240.61(a).

For most of history, however, milk and milk products were not regularly pasteurized and yet were consumed with remarkably few instances of illness, especially prior to urbanization. *See* Donna M. Byrne, *Raw Milk in Context*, 26 J. Envtl. L. & Litig. 109, 126 (2011) (indicating that “country milk,” as opposed to “swill milk” from the city, was seen as pure and wholesome and had a better infant survival rate because sanitation was superior in the country). French scientist Louis Pasteur invented pasteurization in the mid-19th century when he discovered that heating beer and wine reduced the number of bacteria that caused spoilage sufficiently enough to prevent the alcoholic beverages from souring. *See id.* at 110. Following his discovery, milk and milk products were pasteurized beginning in the late 19th century, but did not gain widespread popularity until early in the 20th century. *See* Megan Loder, *A Raw Deal: Why Texas Should Relax and Let Dairies Bring Their Milk into Town*, 15 Tex. Tech Admin. L.J. 231, 233 (2013); Byrne, 26 J. Envtl. L. & Litig. at 127 (discussing how pasteurization was gained popularity over milk certification in the early 20th century because it was cheaper).

Although the use of pasteurization for milk and milk products eventually became widespread in the United States, its adoption was initially met with vigorous objection, causing some dairy processors to pasteurize milk in secret. *See* V.H. Holsinger K.T. Rajkowski and J.R. Stabel, *Milk Pasteurization and Safety: A Brief History Update*, 16 Rev. Sci. Tech. Off. Int. Epiz. 441, 442 (1997). To this day, several ethnic and religious groups continue to prefer to consume unpasteurized raw milk, such as the Amish and Mennonites. *See* Emily Semands, *Food Choice: Should the Government Be at the Head of the Table?*, 67 Okla. L. Rev. 149 (2014) (discussing Amish raw milk farmers). Likewise, organic consumers tend to favor unpasteurized milk and cheese over pasteurized varieties. *See* Christopher M. Anderson, *Striking A Balance: Regulation of Raw Milk and A New Approach for Indiana*, 11 Ind. Health L. Rev. 399, 400 (2014) (explaining how raw milk advocates want the freedom to drink raw milk because they believe it has superior taste and nutritional value and they want to support local dairy farmers and avoid processed foods). A 2007 FoodNet survey³ found that 3 percent of the U.S. population (approximately 9.4 million people) regularly consume unpasteurized milk.

³ Available at <https://www.cdc.gov/foodnet/surveys/FNExpAtl03022011.pdf> (last accessed Mar. 14, 2017).

Unfortunately, the intrastate supply of unpasteurized milk and milk products is insufficient to meet demand. *See* Timothy J. Mayer, "*Don't Have A Cow, Man!': Recognizing Herd Share Agreements for Raw Milk*, 25 Health Matrix 383, 392 (2015) (“[L]ocating raw milk is not easy for consumers in many parts of the country.”). The approach thus far taken by the FDA has been to institute a blanket ban on distribution of unpasteurized milk and milk products interstate. *See* 21 C.F.R. § 1240.61(a). In 25 states, however, intrastate distribution of unpasteurized milk and milk products is lawful, again with a remarkably low incidence of injury attributed to those products. *See Mayer*, 25 Health Matrix at 429 (noting that the following states permit the sale of raw milk: Arizona, Arkansas, California, Connecticut, Illinois, Kansas, Maine, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Vermont, Washington, and Wisconsin); *Byrne*, 26 J. Envtl. L. & Litig. at 114 (estimating that although the rate of foodborne illness from unpasteurized milk is greater than pasteurized milk, the flat rate of foodborne illness from the former is relatively low, i.e., about 1 in every 5,000 people).

Raw milk and raw cheese are among a wide variety of raw foods consumed by people in the United States. *See* U.S. Dept. of Health and Human Services, National Institute of Diabetes and Digestive and Kidney Diseases, *Foodborne Illnesses* (identifying meat, poultry, fish, shellfish, and eggs as examples of raw foods).⁴ All of the raw foods are susceptible to pathogenic contamination. *See id.* (Noting that raw foods can be contaminated with bacteria during growth, harvesting, processing or shipping, making the food harmful to eat). Indeed, pasteurized foods, such as milk, can be the source of contamination with regular outbreaks of illness attributable to them. *See* Damian C. Adams, Michael T. Olexa, Tracey L. Owens, Joshua A. Cossey, *déjà Moo: Is the Return to Public Sale of Raw Milk Udder Nonsense?*, 13 Drake J. Agric. L. 305, 310 (2008) (noting that disease outbreaks are still linked to pasteurized milk as a result of improper handling, and referencing a 2000 salmonella outbreak in New Jersey and Pennsylvania from milk contaminated after pasteurization). Other food sources that are breeding grounds for pathogens include raw vegetables, raw sprouts, raw steak (e.g., steak tartar), raw eggs, raw oysters, and sushi and sashimi, among others, and such foods represent the majority of foodborne illnesses. *See Byrne*, 26 J. Envtl. L. & Litig. at 113 (“[O]nly three percent of food-borne outbreaks in 2006 were related to the consumption of both pasteurized and unpasteurized milk . . .”). Yet, the FDA only subjects one food form to required pasteurization or cooking, i.e., milk and milk products.

There is no need, however, for milk to be pasteurized before it is sold to consumers. Self-pasteurization is as effective as industrial pasteurization in reducing bacterial infection in milk and milk products. *See* Oregon State University Extension Service, *Food Safety & Preservation: Home Pasteurization of Raw Milk* (2011).⁵ Indeed, because self-pasteurization occurs immediately before consumption without the product remaining on store shelves or being transported in unrefrigerated vehicles to the home, it is likely more effective in eliminating harmful bacteria from milk and milk products. *See* U.S. Dept. of Health and Human Services,

⁴ Available at <https://www.niddk.nih.gov/health-information/digestive-diseases/foodborne-illnesses> (last accessed Mar. 14, 2017).

⁵ Available at http://extension.oregonstate.edu/lane/sites/default/files/documents/sp_50-932home_pasteurizationofrawmilk_.pdf (last accessed Mar. 14, 2017).

National Institute of Diabetes and Digestive and Kidney Diseases, *Foodborne Illnesses* (identifying meat, poultry, fish, shellfish, and eggs as examples of raw foods (noting, as discussed above, that foods can become contaminated during shipping)).

Moreover, consumers should be able to choose whether they want to consume unpasteurized milk and milk products after they have been informed of the risks via labeling. After all, several states that allow the intrastate sale of unpasteurized milk and milk products have found labeling to be sufficient to protect the public milk. *See, e.g.*, Wash. Admin. Code 16-101-800(5) (requiring raw milk containers to bear the following labeling statement: “**WARNING:** *This product has not been pasteurized and may contain harmful bacteria. Pregnant women, children, the elderly and persons with lowered resistance to disease have the highest risk of harm from use of this product*”). The use of such a warning will help prevent consumers from unknowingly consuming unpasteurized milk and milk products. Thus, we propose that the FDA exercise its enforcement discretion when an unpasteurized milk or milk product bears a state required warning, or, if no state warning is required, the following warning:

WARNING: This raw (unpasteurized) milk [cream] may contain disease-causing organisms. Persons at highest risk of these organisms include newborns and infants; the elderly; pregnant women; those taking corticosteroids, antibiotics or antacids; and those having chronic illnesses or other conditions that weaken their immunity.

Labeling can also be used to reduce the risk of foodborne illness by providing proper handling instructions. To illustrate, in 2000, FDA’s regulations were amended to require safe handling labeling instructions for shell egg cartons, and that such products be placed under refrigeration at 45°F or lower upon delivery at retail establishments. *See* 65 Fed. Reg. 76091 (Dec. 5, 2000). The label of unpasteurized milk and cream could similarly bear safe handling instructions similar to those for shell egg cartons, such as:

SAFE HANDLING INSTRUCTIONS: To prevent foodborne illness, keep this product refrigerated at 45°F or lower and, prior to consumption, follow the pasteurization process identified below.

Pasteurization Process: (1) Heat milk at 145°F [150°F] for 30 minutes in stainless steel pot; (2) Remove pot of milk from heat and place it in sink or large bowl filled with ice water stirring constantly until milk temperature drops to 40°F; and (3) Store pasteurized milk in a refrigerator at 45°F or lower.

2. Exercising Enforcement Discretion Would Reduce Regulatory Burdens

Petitioners urge FDA to reduce the regulatory burden on raw milk and raw milk products by substituting for its blanket ban an allowance, through enforcement discretion, of interstate distribution of unpasteurized milk and milk products (under otherwise acceptable refrigerated transport and food safety regulation) so long as those products are individually labeled to alert

consumers that the raw products pose a risk of bacterial infection and illness and that self-pasteurization should be undertaken to kill bacteria present as discussed above.

The President has issued several Executive Orders aimed at reducing regulatory burdens. Specifically, on January 24, 2017, in a “Presidential Memorandum Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing,” the President directed the executive departments and agencies “to support the expansion of manufacturing in the United States . . . through” *inter alia*, “reductions in regulatory burdens affecting domestic manufacturing . . .” Similarly, on January 30, 2017, in a “Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs,” the President required the heads of all federal agencies to undertake the following actions whenever they commenced notice and comment rulemaking or proposed a new rule: (1) to delete two existing regulations; (2) to ensure that no new regulation imposed an incremental cost greater than zero, except as approved by the Office of Management and Budget; (3) to ensure that costs of any new regulation be offset by the elimination of costs from two regulations by the elimination of existing costs associated with those two regulations. The President has called for the elimination of 75% of existing federal regulations. On February 24, 2017, in a “Presidential Executive Order on Enforcing the Regulatory Reform Agenda,” the President directed the heads of the executive branch agencies to “designate an agency official as its Regulatory Reform Officer (RRO) . . . [to] oversee the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms” and, in particular, to ensure implementation of prior executive orders germane to regulatory reform as well as a new directive to cause “termination, consistent with applicable law, of programs and activities that derive from or implement Executive Orders, guidance documents, policy memoranda, rule interpretations, and similar documents, or relevant portions thereof, that have been rescinded.” The February 24 Executive Order also creates a joint Regulatory Reform Task Force (“RRTF”) to evaluate existing regulations and “make recommendations to the agency head regarding their repeal, replacement, or modification consistent with applicable law.” The RRTF is required “at a minimum” to identify regulations that “eliminate jobs, or inhibit job creation; are outdated, unnecessary, or ineffective; impose costs that exceed benefits; create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; are consistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. § 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; and derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.”

Here, the enforcement of the unpasteurized milk and milk product prohibition has been extremely burdensome, forcing some farmers out of business. For example:

- **Daniel Allgyer, Pennsylvania:** Mr. Allgyer, an Amish dairy farmer, provided unpasteurized milk to consumers across state lines. *See Semands*, 67 Okla. L. Rev. at 149. In 2010, after a year-long sting operation involving undercover agents who infiltrated a buyer’s group, federal agents raided his Pennsylvania farm, Rainbow Acres. Two years later, following the filing of a civil complaint, Mr. Allgyer was ordered to stop

selling his unpasteurized milk across state lines despite the absence of actual injury from his products and his consumers being willing participants, and he shut down his farm altogether to protect his family from, *inter alia*, armed agents. *See id.*; Stephen Dinan, “Feds Sting Amish Farmer Selling Raw Milk Locally,” *Wash. Times*, Apr. 28, 2011.⁶

- **Mark Nolt, Pennsylvania:** Between 2008 and 2012, state and federal authorities raided Mr. Nolt at least three times. They confiscated thousands of dollars in equipment and products, and arrested him in front of his family.
- **David Hochstetler, Indiana:** Between 2007 and 2011, the federal government confiscated raw milk from his dairy farm and shut his dairy farm down for several weeks on the suspicion that his products caused campylobacter illnesses, costing him thousands of dollars. Extensive testing on his products, however, revealed no pathogens in his milk. Nonetheless, federal authorities sought a grand jury indictment of him in connection with the illnesses. Eventually, the federal government dropped the grand jury case after a local sheriff told the FDA and DOJ he would go after them for trespassing if they continued their semi-monthly inspections without a warrant based on probable cause. The sheriff alleged that the semi-monthly inspections were being used to harass Mr. Hochstetler because inspections normally occurred annually.
- **Amos Miller, Pennsylvania:** Several of Mr. Miller’s raw milk shipments were confiscated between 2010 and 2016, including shipments to California and Florida, resulting in thousands of dollars in lost product. Additionally, the USDA sought one of the largest court-ordered inspections of his farm in 2016. Mr. Miller had to spend thousands of dollars to comply with the order and provide sales receipts of prior sales to food club members.

Rather than persecuting and shutting down farmers like those above who provide a desired good to consumers, consistent with the President’s Executive Orders referenced above, the FDA should exercise its enforcement discretion and allow the sale of unpasteurized milk and milk products in interstate commerce when they bear the labeling recommended in this Citizen Petition. As discussed above, the public health can be adequately protected through labeling bearing a warning and safe handling instructions. Thus, because FDA would be exercising its enforcement discretion with respect to a regulation that is unnecessary and imposes costs that exceed its benefits, it would be acting consistent with the President’s Executive Orders.

D. ENVIRONMENTAL IMPACT

Petitioners believe the actions requested in this Citizen Petition are not within any of the categories for which an environmental assessment is required.

E. ECONOMIC IMPACT

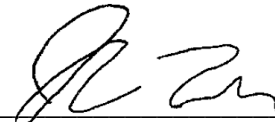
⁶Available at <http://www.washingtontimes.com/news/2011/apr/28/feds-sting-amish-farmer-selling-raw-milk-locally/> (last accessed Mar. 14, 2107).

Information on the economic impact of this proposal will be submitted if requested by the Commissioner following review of this Citizen Petition.

F. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



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