

**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.

**UNITED STATES FOOD AND DRUG
ADMINISTRATION**
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendant.

No. 19-cv-3161 (RC)

DEFENDANT’S ANSWER TO PLAINTIFFS’ SECOND AMENDED COMPLAINT

Defendant United States Food and Drug Administration (“FDA”), by its undersigned counsel of record, and, for their answer to Plaintiffs’ Second Amended Complaint (“Complaint”), states as follows. FDA specifically denies each and every allegation of the Complaint not otherwise expressly admitted, qualified, or denied in this Answer. Moreover, to the extent that the Complaint refers to or quotes from external documents, statutes, or other sources, Defendant may refer to such materials for their accurate and complete contents; however, Defendant’s references are not intended to be, and should not be construed to be, an admission that the cited materials: (a) are correctly cited or quoted by Plaintiffs; (b) are relevant to this, or any other, action; or (c) are admissible in this, or any other, action.

Defendant answers as follows:

FIRST DEFENSE

To the extent that any claim in the Complaint is construed as a challenge to 21 C.F.R. § 1240.3(j) or 21 C.F.R. § 1240.61(a), such claim is barred by the statute of limitations.

SECOND DEFENSE

As to some or all of the claims asserted in this action, Plaintiffs have failed to state a claim upon which relief may be granted under the Administrative Procedure Act, 5 U.S.C. § 551 et seq.

THIRD DEFENSE

Plaintiffs are not entitled to attorneys' fees or costs.

FOURTH DEFENSE

The Court lacks subject matter jurisdiction over Plaintiffs' requests for relief that exceed the relief authorized by statute under 5 U.S.C. § 551 et seq.

FIFTH DEFENSE

Defendant reserves the right to amend this Answer to assert any other matter that constitutes an avoidance or affirmative defense under Federal Rule of Civil Procedure 8(c).

DEFENDANT'S RESPONSES TO THE NUMBERED PARAGRAPHS

In response to the specifically-enumerated paragraphs, as set forth in the Complaint, Defendant admits, denies, and otherwise avers as follows. Any allegations not specifically admitted herein are hereby denied.

INTRODUCTION¹

1. This paragraph states the legal opinions and conclusions of Plaintiffs, including an explanation of their reason for filing the Second Amended Complaint, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that Plaintiffs have filed a Second Amended Complaint and avers that the Second Amended Complaint itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 1.

2. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 U.S.C. § 341, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 U.S.C. § 341 provides FDA authority to establish regulations related to definitions and standards for foods and that 21 U.S.C. § 341 expressly prohibits establishment of a definition and standard of identity and standard of quality for butter. Defendant avers that 21 U.S.C. § 341 itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 2.

3. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 U.S.C. § 321(a), as to which no answer is required. To the extent that an answer to these allegations is required, Defendant denies the allegations of Paragraph 3. By way of further response, Defendant avers that “butter” is defined by statute in 21 U.S.C. § 321a, not 21 U.S.C. § 321(a), and that 21 U.S.C. § 321a itself is the best evidence of its contents.

4. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of “pasteurization regulations” and “requirements under the Pasteurized

¹ Where headings from the Complaint are included herein, they are included merely for ease of reference. By including them, Defendant does not admit the accuracy of the headings.

Milk Ordinance (‘PMO’) and the Federal Food, Drug, and Cosmetic Act (‘FDCA’),” as to which no answer is required. To the extent that an answer to these allegations is required, Defendant denies the allegations of Paragraph 4.

5. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 C.F.R. § 1240.61 and 21 C.F.R. § 1240.3(j), as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.61 contains a pasteurization requirement for milk products that travel in interstate commerce. Defendant further admits that “butter” is included in the definition of “milk products” in 21 C.F.R. § 1240.3(j). Defendant otherwise avers that 21 C.F.R. § 1240.61 and 21 C.F.R. § 1240.3(j) themselves are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 5.

6. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the definition of “milk products” in 21 C.F.R. § 1240.3 includes “cheese (where not specifically exempted by regulation).” Defendant otherwise avers that existing regulations themselves are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 6.

7. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that it did not establish regulations specific to raw butter. Defendant otherwise avers that existing regulations themselves are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 7.

8. Admitted.

9. Defendant admits that Plaintiffs sued FDA on October 22, 2019, to compel action on their Citizen Petition. Defendant further admits that after a stipulated stay of this action, FDA denied the requests in Plaintiffs' Citizen Petition on February 27, 2020. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 9.

10. Denied. By way of further response, Defendant avers that FDA's February 27, 2020, letter to Pete Kennedy, Farm-to-Consumer Legal Defense Fund and Mark McAfee, Organic Pastures Dairy Company ("Citizen Petition Response") itself is the best evidence of its contents and respectfully refers the Court to the Citizen Petition Response for a full and complete statement of its contents.

11. Denied. By way of further response, Defendant avers that the Citizen Petition Response itself is the best evidence of its contents and respectfully refers the Court to the Citizen Petition Response for a full and complete statement of its contents.

12. Denied. By way of further response, Defendant avers that the Citizen Petition Response itself is the best evidence of its contents and respectfully refers the Court to the Citizen Petition Response for a full and complete statement of its contents.

13. Defendant admits that the last outbreak listed in Table 1 of FDA's Citizen Petition Response occurred during an event in England in 2003. By way of further response, Defendant avers that the Citizen Petition Response itself is the best evidence of its contents and respectfully refers the Court to the Citizen Petition Response for a full and complete statement of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 13.

14. Denied.

15. Denied.

16. Denied.

PARTIES

17. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph 17.

18. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph 18.

19. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that FDA is a federal government agency within the Department of Health and Human Services and one of several federal agencies responsible for enforcing federal law pertaining to food safety in the United States. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 19.

JURISDICTION

20. This paragraph states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority and a statement as to the purported jurisdiction of this Court, as to which no answer is required. To the extent that this paragraph contains factual allegations which may require an answer, all such allegations are denied.

21. This paragraph states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority and a statement as to the purported authority of this Court, as to which no answer is required. To the extent that this paragraph contains factual allegations which may require an answer, all such allegations are denied.

22. This paragraph states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority and a statement as to whether venue in this judicial district

is proper, as to which no answer is required. To the extent that an answer to this paragraph is required, all such allegations are denied.

FACTS

Section I:

23. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterizations of 21 U.S.C. § 341, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the heading of 21 U.S.C. § 341 is “Definitions and Standards for Food” and that the section authorizes the promulgation of “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.” Defendant otherwise avers that the statute itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 23.

24. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterizations of 21 U.S.C. § 341, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 U.S.C. § 341 includes the sentence “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 avocados, cantaloupes, citrus fruits, and melons.” Defendant otherwise avers that the statute itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 24.

25. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 U.S.C. § 321(a), as to which no answer is required. To the extent

that an answer to these allegations is required, Defendant denies the allegations of Paragraph 25. By way of further response, Defendant avers that “butter” is defined by statute in 21 U.S.C. § 321a, not 21 U.S.C. § 321(a), and that 21 U.S.C. § 321a itself is the best evidence of its contents.

26. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 U.S.C. § 321(a), as to which no answer is required. To the extent that an answer to these allegations is required, Defendant denies the allegations of Paragraph 26. By way of further response, Defendant avers that “butter” is defined by statute in 21 U.S.C. § 321a, not 21 U.S.C. § 321(a), and that 21 U.S.C. § 321a itself is the best evidence of its contents.

27. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the statutory definition of butter in 21 U.S.C. § 321a neither mandates nor prohibits that butter be made with pasteurized or ultrapasteurized milk or cream. Defendant otherwise avers that the statute itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 27.

28. This paragraph states the legal opinions and conclusions of Plaintiffs, including their characterization of 21 C.F.R. 131.110, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 131.110(a) contains a “description” of milk, which reads, “Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent milkfat. Milk may

have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.” Defendant otherwise avers that existing regulations themselves are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 28.

Section II:

29. Denied.

30. Denied.

31. Denied.

32. The sentence, “As Congress specified by statute, butter must be at least 80% fat by weight” states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to this sentence is required, Defendant admits that the statutory definition of butter in 21 U.S.C. § 321a includes in the standard for butter the requirement that butter contain “not less than 80 per centum by weight of milk fat.” Defendant otherwise avers that the statute itself is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 32.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Defendant admits that the Citizen Petition Response did not cite to the 2017 draft guidance document, entitled “Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry” (hereinafter “2017 FDA Draft Guidance Document”). By way of further

response, Defendant avers that the 2017 FDA Draft Guidance Document itself is the best evidence of its contents and respectfully refers the Court to the Citizen Petition Response for a full and complete statement of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 37.

38. Defendant admits that a research paper entitled, “Survey for *Listeria monocytogenes* in and on Ready-to-Eat Foods from Retail Establishments in the United States (2010 through 2013): Assessing Potential Changes of Pathogen Prevalence and Levels in a Decade” (hereinafter “2017 Luchansky Paper”) was published in the Journal of Food Protection, Vol. 80, No. 6, pp. 903-921, and included five authors who were employees of FDA’s Center for Food Safety and Applied Nutrition. Defendant further admits that unsalted butter and dairy-based dip were classified in the study as “cultured milk products.” Defendant further admits that Table 2 of the published article indicates that 1 of 468 cultured milk product samples included detection of *L. monocytogenes* in ready to eat foods. By way of further response, Defendant avers that the research paper 2017 Luchansky Paper itself is the best evidence of its contents and respectfully refers the Court to the research paper for a full and complete statement of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 38.

39. Plaintiffs’ allegation is vague because it does not provide information sufficient for Defendant to identify the “2001 FDA report” to which they refer. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph.

40. Denied.

Section III:

41. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that FDA published a notice at 38 Fed. Reg. 27924 (Oct. 10, 1973) that included pasteurization as part of the standard of identity for certain uses of milk and certain other milk products. Defendant otherwise avers that the Federal Register notice at 38 Fed. Reg. 27924 (Oct. 10, 1973) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 41.

42. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that FDA published a notice at 38 Fed. Reg. 27924 (Oct. 10, 1973) that included a definition of cream and a standard of identity for each of the following: milk, lowfat milk, skim milk, half-and-half, light cream, light whipping cream, heavy cream, evaporated milk, concentrated or condensed milk, sweetened condensed milk, and various types of nonfat dry milk. Defendant further admits that the Federal Register notice did not contain a definition or standard of identity for butter. Defendant otherwise avers that the Federal Register notice at 38 Fed. Reg. 27924 (Oct. 10, 1973) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 42.

43. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that FDA published a notice at 39 Fed. Reg. 42351 (Dec. 5, 1974) that stated that FDA intended to hold a public hearing regarding the provisions that require certified raw milk to be pasteurized and stayed the effect of those provisions until after such a public hearing could be

held. Defendant otherwise avers that the Federal Register notice at 39 Fed. Reg. 42351 (Dec. 5, 1974) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 43.

44. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that Public Citizen filed a lawsuit in 1984 to compel action on a citizen petition that sought to ban all domestic sales of raw milk and raw milk products and that the district court ordered FDA to “publish a proposed rule reflecting its decision on plaintiffs’ petition.” *See Public Citizen v. Heckler*, 602 F. Supp. 611, 614 (D.D.C. 1985) (“*Heckler I*”). Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 602 F. Supp. 611 (D.D.C. 1985) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 44.

45. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that FDA denied the citizen petition in 1985. Defendant further admits that its citizen petition response stated that “there is no reason to believe that unpasteurized milk marketed in interstate commerce represents a greater source of risk than unpasteurized milk marketed intrastate” and that the Department lacked legal authority to prohibit the intrastate marketing of unpasteurized milk and milk products. *See Public Citizen v. Heckler*, 653 F. Supp. 1229, 1235 (D.D.C. 1986) (“*Heckler II*”). Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 45.

46. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the petitioners filed a lawsuit challenging FDA's denial of their citizen petition and FDA's failure to terminate the 1974 stay of the 1973 regulation that would have, in effect, prohibited the sale of all unpasteurized milk in interstate commerce. *See Heckler II*, 653 F. Supp. at 1231. Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 46.

47. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the district court stated in its opinion that, "There is no longer any question of fact as to whether the consumption of raw milk is unsafe." *See Heckler II*, 653 F. Supp. at 1241. Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 47.

48. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the district court ordered that FDA and the Department of Health and Human Services "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." *Heckler II*, 653 F. Supp. at 1242. Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the

best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 48.

49. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the *Heckler II* district court opinion did not specifically mention “butter.” *See generally Heckler II*, 653 F. Supp. 1229. Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 49.

50. Admitted.

51. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the district court was addressing, among other things, plaintiffs’ request with respect to a regulation that revised the existing standards of identity for milk and milk products. *Heckler II*, 653 F. Supp. at 1231. Defendant otherwise avers that the court opinion at *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 51.

Section IV:

52. Defendant admits that the regulations at issue in this matter, 21 C.F.R. § 1240.3(j) and 21 C.F.R. § 1240.61(a), are included in 21 C.F.R. Part 1240, which is entitled, “Control of Communicable Diseases.” Defendant further admits that the definition of “milk products” in 21 C.F.R. § 1240.3(j) includes butter and certain cheese and other dairy products. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 52.

53. Defendant admits that the definition of “milk products” in 21 C.F.R. § 1240.3(j) includes butter and certain cheese and other dairy products. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 53.

54. Admitted.

55. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.61(a) reads 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 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.” Defendant otherwise avers that 21 C.F.R. § 1240.61 is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 55.

56. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.3(j) excepts certain cheeses specifically exempted by regulation from the definition of “milk products” and that 21 C.F.R. § 1240.61(a) contains exceptions for milk products for which alternative procedures to pasteurization are provided by regulation, such as in 21 C.F.R. Part 133 for curing certain cheese varieties. Defendant otherwise avers that 21 C.F.R. §§ 1240.3 and 1240.61 are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 56.

57. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.3(j) does not contain parenthetical language regarding 21 U.S.C. § 341's definition of butter. Defendant otherwise avers that 21 C.F.R. §§ 1240.3 and 1240.61 are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 57.

Section V:

58. Defendant admits that American consumers consume hundreds of millions of pounds of butter annually. Defendant otherwise avers that the USDA document Foreign Agricultural Service, *Dairy: World Markets and Trade*, 17 (July 2019) is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 58.

59. Defendant admits that some states allow the intrastate production and sale of raw butter or raw cream butter. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 59.

60. Denied. By way of further response, Defendant avers that the CDC Foodborne Outbreak Online Database (hereinafter "FOOD Tool") is the best evidence of its contents.

61. Denied. By way of further response, Defendant avers that the FOOD Tool is the best evidence of its contents.

62. Denied. By way of further response, Defendant avers that the FOOD Tool is the best evidence of its contents.

63. Denied. By way of further response, Defendant avers that the FOOD Tool is the best evidence of its contents.

64. Denied.

65. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph 65.

66. Admitted.

Section VI:

67. Admitted.

68. Denied. Defendant otherwise avers that the PMO is the best evidence of its contents.

69. Denied.

70. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.61(a) contains exceptions for milk products for which alternative procedures to pasteurization are provided by regulation, such as in 21 C.F.R. Part 133 for curing certain cheese varieties. Defendant otherwise avers that 21 C.F.R. § 1240.61 is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 70.

71. This paragraph states the legal opinions and conclusions of Plaintiffs, as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that 21 C.F.R. § 1240.61(a) prohibits the delivery into interstate commerce of milk or milk products, including butter, unless they have been pasteurized or unless another regulatory exemption applies. Defendant otherwise avers that 21 C.F.R. § 1240.61 is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 71.

72. Denied.

Section VII:

73. To the extent that Plaintiffs refer to the 2001 report entitled, “A Report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services,” (hereinafter “2001 Report”) pursuant to IFT/FDA Contract No. 223-98-2333, Task Order No. 4 (Dec. 31, 2001), *available at* <https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf>, Defendant admits that the report considered whether butter was a potentially hazardous food and that report lists the following process controls for butter in Table 4-1: “production/raw ingredient quality control, moisture droplet size in the water-in-oil emulsion, water phase salt, *a_w*.” Defendant otherwise avers that the 2001 Report is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 73.

74. Defendant admits that pasteurized milk and the “high fat and other dairy products” group—which included butter—were classified as “high-risk products,” in the FDA, Interpretive Summary: Quantitative Assessment of the Relative Risk to the Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, Sept. 2003 (hereinafter “2003 FDA Interpretive Summary”), at 23, Summary Figure 1. Defendant otherwise avers that the 2003 FDA Interpretive Summary is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 74.

75. Defendant admits that the 2003 FDA Interpretive Summary labeled commonly-consumed commodities as “high-risk,” while relatively few outbreaks and illnesses were associated with these products. Defendant otherwise avers that the 2003 FDA Interpretive

Summary is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 75.

76. Denied.

77. Denied.

78. Denied.

79. Defendant admits that its Citizen Petition Response did not cite FDA's Draft Guidance entitled, "Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry" (January 2017) (hereinafter "2017 Draft Guidance"), available at <https://www.fda.gov/media/102633/download>. Defendant further admits that the 2017 Draft Guidance includes the following statement: "It is well established (Ref. 12, Ref. 15, and Ref. 17 through Ref. 20) that *L. monocytogenes* do not grow when: i. The pH of the food is less than or equal to 4.4; ii. The water activity of the food is less than or equal to 0.92; and iii. The food is formulated to contain a combination of factors scientifically demonstrated to be effective in preventing growth (the 'hurdles' concept)." Defendant otherwise avers that the 2017 Draft Guidance is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 79.

80. Defendant admits that its Citizen Petition Response did not cite the 2017 Draft Guidance or a 2000 study by Tienungoon, et al. Defendant otherwise avers that the Citizen Petition Response is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 80.

81. Defendant admits that the 2017 Draft Guidance includes Appendix 1, which is entitled, "Potential Sources of *L. monocytogenes*," and Appendix 2, which is entitled, "Examples of Scenarios That Could Lead to Contamination of RTE Foods with *L. monocytogenes*."

Defendant otherwise avers that the 2017 Draft Guidance is the best evidence of its contents.

Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 81.

82. Denied.

83. Defendant admits that the review “A review of *Listeria monocytogenes*: An update on outbreaks, virulence, dose-response, ecology, and risk assessments,” Food Control 75 (2017) 1-13 (hereinafter “2017 Buchanan Review”), was authored, in part by Dr. Robert Buchanan, who had previously been employed by FDA. Defendant further admits that the 2017 Buchanan Review contains the following sentences in a discussion about dose-response modelling: “Given the low incidence of listeriosis in a population despite the frequent exposure to *L. monocytogenes*, these models presume that illnesses most frequently come from exposure to the high doses. The models further predict that at the low doses and at illness rates characteristic of listeriosis, the rate of infection is directly proportional to the dose.” 2017 Buchanan Review at 9. Defendant further admits that the 2004 technical report entitled, “Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods” published by the Food and Agriculture Organization of the United Nations and the World Health Organization (hereinafter the “2004 WHO/FAO Report”) contains the following statement: “The effect of other microbiota (e.g. lactic acid bacteria) in vacuum-packed, cold-smoked fish is well known, but the magnitude of the effect could not be quantified with certainty. In the modelling presented, it was assumed that growth rate of *L. monocytogenes* was inhibited by between 85% and 100%, but there are no data to evaluate the validity of this assumed level of inhibition.” 2004 WHO/FAO Report at 132 (emphasis in original). Defendant otherwise avers that the 2017 Buchanan Review and the 2004 WHO/FAO Report themselves are the best evidence of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 83.

84. Defendant admits that the 2003 FDA Interpretive Summary assessment used mathematical functions anchored to epidemiological evidence in modeling dose-response. Defendant otherwise avers that the 2003 FDA Interpretive Summary is the best evidence of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 84.

Section VIII:

85. Admitted.

86. Admitted.

87. Admitted.

88. Defendant admits that Plaintiffs' Citizen Petition included excerpts from and citations to the FDCA, as well as citations to other information that they claimed supported the actions they requested. Defendant otherwise avers that Plaintiffs' Citizen Petition is the best evidence of its contents and refers the Court to it for a full and complete statement of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 88.

89. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the paragraph purports to describe United States Supreme Court case law and refers the Court to the cited cases for a full and complete statement of their contents.

90. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the paragraph purports to describe certain provisions of the Code of Federal

Regulations and refers the Court to the cited regulatory provisions for a full and complete statement of their contents.

91. Denied.

92. Plaintiffs' allegation is vague, but to the extent that a response is required, Defendant denies this allegation.

93. Denied.

94. Denied.

95. Denied.

96. Defendant admits that typhoid fever, diphtheria, and tuberculosis are not included as "pathogens of concern" in Table 1 on page 11 of the report prepared by the Institute of Food Technologists ("IFT") (FDA/IFT, 2001), *available at* <https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf>. Defendant otherwise avers that the IFT report itself is the best evidence of its contents and refers the Court to it for a full and complete statement of its contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 96.

97. Denied.

98. Denied.

99. Denied.

FIRST CLAIM FOR RELIEF

100. Defendant reasserts and incorporates by reference herein each of its responses to Paragraphs 1 through 99 of the Complaint as though set forth fully herein.

101. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant

admits that the paragraph purports to describe certain regulatory provisions and refers the Court to the cited regulatory provisions for a full and complete statement of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 101.

102. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the paragraph purports to describe certain statutory provisions of the FDCA and refers the Court to the cited statutory provisions for a full and complete statement of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 102.

103. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the paragraph purports to describe certain statutory provisions of the FDCA and refers the Court to the cited statutory provisions for a full and complete statement of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 103.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

SECOND CLAIM FOR RELIEF

108. Defendant reasserts and incorporates by reference herein each of its responses to Paragraphs 1 through 107 of the Complaint as though set forth fully herein.

109. This paragraph states the legal opinions and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to these allegations is required, Defendant admits that the paragraph purports to describe certain regulatory provisions and refers the Court to the cited regulatory provisions for a full and complete statement of their contents. Except as so expressly admitted, Defendant otherwise denies the allegations in Paragraph 109.

110. Denied.

111. Denied.

112. Denied.

The remainder of the allegations in the Complaint constitutes a prayer for relief, to which no response is required. To the extent an answer is required, Defendant denies that Plaintiffs are entitled to the relief requested therein or to any relief whatsoever.

All allegations not specifically admitted or denied in the foregoing numbered responses are hereby denied.

WHEREFORE, based on all the foregoing, Defendant requests judgment in its favor with respect to the Complaint in its entirety and granting such other and further relief as the Court deems just and equitable.

Dated: July 24, 2020

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 24th day of July, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia using the CM/ECF system, which will provide notice to counsel for Plaintiffs.

/s/ Thomas Rosso
THOMAS ROSSO
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