UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MARK MCAFEE 7221 So. Jameson Fresno, CA 93706, and **FARM-TO-CONSUMER LEGAL DEFENSE FUND** 8116 Arlington Blvd, Ste. 263 Falls Church, VA 22042 Plaintiffs, v. **U.S. FOOD AND DRUG ADMINISTRATION,** White Oak Building 1, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	Civil Action No. 19-3161

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Mark McAfee and Farm-to-Consumer Legal Defense Fund (collectively, "Plaintiffs") bring this action pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*., and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 706, to compel the United States Food and Drug Administration ("FDA") to act on Plaintiffs' petition requesting that the FDA: (1) amend the definition of "milk products" in 21 C.F.R. 1240.3(j) to exclude butter; and (2) amend 21 CFR 1240.61(a), which prohibits transportation of unpasteurized "milk or milk products" across state lines, to explicitly exclude unpasteurized butter from the prohibition.

2. Plaintiffs petitioned the FDA on June 22, 2016, and the FDA acknowledged receipt of Plaintiffs' petition on December 16, 2016. This was the last correspondence that Plaintiffs received from the FDA regarding their request.

3. Raw butter is a low-risk product that does not merit the regulatory restrictions imposed by the FDA—restrictions that are inconsistent both with Congress' intent and with the FDA's own positions regarding the relative safety of raw butter and other manufactured products created from raw milk.

4. The FDA has unreasonably delayed acting on Plaintiffs' petition, and, to avoid further harm from the arbitrary and capricious regulations enacted by the FDA, Plaintiffs seek an order requiring the FDA to issue a decision within 30 days.

PARTIES

5. Plaintiff Mark McAfee is the founder of Organic Pastures Dairy Company ("OPDC"), which was established in 1999 in Fresno, California. OPDC is a Grade A licensed raw[1] dairy that sells butter throughout California. There have been no reported foodborne illnesses from OPDC's butter.

6. Plaintiff Farm-to-Consumer Legal Defense Fund ("FTCLDF") is a grassroots, nonprofit organization based in Virginia with members located across the country. Founded in 2007, FTCLDF protects the rights of farmers and consumers to engage in direct commerce while working to create a food system in which consumers are able to obtain the foods of their choice from the sources of their choice. FTCLDF's members include small farms located all over the United States that have been negatively impacted by the interstate ban on raw butter.

[1] Plaintiffs use the term "raw" dairy to refer to unpasteurized dairy to remain consistent both with Plaintiffs' petition to the FDA and the terminology used by producers and consumers of raw butter and other raw milk products.

7. Defendant FDA is a federal government agency within the Department of Health and Human Services ("HHS"). The FDA is responsible for administration of the FDCA, including the provisions regarding definitions and standards for food (except as to butter), along with food safety protocols.

JURISDICTION

8. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

I. Congress defines "butter" and precludes the FDA from revising the definition or standard of identity for butter.

9. Congress has authorized the FDA to issue regulations establishing standard-of-identity requirements in the FDCA for most foods. *See* 21 U.S.C. § 341 ("Definitions and standards for food"). Specifically, the FDA can "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container." *Id.*

10. However, the FDCA limits the FDA's ability to change the definition or standard of identity for butter: "No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, **or butter**, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons." *Id.* (emphasis added).

11. This is consistent with Congress' earlier decision to define butter explicitly by statute. Title 21 of United States Code § 321a (adopted in 42 Stat. 1500 (1923)) provides:

> For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with

> or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

II. By its very composition, as defined by Congress, butter—whether pasteurized or raw—poses a low risk of foodborne illness.

12. Pathogens do not grow in properly-produced butter, contrary to prior FDA assumptions that are no longer supported by advancements in microbiology and scientific studies conducted after 1985. *See* Pet. at 12 (internal citations omitted).

13. Moreover, contamination of commercial butter with pathogens is rare in current practice, and, when present, pathogen counts are too low to cause illness (<100 *L. monocytogenes/g*). *Id.*

14. For several reasons, butter's composition renders it a poor medium for bacteria growth. *Id.* at 12–13.

15. *First*, the hardened butterfat inhibits the growth of bacteria. As Congress specified by statute, butter must be at least 80% fat by weight. *Id.* at 12. This fat is the continuous phase, and a small amount of water in the form of droplets are dispersed in the fat. *Id.* Bacterial growth is thought to be restricted to the water droplets originally colonized during the manufacture because migration of bacteria between water droplets is restricted by fat. *Id.* at 13. When butter is "well-worked," as it is in commercial production, the water droplets become too fine to support bacterial growth. *Id.*

16. *Second*, butter's acidic pH limits or prevents pathogen growth. *Id.*

17. *Third*, the low temperatures at which butter is kept (either refrigerated or frozen) reduce or eliminate bacterial growth. *Id.*

18. *Fourth*, in the case of salted butters, the dispersion of salt inhibits bacterial growth. *Id.*

19. In determining previously that butter would support *Listeria* growth, the FDA relied on a 30-year-old study that did not take into consideration the foregoing factors. *Id.* at 16. In addition to conflicting with the modern research, the outdated study on which the FDA relied also failed to create real-world scenarios that could form the basis for regulations. For instance, the butter that was the subject of the study was prepared in a laboratory, rather than in a commercial setting, and, therefore, lacked many of the important qualities described above. *Id.* Additionally, the study involved artificially high inoculation levels that are unlikely to occur naturally. *Id.*

20. By contrast to the obsolete study on which the FDA relied, more modern studies have reviewed ranges of pathogens likely to occur naturally, as well as butter that has been naturally—as opposed to artificially—contaminated with pathogens. These studies have also focused on the effect of smaller moisture droplets in pathogen growth to better-predict the results in modern commercially-made butter. For instance:

a. In a 2015 study, butter inoculated with *L. monocytogenes* or *L. innocua* was incubated at 8 degrees Celsius for 42 days, even though most regulations require that butter be kept at 4 or 5 degrees Celsius. *Id.* at 18. Even though the warmer temperatures created better conditions for pathogen growth than would be legally permitted with respect to butter for sale in the U.S., no pathogen growth was observed in fine laboratory butters with large or small droplet sizes. *Id.* Moreover, the pathogen count only increased marginally for coarse laboratory butter with large droplet sizes. *Id.* The growth potential for *L. monocytogenes* remained below the limit value for ready-to-eat food classification of the European Union for the duration of the inoculated butter's shelf life. *Id.*

b. In another study, butters of different water droplet size and salt concentrations were prepared using a bench-top butter churn, inoculated with *L. monocytogenes* at various salt concentrations, incubated at 8 degrees Celsius or 21 degrees Celsius, and monitored for 30 days. *Id.* Again, the temperatures were higher than what U.S. regulations permit. *Id.* While pathogen growth occurred in coarse butter, fine butter (comparable to commercially-produced butter) inhibited pathogen growth as did the introduction of salt. *Id.*

c. Another study inoculated separate butter samples with *Listeria*, *Escherichia coli* O157:H7, or *Salmonella* species. *Id.* The commercial butter samples did not support significant growth of any of these pathogens inoculated at moderate levels when incubated at 4.4 degrees Celsius for up to 21 days. *Id.* In every case, the pathogen populations actually decreased over time (by contrast to inoculated cream, which showed significant growth even at a lower refrigeration temperature). *Id.* at 18–19. These pathogens inoculated into commercial butter at high levels also did not grow significantly at refrigeration temperatures.

21. The biological properties of butter also prevent pathogen growth as revealed by the advances in the field of metagenomics, which interconnects the microbial ecology and the Human Microbiome Project ("HMP"). *Id.* 13–14. For example, the natural microbiota provide active competition and other protections against growth of potentially pathogenic contaminants through "colonization resistance." *Id.* at 15.

22. The World Health Organization/Food and Agricultural Organization of the United Nations ("WHO/FAO") has determined that competition by the food microbiota can lower risk estimates for listeriosis as compared to simulations based on assumptions of optimal pathogen growth representative of pure cultures in media such as heat-treated foods. *Id.*

23. In a 2001 FDA report, the food microbiota is described as an intrinsic factor of foods limiting the growth of pathogens. *Id.* Yet the agency ignores this fact, and fails to acknowledge the effect of butter microbiota, in its rulemaking on butter. *Id.* In their petition, Plaintiffs provided numerous references to international studies of butter microbiota that comport with the FDA's earlier determinations regarding the importance of microbiota. *See e.g.*, 16–17; 20–22.

24. This microbiota research along with additional studies have disproven the FDA's assumptions regarding *Listeria* growth in raw butter. More modern studies have shown that (1) *Listeria* can be found in even higher amounts in pasteurized butter than in unpasteurized butter when both are inoculated and tested; and (2) the mere presence of *Listeria* at low levels does not

necessarily pose a risk, especially as the gut microbiota of healthy humans provides colonization resistance against many pathogens. *Id.* at 20–21. The detection of *Listeria* in pasteurized but not raw butter may reflect the lack of a protective microbiota and enhanced growth rates of *Listeria* species in heat-treated milks. *Id.* at 15.

III. In 1973, the FDA begins requiring pasteurization of milk and cream.

25. In 1973, the FDA issued a regulation that required pasteurization as part of the standard of identity for raw milk and specific raw-milk products transported interstate. *See* 38 Fed. Reg. 27924 (Oct. 10, 1973).

26. Consistent with the FDCA, the 1973 pasteurization regulation was limited to "milk and cream" and included a definition of cream (*see id.* § 18.1) along with a standard of identity for each of the following: milk (*id.* § 18.2), lowfat milk (*id.* § 18.10), skim milk (*id.* § 18.20), half-and-half (*id.* § 18.30), light cream (*id.* § 18.501), light whipping cream (*id.* § 18.511), heavy cream (*id.* § 18.515), evaporated milk (*id.* § 18.520), concentrated or condensed milk (*id.* § 18.525), sweetened condensed milk (*id.* § 18.530), and various types of nonfat dry milk (*id.* § 18.540). It did not define or identify butter or other manufactured milk products.

27. Shortly thereafter, in 1974, the FDA stayed the effect of the 1973 pasteurization order as to certified raw milk, stating that it would hold a public hearing to resolve the factual dispute over the safety of certified raw milk, while the pasteurization requirement went into effect for all other raw-milk products. *See* 39 Fed. Reg. 42351 (Dec. 5, 1974).

28. No further action was taken on the stay until 1985, when suit was brought to compel action on a petition asking the FDA to ban all domestic sales of raw milk and raw-milk products, including certified raw milk. *See Public Citizen v. Heckler*, 602 F. Supp. 611 (D.D.C.

1985) (hereafter, "*Heckler I*"). The district court ordered the FDA to issue a regulation addressing certified raw milk. *Id.* at 614.

29. Accordingly, the FDA acted on March 15, 1985, by denying the petition. *See Public Citizen v. Heckler*, 653 F. Supp. 1229, 1235 (D.D.C. 1986) (hereinafter, "*Heckler II*"). As part of its rationale, the FDA stated: "[T]here is no reason to believe that unpasteurized milk marketed in interstate commerce represents a greater source of risk than unpasteurized milk marketed intrastate." *Id.* The FDA further noted its lack of authority to prohibit intrastate activity. *Id.*

30. In 1987, the petitioners sued again, in *Heckler II*, asking the district court to compel the FDA to lift the stay as to the sale of certified raw milk. The district court then extended the scope to order the FDA to "approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified, based on the now completed rulemaking proceedings and consistent with the opinion herein." *Id.* at 1242.

31. The district court stated that "[t]he statutory source of HHS's authority was found by the court to have been granted by both the Public Health Service Act's authorization of regulations to control communicable diseases, 42 U.S.C. § 264 (1982), and the Food, Drug and Cosmetic Act's provisions for the control of adulterated foods, 21 U.S.C. § 342 (1982)." *Id.* at 1235 n.5.

32. In *Heckler II*, at no time was butter or any other manufactured dairy product discussed. While the court included the phrase "all raw milk and raw milk products" in the opening and final sections of its order, the analysis focused solely on certified raw milk, and it did not treat "raw milk products" as a term requiring independent analysis.

33. The issues and discussion presented in *Heckler II* did not involve butter, and instead, focused on raw milk. *See, e.g.*, *Heckler II*, 653 F. Supp. at 1233 ("In accordance with the Secretary's first letter to Dr. Wolfe, on October 11 and 12, 1984, an informal hearing was held by HHS on two issues: (1) whether the consumption of raw milk is a public health concern; and (2) if so, whether requiring pasteurization of all raw milk is the most reasonable regulatory option."). Moreover, at the time that *Heckler II* was considered and decided, the FDA had already excluded butter from its definition of "milk and milk products" in its 1978 Pasteurized Milk Ordinance ("PMO"). *See* FDA, U.S. Department of Health, Education and Welfare, Part I *in* GRADE A PASTEURIZED MILK ORDINANCE 1987 RECOMMENDATIONS, 20–21 (Rev. 2011).

34. Neither the FDA nor the district court addressed the FDA's authority or actions with respect to butter, which is unique from milk and is—and was—explicitly excluded from the FDA's authority by 21 U.S.C. § 342.

35. The FDA's 1987 regulation implementing the *Heckler II* decision was included in the regulations for "control of communicable diseases." Without any precedent, and without providing any explanation or justification, the FDA included butter, cheese, and other manufactured dairy products in this regulation. *See* 21 C.F.R. Part 1240.

36. Rather than interpreting "milk products" to only include actual milk and cream items—the subject of the litigation—the FDA's rulemaking extended to products manufactured from raw milk products, including butter and cheese. *Id.* Although the *Heckler* decisions did not involve butter or cheese, the FDA included these products in its rulemaking process, without explanation. Moreover, without explaining a reason for the differentiation, the FDA permitted exclusion of raw milk aged cheeses in rulemaking.

37. The FDA defined "Milk products" in 21 C.F.R. § 1240.3(j) to include:

> Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

38. The FDA also included within this regulation a prohibition on the interstate sale of any milk product as defined by § 1240.61(a):

> No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

IV. In addition to contravening the FDCA, the prohibitions enacted by the FDA do not reasonably relate to the actual rates of illness linked to raw butter.

39. Hundreds of millions of pounds of butter are consumed by Americans annually. The United States Department of Agriculture ("USDA") estimates that butter was produced and consumed at a rate of 834,000 metric tons in the U.S. in 2016 alone. *See* USDA, Foreign Agricultural Service, *Dairy: World Markets and Trade*, 17 (July 2019). That number rose to 870,000 metric tons in 2018. *Id.*

40. Yet throughout the U.S. there were few or no reported foodborne illness outbreaks linked directly to butter commercially prepared from raw milk from 1998 to 2016 (the year that Plaintiffs submitted their petition). *See* Pet. at 10–11. And only a small number of outbreaks have been linked to butter at all, commercial or homemade. *Id.*

41. To locate this information, Plaintiffs searched the Center for Disease Control's ("CDC") Foodborne Outbreak Online Database ("FOOD Tool") for the available years. *Id.* at 10. In 2016, the FOOD Tool provided information on foodborne outbreaks reported to the CDC from 1998 forward. *Id.*

42. The database listed only 10 outbreaks in which butter was *one* of the listed "food vehicles" for the outbreak. *Id.* at 10–11. In most of these outbreaks, other food vehicles were also listed that were of higher risk and more likely to have been the source of the outbreak—such as seafood or pork. *Id.* Moreover, even in the unlikely event that butter was responsible for all of these outbreak cases, the worst-case scenario reflects only 242 illnesses over a period of 18 years, or an average of fewer than 14 illnesses per year. *Id.* These numbers include butter made from both pasteurized and raw milk, and prepared both homemade and commercially. *Id.* The CDC database lists only one outbreak involving butter produced from raw milk in 2007. *Id.* Based on the Utah Health Department's description of that outbreak, these products appear to have been made at home from the milk and were not commercially prepared and sold. *Id.*

43. Plaintiff McAfee's dairy, by way of example, sold over 2 million pounds of butter from 2001 to April 2016, and not a single foodborne illness was linked to these sales. *Id.* at 11. Since April 2016, he has sold another 290,000 pounds of butter without any reported illness or recalls.

V. The FDA's regulations in § 1240 conflict with the FDA and other government agencies' regulations recognizing the lower risks of raw butter as compared to raw milk.

44. The USDA has recommended requirements for milk used for manufacturing purposes, including butter, and for milk created for fluid consumption. *See* Pet. at 23. For the

former, the quality standards for both the milk itself and for the farms on which it is produced are lower than are the standards for fluid consumption. *Id.*

45. The PMO, established by the FDA, sets a limit of 300,000 bacteria per milliliter for fluid milk. *Id.* The requirements for milk for manufacturing purposes allow up to 500,000 bacteria per milliliter. *Id.*

46. Raw milk cheeses that have been aged for at least 60 days are a low-risk product that have resulted in only a small handful of outbreaks over the last two decades. As discussed above, raw butter has been linked to–at most–one outbreak over that same period. *Id.*

47. Recognizing the safety of both raw butter and raw cheese, the FDA's PMO specifically excludes both butter and aged cheese from the definition of "milk and milk products." *Id.*

48. The FDA similarly excludes aged cheese from the pasteurization requirements in 21 C.F.R. 1240.61. *Id.* Yet without any stated rationale or scientific support, butter is not excluded.

49. While raw cheeses are legal to sell in interstate commerce, raw butter is not. The different treatment of these two manufactured dairy products is not based on any scientific evidence and is not rational.

VI. Plaintiffs' petition to the FDA seeks to exclude raw butter from the existing raw-milk prohibitions.

50. On June 22, 2016, in a petition submitted pursuant to 5 U.S.C. § 553(e), 21 C.F.R. §§ 10.20, 10.30, and the First Amendment of the Federal Constitution, Plaintiffs requested that the FDA reverse its ban on the interstate transport of raw butter. Plaintiffs further requested the FDA reconsider whether the Public Health Service Act's provisions regarding the control of

communicable diseases and the FDCA's provisions regarding adulterated foods support a ban on the interstate transport of commercially prepared raw butter.

51. Specifically, Plaintiffs requested two actions from the FDA.

52. *First*, Plaintiffs requested that the FDA amend the definition of milk products in 21 C.F.R. § 1240.3(j) by striking "butter" and adding this sentence to the end: "This definition shall not include butter meeting the standard established by 21 USC 321a."

53. *Second*, Plaintiffs requested that the FDA amend 21 C.F.R. § 1240.61 to allow for interstate sales of unpasteurized butter by adding the bolded text as follows: "No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product . . . unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties **or except for butter meeting the standard established by 21 USC 321a**."

54. In support of its petition, Plaintiffs provided both the text of the FDCA and the legal background of butter's definition to demonstrate that the FDA contravened both the FDCA and legal precedent by including butter in the restrictions referenced above. Additionally, Plaintiffs provided: (1) significant research compiled using a CDC database to demonstrate the low likelihood that any outbreaks in the U.S. in a nearly two-decade period could be attributed to raw butter; and (2) information about the microbial ecology of raw butter demonstrating that raw butter—by its microbial make-up—presents a low risk of contamination and does not promote bacteria growth. Plaintiff also cited numerous other conflicting provisions from the FDA and other government agencies regarding butter and other low-risk manufactured milk products like

cheese to demonstrate that butter was improperly included in the restrictions referenced above. Since the filing of the petition, additional peer reviewed studies support the necessity of FDA changes and the allowance for interstate transport of raw milk.

55. An agency may change its interpretation of a statute as long as it provides a "reasoned analysis" explaining its altered stance. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 42 (1983) ("An agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances.") (quoting *Permian Basin Area Rate Case*, 390 U.S. 747, 784 (1968)).

56. FDA regulations state that the agency will respond to each citizen petition within 180 days of receipt of the petition. *See* 21 C.F.R. § 10.30(e)(2). The response must either approve the petition, deny the petition, dismiss the petition as moot, or provide a tentative response explaining why the agency has been unable to reach a decision.

57. On December 13, 2016, the FDA responded to Plaintiffs' petition with a letter stating that it had filed the petition under docket no. FDA-2016-P-1852. It further stated that it had not "been able to reach a decision on your petition within the first 180 days of the filing of the petition because of the limited availability of resources and other agency priorities." The letter provided no timeline for consideration of the petition, stating instead: "We hope to be able to complete the review of your petition and respond to your request in the near future."

58. Plaintiffs' petition provides sufficient grounds for the FDA to review and amend the regulations as Plaintiffs' petition requests.

59. Since the time that Plaintiffs submitted their 2016 petition, numerous studies and reports have further demonstrated the benefits and low health risks associated with raw butter.

60. To date, the FDA has not issued a decision on Plaintiffs' petition and has taken no further action to remove butter from the regulations prohibiting interstate sale of unpasteurized milk and milk products.

61. The FDA has failed to act despite the wealth of government data and medical information demonstrating that raw butter is safe for consumer use, the FDA's own regulations recognizing that raw butter presents lower risks than raw milk, and Congress' specific prohibition on changing the standard of identify for butter in the FDCA.

62. The FDA's decisional process is unreasonable in light of the nature and extent of the interests addressed in the petition and the statutory limitations imposed by Congress. The public is being harmed by the FDA's delay in addressing its arbitrary and capricious prohibition.

CLAIMS FOR RELIEF

1. The FDA's failure to act on Plaintiffs' petition constitutes agency action unlawfully withheld or unreasonably delayed under the APA, 5 U.S.C. § 706(1).

2. The FDA's failure to act on Plaintiffs' petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, under the APA, 5 U.S.C. § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court:

A. declare unlawful the FDA's failure to act on Plaintiffs' petition;

B. compel the FDA to issue a decision on Plaintiffs' petition within 30 days of the Court's Order;

C. award Plaintiffs their reasonable costs and attorneys' fees pursuant to 28 U.S.C. § 2412; and

D. grant all other just and appropriate relief.

Respectfully submitted,

Dated: October 22, 2019

/s/ Samantha J. Ellingson

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