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## Mooove Over Cow's Milk: Why the FDA Should Amend Their Guidelines to Include for Plant-Based Alternatives

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# Mooove Over Cow’s Milk: Why the FDA Should Amend Their Guidelines to Include for Plant-Based Alternatives to Conventional Animal-Based Foods

LAUREN HARRIS\*

*Along with the rise in plant-based alternatives to conventional animal-based foods has been a concern over the use of terms established by the FDA that are specific to animal-based products. Can companies use terms such as "milk" when the product does not come from an animal or "mayo" when the product does not contain eggs? What if a company uses these terms in violation of the FDA's established guidelines and the FDA chooses not to take action? This article explores the history of the FDA, the rise of plant-based alternatives to conventional animal-based foods, consequent litigation and proposed legislation over the use of these defined terms, as well as a proposed solution that the FDA can adopt to combat this ongoing problem.*

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\* Juris Doctor, December 2018. First, I would like to thank my wonderful husband, Adam, for his love and support not only while I was writing this article, but during my entire law school journey. I would also like to thank my family and my in-laws for all of your encouragement and cheerleading. Additionally, I want to thank the entire NIU COL Law Review for all of their hard work making this article ready for publication. Finally, I would like to dedicate my article to all of the plant-based companies out there who are working tirelessly to come up with alternatives to animal-based foods. You are paving the way for a brighter future for both animals and people.

## I. INTRODUCTION

Think back to when you were a child and became hungry for a snack. In opening the refrigerator, most, if not all Americans, can remember seeing many common staples: eggs, meat, and cheese to name a few. But perhaps the most popular items in your fridge are the ones that are in controversy today: milk and mayonnaise. In fact, milk and mayonnaise have found themselves in the middle of a hot debate, with supporters of the original, animal-product versions on one side, and those in favor of plant-based alternatives on the other.

The Food and Drug Administration (“FDA”) has established guidelines for milk and mayonnaise products, which require milk to be from a cow<sup>1</sup> and mayonnaise to contain eggs.<sup>2</sup> However, plant-based companies have put the term “milk” on their plant-based products, including “soy milk” and “almond milk,” and have called their mayonnaise “mayo” when it in fact contains no eggs. One would think that the FDA would have stepped in and enforced their regulations prohibiting this, however the FDA has rarely gotten involved, and when they have, they have allowed these plant-based companies to continue to use terms in violation of the established guidelines.<sup>3</sup>

Recently proposed legislation, such as Wisconsin’s Dairy Pride Act, is attempting to keep milk and mayonnaise limited to the requirements put forth from the FDA.<sup>4</sup> The ever-present threat of litigation from companies who are following the FDA’s guidelines puts plant-based companies in the danger of suffering a financial loss.<sup>5</sup> The arguments on both sides are coming to a head, and the FDA can no longer stay silent.

This article argues that the FDA should amend their current guidelines involving conventional animal-based food products to include for plant-based alternatives, so that plant-based companies can continue to use terms such as “milk” and “mayo” without the fear of retaliatory legislation, lawsuits from corporate giants, and potential penalties from the FDA.

Part II of this article discusses the creation of the FDA and their grant of power from Congress, how the FDA operates in relation to the oversight of food products, and the rise of plant-based alternatives to conventional animal-based foods.

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1. 21 C.F.R. § 131.110 (2005).

2. 21 C.F.R. § 169.140 (1993).

3. See Beth Kowitt, *Hampton Creek: The History of a Mayo Startup in 5 Controversies*, FORTUNE (September 23, 2016), <http://fortune.com/2016/09/23/hampton-creek-controversies/> [https://perma.cc/L924-UD3Y].

4. Dairy Pride Act, S. 130, 115th Cong. (2017).

5. See *Conopco, Inc. d/b/a Unilever v. Hampton Creek, Inc.*, No. 2:14-cv-06856 (D. N.J. 2014).

Part III of this article discusses the controversies surrounding milk and Hampton Creek's eggless product, Just Mayo. Recent litigation involving Hampton Creek is discussed, including the FDA's decision to allow, rather than ban, Hampton Creek's use of the term "mayo" on their plant-based mayonnaise. The Dairy Pride Act is critiqued, including analysis of both sides of the issue, and concludes the Dairy Pride Act is a flawed and unconstitutional attempt to prevent plant-based companies from using these terms.

Part IV of this article discusses why now is the time for the FDA to take a stand regarding use of the terms "milk" and "mayo." Ultimately, the most practical and cost-effective solution is for the FDA to amend their current guidelines to include plant-based alternatives in their definition. This determination is supported by evidence demonstrating the FDA's lack of enforcement regarding the terms "milk" and "mayo," and when the FDA has gotten involved, rather than forbidding plant-based products from using these terms, the FDA has allowed them to continue to use it. As an attempt to force the FDA into keeping the current guidelines and enforcing them, the Dairy Pride Act falls short. Amending their current guidelines to include for plant-based alternatives is a convenient and strategic way for the FDA to solve this ongoing debate.

## II. HISTORICAL ANALYSIS & CURRENT TRENDS

### A. CREATION OF THE FDA

One cannot think about the creation of the Food and Drug Administration (FDA) without also thinking about Upton Sinclair and his groundbreaking novel, *The Jungle*. Published in 1906, this novel was meant to expose the horrific conditions that those working in the meatpacking industry faced on a daily basis, but it also revealed the disgusting behind-the-scenes treatment of meat that consumers were purchasing and eating.<sup>6</sup> "The Jungle's grotesque descriptions of conditions endured by workers and livestock, and the contaminated food that came of them, made it a runaway hit and catalyzed the public's fear and fury."<sup>7</sup> Sinclair was quoted as saying, "I aimed for the public's heart, and by accident I hit it in the stomach."<sup>8</sup>

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6. Jesse Greenspan, *7 Things You May Not Know About "The Jungle,"* HISTORY (2016), <http://history.com/news/7-things-you-may-not-know-about-the-jungle> [https://perma.cc/QP5R-RWHD].

7. Daniel E. Slotnik, *Upton Sinclair, Whose Muckraking Changed the Meat Industry,* N.Y. TIMES (June 30, 2016), <https://www.nytimes.com/interactive/projects/cp/obituaries/archives/upton-sinclair-meat-industry> [https://perma.cc/CAR8-DAQF].

8. *Id.*

The public's outrage and demand for more sanitary conditions at meat-packing plants eventually made its way to President Theodore Roosevelt, who initiated an investigation into the matter.<sup>9</sup> In June of 1906, merely months after *The Jungle* was published, Congress enacted two historic acts: the Pure Food and Drug Act and the Meat Inspection Act.<sup>10</sup> Specifically, the Pure Food and Drug Act prevents "the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs or medicines, and liquor."<sup>11</sup> With the passage of the Pure Food and Drug Act, the FDA took on the role of a federal consumer protection agency.<sup>12</sup> Understandably, since this was a new area that the FDA was put in charge of, there were some hiccups in the regulation and enforcement of the 1906 Act.<sup>13</sup> Some examples of shortcomings within the 1906 Act included products that were dangerous and hazardous, yet legal for consumers to use and consequently, many consumers were injured or even killed by these products.<sup>14</sup>

It was not until 1937 when the Pure Food and Drug Act underwent major revision.<sup>15</sup> By 1938, the Act was renamed to include the term "cosmetic" and removed the word "pure."<sup>16</sup> The revised Act "tightened controls over drugs and food, included new consumer protection laws against unlawful cosmetics and medical devices, and enhanced the government's ability to enforce the law."<sup>17</sup> It is this version of the Act that remains in effect today.<sup>18</sup>

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9. *Id.*

10. Greenspan, *supra* note 6.

11. Historical Highlights, *The Pure Food and Drug Act*, HISTORY, ART, AND ARCHIVES, UNITED STATES HOUSE OF REPRESENTATIVES, <http://history.house.gov/HistoricalHighlight/Detail/15032393280> [https://perma.cc/QJG6-9ZRE].

12. U.S. Food and Drug Admin., *When and Why Was the FDA Formed?* FDA (January 10, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm214403.htm> [https://perma.cc/CPK2-Z7R7].

13. U.S. Food and Drug Admin., *How Did the Federal Food, Drug, and Cosmetic Act Come About?* FDA (January 10, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm214416.htm> [https://perma.cc/CPK2-Z7R7].

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. U.S. Food and Drug Admin., *How Did the Federal Food, Drug, and Cosmetic Act Come About?* FDA (January 10, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm214416.htm> [https://perma.cc/CPK2-Z7R7].

## B. HOW THE FDA OPERATES

The FDA operates under the U.S. Department of Health and Human Services.<sup>19</sup> The FDA is led by the Office of the Commissioner and is broken down into four offices: Medical Products and Tobacco; Foods and Veterinary Medicine; Global Regulatory Operations and Policy; and Operations.<sup>20</sup> The FDA operates under the Federal Food, Drug, and Cosmetic Act which was enacted by Congress under 21 U.S.C. § 301.<sup>21</sup> Under § 301, the FDA is allowed to regulate the food we consume, including additives to food and how foods are “processed, packaged, and labeled.”<sup>22</sup> The FDA has compliance and enforcement procedures in place, including ensuring food safety through inspections and sampling, issuing recalls and seizures, seeking injunctions and even initiating criminal prosecutions.<sup>23</sup> The FDA also creates regulations, codified as federal law, under Title 21 of the Code of Federal Regulations.<sup>24</sup>

The FDA has procedures in place for allowing a food product into the marketplace.<sup>25</sup> When a corporation or small business creates food for con-

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19. U.S. Food and Drug Admin., *How is FDA Organized?* FDA (January 11, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm194884.htm> [https://perma.cc/CPK2-Z7R7]; See U.S. Dep’t of Health & Hum. Serv., *About HHS*, HHS.GOV (January 11, 2018), <http://www.hhs.gov/about> [https://perma.cc/D2YM-5P7K] (stating that the mission of the U.S. Department of Health & Human Services is to provide services that “protect the health and well-being of all Americans.”). In addition to the FDA, the U.S. Department of Health & Human Services oversees ten agencies, including Centers for Disease Control and Prevention (“CDC”), Centers for Medicare and Medicaid Services (“CMS”), and Office of Inspector General (“OIG”). See U.S. Dep’t of Health & Hum. Serv., *HHS Agencies & Offices*, HHS.GOV (January 11, 2018), <http://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html> [https://perma.cc/U9EL-CY7M].

20. U.S. Food and Drug Admin., *How is FDA Organized?* FDA (January 11, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm194884.htm> [https://perma.cc/CPK2-Z7R7].

21. U.S. Food and Drug Admin., *What is the Difference Between the Federal Food, Drug and Cosmetic Act (FD&C Act), FDA Regulations, and FDA Guidance?* FDA (January 11, 2018), <http://fda.gov/AboutFDA/Transparency/Basics/ucm194909.htm> [https://perma.cc/UYA6-KXLS].

22. U.S. Food and Drug Admin., *Ingredients, Packaging & Labeling*, FDA (February 17, 2018), <https://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm> [https://perma.cc/Y6LA-C9KK].

23. U.S. Food and Drug Admin., *Compliance & Enforcement*, FDA (February 17, 2018), <https://www.fda.gov/Food/ComplianceEnforcement/default.htm> [https://perma.cc/JNC9-VFQJ].

24. U.S. Food and Drug Admin., *supra* note 19. Some examples of FDA regulations include 21 C.F.R. § 101, which is for food labeling and 21 C.F.R. § 104, which is for nutritional quality guidelines for foods.

25. See U.S. Food and Drug Admin., *How to Start A Food Business*, FDA (January 11, 2018), <http://www.fda.gov/Food/ResourcesForYou/Industry/ucm322302.htm>

sumption, it is ultimately their responsibility to comply with FDA rules and regulations.<sup>26</sup> This includes proper and accurate food labeling, recordkeeping, and any other specialized requirements laid out by the FDA.<sup>27</sup> When the FDA receives a complaint that a product is inaccurate, they will conduct their own investigation to determine if the allegations have merit.<sup>28</sup> In cases where a misbranded label is at issue, the FDA can contact the manufacturer directly and issue a warning letter informing the manufacturer of the violation and requiring the manufacturer to take the necessary steps towards compliance.<sup>29</sup> Companies that do not take remedial action can have their product(s) removed from the shelves until they comply.<sup>30</sup>

Certain products, including milk and eggs,<sup>31</sup> have to meet the “standard of identity” identified in the FDA’s regulations.<sup>32</sup> The purpose of a standard of identity is so that the consumer knows what they are getting in the product is what the label says, and by protecting consumers from buying unlisted imitation ingredients.<sup>33</sup> At issue in this controversy are the standard identities for milk and mayonnaise. The standard of identity for milk has been codified in 21 C.F.R. § 131.110.<sup>34</sup> “Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.”<sup>35</sup> The standard of identity for mayonnaise has been codified in 21 C.F.R. § 169.140.<sup>36</sup> “Mayonnaise is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying

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[<https://perma.cc/P7ND-YTP6>]. Interestingly, the FDA does not regulate meat, poultry, and certain processed egg products. These products are under the authority of the USDA.

26. *Id.*

27. *Id.* For example, low-acid canned foods, milk, eggs, juice, seafood, and infant formula all have additional requirements which need to be met in order to be sold to consumers.

28. U.S. Food and Drug Admin., *FDA: Foods Must Contain What Label Says*, FDA (January 11, 2018), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm337628.htm> [<https://perma.cc/R26P-LUJG>]. Complaints to the FDA come from industry competitors as well as consumers.

29. *Id.*

30. *Id.*

31. *Id.* Other types of food with a standard of identity include cheese, frozen desserts, bakery products, cereal flours, macaroni and noodle products, canned fruits and vegetables, fruit and vegetable juices, jellies and preserves, fruit pies, fish and shellfish, nut products, beverages, margarine, sweeteners, dressing and flavorings.

32. *Id.*

33. U.S. Food and Drug Admin., *FDA: Foods Must Contain What Label Says*, FDA (January 11, 2018), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm337628.htm> [<https://perma.cc/R26P-LUJG>].

34. 21 C.F.R. § 131.110 (2005).

35. *Id.*

36. 21 C.F.R. § 169.140 (1993).

ingredients specified in paragraph (b) of this section, and one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section.”<sup>37</sup>

Both the Soyfoods Association and Good Foods Institute have filed citizen petitions with the FDA in an attempt to get the FDA to take action regarding use of the term “milk.”<sup>38</sup> When the FDA has chosen not to act, interested parties can file a citizen’s petition in an attempt to force the FDA to make a determination on an issue.<sup>39</sup> The Administrative Procedures Act<sup>40</sup> requires that an administrative agency, such as the FDA, respond in some manner to the petition within 180 days of the date of filing.<sup>41</sup> The FDA responded to the Good Foods Institute’s petition on August 29, 2017, stating that the FDA was unable to make a determination within the 180-day period, but that they were still working on completing a review of the petition.<sup>42</sup> If the FDA makes a final determination in which it refuses to grant the relief requested by the Good Foods Institute, they then have the opportunity for judicial review under the Administrative Review Act.<sup>43</sup> A court will then determine if the FDA, in refusing to grant the citizen’s petition relief, “failed to consider an important aspect of the problem, offered an explanation . . . that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view.”<sup>44</sup> A court, however, cannot demand that the FDA make a decision one way or another; rather a court can simply make sure that the decision was made by the FDA using all available evidence.<sup>45</sup>

The court in *Tummino v. Von Eschenbach* dealt with FDA inaction, and determined that the FDA acted in bad faith in dealing with the citizen’s petition filed by the plaintiffs.<sup>46</sup> The court here stated, “[b]y its inaction in making a final determination on the Citizen Petition, one way or the other, the agency has evaded judicial review of its decision-making . . . .”<sup>47</sup> In listing the reasons why the FDA acted in bad faith, the court pointed to the

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37. *Id.*

38. *See* Soyfoods Petition, *infra* note 75; *see* GFI Petition, *infra* note 180.

39. *See* Ariele Lessing, *Killing Us Softly: How Sub-Therapeutic Dosing Of Live-stock Causes Drug-Resistant Bacteria In Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 482 (2010).

40. *See* 21 C.F.R. § 10.30 (2017).

41. Lessing, *supra* note 39.

42. Letter from Douglas A. Balentine, Ph.D. Dir. Office of Nutrition and Food Labeling Ctr. for Food Safety and Applied Nutrition to Nigel Barrella, Attorney for the Good Foods Institute (Aug. 29, 2017) (on file with author). The FDA stated the reason for not making a determination within the 180-day period as “[o]ther agency competing priorities.”

43. Lessing, *supra* note 39, at 488.

44. *Id.*

45. *Id.* at 489.

46. *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 232 (E.D.N.Y. 2006).

47. *Id.*



length of delay in making a determination on the citizen petition that was filed, noting that it took the FDA five years to make a decision.<sup>48</sup> "Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision."<sup>49</sup> However, when a determination of bad faith has been made, the scope of review is expanded.<sup>50</sup> In *Tummino*, the bad faith on the part of the FDA allowed for the court to order "discovery beyond the administrative record."<sup>51</sup>

Soyfoods Association filed their citizen petition over twenty years ago, and to date the FDA has not made a determination. If the FDA ever makes a determination on the Soyfoods Association's petition, and that decision is not in favor of allowing plant-based dairy alternatives to use the term "milk," Soyfoods Association has the option of judicial review, and there will be a strong argument that, by waiting twenty years to make a determination, the FDA has acted in bad faith. The court will then have the option of issuing a ruling that extends beyond the scope of judicial review, thereby bypassing the FDA's authority to exercise their authority to enforce their own guidelines.

The case of *Ault v. J.M. Smucker Co.*, involved concerns over use of the term "all natural."<sup>52</sup> Here, *J.M. Smucker Co.* interprets the FDA's "lack of action as approval for . . . use of the phrase 'All Natural . . .'"<sup>53</sup> The court here held "[w]here the FDA is unable to address a potentially deceptive practice, state claims are one of the few means of safeguarding consumers and therefore should not be preempted by the FDA's inaction."<sup>54</sup>

#### C. THE RISE OF PLANT-BASED ALTERNATIVES

Over the years, milk and mayonnaise containing animal products have been more accessible to consumers than milk and mayonnaise made with only plant-based ingredients. In fact, for a long time, the only option for consumers was to purchase milk and mayonnaise containing animal products. Early on, plant-based products were not mainstream and were sold

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48. *Id.*

49. *Id.* at 230.

50. *Id.* The Supreme Court in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971) first determined that a showing of bad faith by an administrative agency could serve as a basis for expanding the scope of judicial review.

51. *Tummino*, 427 F. Supp. 2d at 231.

52. *Ault v. J.M. Smucker Co.*, 2015 U.S. Dist. LEXIS 103328 (S.D.N.Y., Aug. 6, 2015).

53. *Id.* at 9.

54. *Id.* at 10.

mostly in small shops.<sup>55</sup> In the 1970s, consumer interest in soy and other non-dairy products soared.<sup>56</sup> Silk Soymilk, owned by the company White-Wave, was introduced into supermarkets in 1978 and is still in supermarkets today.<sup>57</sup>

A major reason why both the dairy industry and plant-based companies are fiercely fighting over terms like “milk” and “mayo” has to do with money. The dairy industry has seen a steady decline in profits over the last decade,<sup>58</sup> while plant-based companies have seen tremendous growth.<sup>59</sup> There are many reasons why consumers are making the shift towards plant-based foods,<sup>60</sup> and they are not just limiting themselves to fruits and vegetables. In fact, plant-based dairy and meat products are more popular now than ever before. The reason why? Millennials.<sup>61</sup> According to one article, “[m]illennials have consistently demonstrated that they care about food, which also means caring about health, the environment, sustainability, and community.”<sup>62</sup>

In response to consumer demand, plant-based foods have become more mainstream.<sup>63</sup> “The global trend was seen from grocery stores to the financial world.”<sup>64</sup> Celebrities such as Arnold Schwarzenegger,<sup>65</sup> Tom

55. Nancy Byrk, *Soy Milk, How PRODUCTS ARE MADE*, <http://www.madehow.com/Volume-5/Soy-Milk.html#ixzz4vQSF9faI> [<https://perma.cc/N5W7-5JZ6>].

56. *Id.*

57. *The History of Silk: The Silk Soymilk Story*, SILK, <https://silk.com/our-story/history> [<https://perma.cc/AZ7M-FBDQ>].

58. Christina Troitino, *The Dairy Pride Act's Beef With Plant-Based Milk*, FORBES (Apr. 6, 2017), <https://www.forbes.com/sites/christinatroitino/2017/04/06/the-dairy-pride-acts-beef-with-plant-based-milk/> [<https://perma.cc/JS8R-PVNV>] (“traditional milk sales have dropped 11% over the last year.”).

59. *Id.* Plant-based milks reached sales of \$5.8 billion in 2014 and are predicted to reach sales of \$10.9 billion by 2019.

60. See Ben McKean, *Vegetables Will Replace Meat By 2020-And Millennials Are Driving The Shift*, OBSERVER (Oct. 10, 2016), <http://observer.com/2016/10/vegetables-will-replace-meat-by-2020-and-millennials-are-driving-the-shift/> [<https://perma.cc/RKD9-YXTD>] (scientific research and food advocates have opened consumer's eyes to the need to eat more vegetables and less animal products).

61. *Id.*

62. *Id.*

63. Avery Yale Kamila, *Concern Over Climate Change Fueled Meatless Movement in 2016*, PORTLAND PRESS HERALD (Jan. 4, 2017), <https://www.pressherald.com/2017/01/04/vegan-kitchen-meatless-movement-made-mega-strides-toward-mainstream-in-2016/> [<https://perma.cc/93HU-CTHK>].

64. *Id.*

65. *Id.* Schwarzenegger urged consumers in China and the United States to eat less meat.

Brady,<sup>66</sup> and, Oprah Winfrey<sup>67</sup> all made health choices towards a more plant-based life in 2016.<sup>68</sup>

Plant-based companies have also become more mainstream. As discussed in this article, Hampton Creek's brand of eggless mayo, as well as other eggless products such as cookie dough, dressings, and even eggless scrambled egg products<sup>69</sup> have wound up on the shelves of major retail chains, thus making them more accessible to consumers.<sup>70</sup> Plant-based milks, such as soy, almond, and coconut, are available in major grocery stores, in the dairy aisle right next to cow's milk.<sup>71</sup> Plant-based startup Beyond Meat's plant-based burger "patties debuted in Boulder, Colorado's Whole Foods and sold out within an hour."<sup>72</sup> Poultry conglomerate Tyson Foods even purchased a 5% interest in Beyond Meat.<sup>73</sup> Recently, Beyond Meat and restaurant chain TGI Friday's teamed up, and the Beyond Burger is now on the TGI Fridays's menu.<sup>74</sup>

### III. THE CONTROVERSIES

#### A. COW'S MILK VS. PLANT MILK

The battle over use of the term "milk" has been going on for decades. In February 1997, Soyfoods Association of America had petitioned the FDA to "recognize the term 'soymilk' as the established common or usual name"<sup>75</sup> for a product derived from soybeans and water.<sup>76</sup> The FDA responded via letter on August 4, 1997, to Soyfoods Association of America's petition and stated that they were not able to reach a decision (within the 180 day timeframe as required by 21 C.F.R. § 10.30(e)(2)) as to whether the FDA should establish a common or usual name for the term

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66. *Id.* Brady came out with a line of popular vegan snacks.

67. *Id.* Winfrey joined (and encouraged others to join) the Meatless Monday movement.

68. Kamila, *supra* note 63.

69. *See infra* note 103.

70. *See infra* note 103.

71. Troitino, *supra* note 58.

72. Kamila, *supra* note 63.

73. Kamila, *supra* note 63.

74. *In the Fastest Test-to-Table Launch in TGI Fridays History, the Plant-Based Beyond Burger is Joining the Menu Nationwide*, BUSINESS WIRE (Jan. 2, 2018), <https://www.businesswire.com/news/home/20180102005138/en/Fastest-Test-to-Table-Launch-TGI-Fridays-History-Plant-Based> [<https://perma.cc/85E7-6GT9>].

75. PETER GOLBITZ, CITIZEN PETITION 1 (1997), <http://www.soyfoods.org/wp-content/uploads/SANA-Citizen-Petition-No.-97P-0078-2-28-97.pdf> [<https://perma.cc/535C-5CEP>].

76. *Id.*

“soymilk.”<sup>77</sup> To date, the FDA has not made a determination regarding Soyfoods Association of America’s request for the term “soymilk.”<sup>78</sup>

In February 2000, the National Milk Producers Federation (NMPF) sent a letter to the FDA, asking the agency to crack down on the labeling of plant-based drinks as “milk.”<sup>79</sup> In their letter, the NMPF filed an official complaint with the FDA, alleging that plant-based milks are misbranded, and this is causing consumer confusion.<sup>80</sup> Specifically, NMPF cites to the standard of identity for milk, 21 C.F.R. § 131.110, and concludes that because plant-based milks do not come from a cow, they cannot legally be called milk.<sup>81</sup> While this may be true, the NMPF’s complaint revealed other reasons for the attack on plant-based “milks”:

[H]istorically, non-dairy beverage products have been primarily sold in limited quantities in specialty supermarkets and health food stores. However, many of these products have recently been appearing in mainstream, major grocery chains. With the recent promulgation of 21 CFR 101.82 *Health claims: Soy protein and risk of coronary heart disease* by FDA, this trend can only be expected to increase. In many instances, these soy-based beverage products are positioned on the grocery shelf alongside milk and other dairy products in a clear attempt to compete with dairy products as a beverage.<sup>82</sup>

It would appear that the real reason for the NMPF’s complaint is to bring attention to the fact that the dairy industry is losing profits,<sup>83</sup> and by alleging a violation of 21 C.F.R. § 131.110, the NMPF and the dairy indus-

77. Interim Response Letter from F. Edward Scarbrough, Dir., Off. of Food Labeling Ctr. for Food Safety and Applied Nutrition, to Peter Golbitz, Comm. Chairperson, Soyfoods Ass’n. of Am. (Aug. 4, 1997) (on file with author). Interestingly, the reasons the FDA gave for not responding within the 180-day timeframe was due to other priorities and limited resources.

78. Letter from Nancy Chapman, Exec. Dir. of Soyfoods of N. Am., to Stephen Ostroff, Acting Comm’r of the FDA (Feb. 2, 2017) (on file with author).

79. Letter from Robert D. Byrne, Vice President of Reg. Aff., to Joseph A. Levitt, Dir. Ctr. for Food Safety and Applied Nutrition, FDA (Feb. 14, 2000) (on file with author).

80. *Id.*

81. *Id.*

82. *Id.*

83. See Press Release, Nat’l Milk Producers Fed’n, Misbranded Dairy Imitations Mislead Ams., Require Enf’t. Action, NMPF Tells FDA Comm’r Scott Gottlieb (Oct. 26, 2017) (on file with author). At the bottom of the press release, the NMPF states, “[T]he National Milk Producers Federation. . . develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own.” One could reasonably infer that “well-being of dairy producers” would include the profits made, which in turn benefit the NMPF.

try are hoping to stiffen the competition. The FDA did not take any action in response to the NMPF's complaint.<sup>84</sup>

On December 16, 2016, just weeks shy of the introduction of the Dairy Pride Act, Representative Peter Welch (D-VT)<sup>85</sup> wrote a letter to the FDA, urging the Commissioner to take action against plant-based milks, which Welch alleged were misbranded in violation of 21 C.F.R. § 131.110.<sup>86</sup> Similar to the complaint sent by the NMPF, Welch's letter includes how the dairy industry is losing profits, including that "milk prices have plunged 40 percent since 2014"<sup>87</sup> and how "dairy farmers are facing a serious financial crisis."<sup>88</sup>

In the litigation field, there have been a few state cases addressing the issue of plant-based dairy products using the term "milk" despite not containing any cow's milk.<sup>89</sup> The courts in these cases have either ruled in favor of the plant-based companies or sent the case to the jurisdiction of the FDA. The case of *Ang v. Whitewave Foods Co.*, involved a class action suit alleging, among others, claims for misbranding of plant-based milks.<sup>90</sup> In writing his opinion, Judge Conti stated, "names 'soy milk,' 'almond milk,' and 'coconut milk' accurately describe Defendants' products. As set forth in the regulations, these names clearly convey the basic nature and content of the beverages, while clearly distinguishing them from milk that is derived from dairy cows."<sup>91</sup>

In the case of *Kelley v. WWF Operating Co.*, the plaintiff alleged consumer confusion in purchasing almond milk, specifically that she believed

84. *Id.* The NMPR stated, "NMPF has made several attempts over the last decade seeking FDA's attention to this issue, but the agency has yet to take any significant enforcement action. . .".

85. Letter from Peter Welch, (D-VT), to Robert M. Califf, Comm'r FDA (Dec. 16, 2016) (on file with author).

86. April McCullum, *Don't call it soy milk, Rep. Welch says*, BURLINGTON FREE PRESS (Dec. 16, 2016), <http://www.burlingtonfreepress.com/story/news/politics/2016/12/16/vermont-peter-welch-soy-almond-milk-fda/95522510/> [<https://perma.cc/4MQV-ECPV>]. Welch was joined by "23 other members of Congress from dairy-producing states" in the writing of the letter to the FDA.

87. *Id.*

88. *Id.* It is interesting to note that Welch's letter states that unless the FDA takes action regarding misbranded plant-based milks, dairy farmers will continue to lose profits. However, Welch concludes by stating that "addressing this serious issue will not solve all the challenges confronting dairy farmers. . .".

89. See *Ang v. Whitewave Foods Co.*, No. 13-cv-1953, 2013 WL 6492353 (N.D. Cal. Dec. 1, 2015); *Gitson v. Trader Joe's Co.*, No. 13-cv-01333-VC, 2015 WL 9121232 (N.D. Cal. Dec. 1, 2015); *Painter v. Blue Diamond Growers*, No. 2:17-cv-02235, Doc. 21, p. 2 (C.D. Cal. May 24, 2017).

90. *Ang v. WhiteWave Foods Co.*, No. 13-cv-1953, 2013 WL 6492353, at \*3 (N.D. Cal. Dec. 1, 2015)

91. *Id.* at \*4.

it was more nutritious than cow's milk.<sup>92</sup> The plaintiff claims that if she would have known they were not nutritionally comparable, she would likely not have purchased the almond milk, and she filed suit based on the federal statute for misbranded food and state laws of unfair competition and false advertising.<sup>93</sup> In *Kelley*, Judge O'Neill stated, "there is no dispute that Congress has enacted a comprehensive scheme to maintain uniformity in food labeling and has delegated the authority of administering it to the FDA."<sup>94</sup> Judge O'Neill further said, "[t]he issue of whether Defendant's products (or any other plant-based 'milk') should be deemed an 'imitation' under § 101.3(e) fits squarely within the FDA's authority, and will require the agency's expertise in determining how to fashion labels so they adequately inform consumers."<sup>95</sup> Judge O'Neill ultimately determined that the FDA has primary jurisdiction over issues that fall within the regulations assigned to them by Congress, and therefore the issues regarding use of the term "milk" are best left to the FDA, and not Congress or the judiciary.<sup>96</sup> Clarification by the FDA "of the law would preempt meritless lawsuits" such as the ones listed above.<sup>97</sup>

While it may appear that the entire dairy industry is opposed to plant-based alternatives using the term "milk," some dairy companies do not mind. "In March 2000, the nation's largest milk producer, Dean Foods, submitted a letter to the FDA saying it had no problem with the term 'soy milk.'"<sup>98</sup> Further, the International Dairy Foods Association's CEO said "[t]hat the labeling issue contained in the Dairy Pride Act is 'best resolved in the marketplace.'"<sup>99</sup>

#### B. EGG-FREE PLANT-BASED "MAYO"

Milk is not the only product to experience controversy—mayonnaise has also had its fair share of turmoil. At the center of the action is startup Hampton Creek and their Just Mayo brand of eggless mayonnaise.<sup>100</sup>

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92. *Kelley v. WWF Operating Co.*, No. 1:17-cv-00117, 2017 WL 2445836, at \*1 (E.D. Cal. June 6, 2017).

93. *Id.*

94. *Id.* at \*4.

95. *Id.* at \*5.

96. *Id.*

97. See Barrella, *infra* note 180.

98. Chase Purdy, *There's a war over the definition of "milk" between dairy farmers and food startups—and Trump may settle it*, QUARTZ MEDIA, LLC (Mar. 2, 2017), <https://qz.com/923234/theres-a-war-over-the-definition-of-milk-between-dairy-farmers-and-food-startups-and-donald-trump-may-settle-it/> [<https://perma.cc/88MB-WYW7>].

99. Troitino, *supra* note 58.

100. See Kowitt, *supra* note 3; Sarah Kaplan, *How little 'Just Mayo' took on Big Egg and Won*, WASH. POST (Dec. 18, 2015), <https://www.washingtonpost.com/news/morning->

Hampton Creek was first sued by corporate giant Unilever, was then hit with a warning letter from the FDA, and finally was personally attacked by the American Egg Board (AEB).<sup>101</sup> What makes the attack on Hampton Creek so significant is that Hampton Creek ultimately succeeded on all three fronts; Unilever dropped its suit, the FDA allowed Hampton Creek to continue to use the term “mayo” despite Just Mayo containing no eggs, and the investigation into the AEB by the United States Department of Agriculture revealed that the AEB had acted inappropriately.<sup>102</sup>

Hampton Creek was founded in 2011 by current CEO, Josh Tetrick.<sup>103</sup> Hampton Creek’s mission was to create plant-based products available in mass retail stores such as Walmart, Whole Foods, and Costco.<sup>104</sup> Hampton Creek’s products include dressings, cookies, cookie dough, and mayo.<sup>105</sup> Hampton Creek’s ideas were so cutting edge, and had the potential to influence the market in such a way, that it was able to secure investments from some of the biggest names in business, including: Asia’s richest man, Li-Ka Shing; the world’s richest man, Bill Gates; and Yahoo founder Jerry Yang.<sup>106</sup>

On October 31, 2014, Unilever, who owns the mayonnaise brand Hellman’s,<sup>107</sup> filed suit in United States District Court for the District of

mix/wp/2015/12/18/how-little-just-mayo-took-on-big-egg-and-won/?utm\_term=.c933cb2b6111 [https://perma.cc/NVC5-LVSH].

101. See Kowitz, *supra* note 3.

102. *Id.* See also Beth Kowitz, *USDA Says American Egg Board’s Ant-Vegan Mayo Campaign was ‘Inappropriate’*, FORTUNE (Oct. 10, 2016), <http://fortune.com/2016/10/10/american-egg-board-hampton-creek/> [https://perma.cc/XV4T-2XXW] (Hampton Creek’s CEO had nine allegations against the AEB, including threatening him via email, trying to block the sales of Just Mayo at Whole Foods, hired a consulting firm to execute a campaign against Just Mayo, and trying to interfere with Just Mayo’s litigation. While the investigation revealed that the AEB did not act illegally, “[t]he AEB had gone beyond its mandate by targeting a specific product and company”); Geoffrey Mohan, *The Egg Industry Launched a Secret Two-Year War Against a Vegan Mayonnaise Competitor*, L.A. TIMES (Oct. 7, 2016), <http://www.latimes.com/business/la-fi-egg-board-investigation-20161007-snap-story.html> [https://perma.cc/6BXU-MFN8] (“The American Egg Board. . . spent at least \$59,500 to counter [Just Mayo’s] publicity advances.”).

103. *Hampton Creek Success Story*, SUCESSSTORY, <https://successstory.com/companies/hampton-creek> [https://perma.cc/FST8-WS5T].

104. *Just For All*, <https://justforall.com/en-us/stories/mission> [https://perma.cc/CJD4-AV5C].

105. *Id.*

106. Jay Yarow, *How A 34-Year-Old With No Experience In Food Science Convinced Investors To Give Him \$30 Million To Make Eggs Obsolete*, BUS. INSIDER (Mar. 24, 2014), <http://www.businessinsider.com/hampton-creek-pitch-deck-2014-3?op=1/#is-is-the-hampton-creek-logo-1> [https://perma.cc/6489-5XVA].

107. Beth Kowitz, *Mayo Wars: How Big Food Is Getting in on Egg-Free ‘Mayo’*, FORTUNE (Feb. 2, 2016), <http://fortune.com/2016/02/02/unilever-hampton-creek-mayo-wars/> [https://perma.cc/XMZ2-8RXL]; See also Strom, *infra* note 127 (Hellman’s mayonnaise is known as “Best Foods” mayonnaise on the West Coast.).

New Jersey against Hampton Creek.<sup>108</sup> The complaint alleged that Hampton Creek's Just Mayo was in violation of the Lanham Act for false advertising and violated state consumer fraud and deceptive practice laws.<sup>109</sup> A quick read of the complaint, and the allegations contained within, sound oddly familiar to the issues that the NMPF and Peter Welch had raised with regards to plant-based milks.<sup>110</sup> For instance, paragraph eleven of the complaint references the FDA's standard of identity for mayonnaise, specifically that it must contain eggs.<sup>111</sup> The complaint also alleges that Just Mayo's mislabeling will cause consumer confusion.<sup>112</sup> Finally, the complaint alleges that Hellman's was losing profits to Just Mayo.<sup>113</sup>

Surprisingly, Hampton Creek never even had to file a response to Unilever's complaint, as Unilever *voluntarily dismissed* its case against Hampton Creek on December 18, 2014.<sup>114</sup> Unilever stated the reason for dismissing its complaint was so the FDA could resolve the misbranded label issues.<sup>115</sup> But the real reason may come from consumer reaction to the litiga-

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108. Conopco, Inc. d/b/a Unilever v. Hampton Creek, Inc., No. 2:14-cv-06856 (D.N.J. 2014).

109. *Id.*

110. *Id.*

111. *Id.*

112. Complaint at 3, Conopco, Inc. d/b/a Unilever v. Hampton Creek, Inc., No. 2:14-cv-06856 (D.N.J. 2014).

113. *Id.* Specifically, the complaint states, “[o]n information and belief, Just Mayo already is stealing market share from Hellmann’s.”

114. See Notice of Voluntary Dismissal, Conopco, Inc. d/b/a Unilever v. Hampton Creek, Inc., No. 2:14-cv-06856 (D.N.J. 2014). See also Associated Press, *Mayonnaise maker Hellman's Gives Vegan a Go After Suing Eggless Spread Maker*, CHI. TRIB. (Feb. 2, 2016), <http://www.chicagotribune.com/business/ct-hellmanns-vegan-mayonnaise-20160202-story.html> [<https://perma.cc/R9Z8-Q7N2>] (Interestingly, some of Hellman's mayonnaise products wouldn't fit the standard of identity for mayonnaise, either. Unilever made some corrections on its website to replace the term “mayonnaise” with “mayonnaise dressing.”).

115. Ryan Mac, *Unilever Drops Mayo Lawsuit Against Egg-Replacing Startup Hampton Creek*, FORBES (Dec. 18, 2014), <https://www.forbes.com/sites/ryanmac/2014/12/18/unilever-drops-mayo-lawsuit-against-egg-replacing-startup-hampton-creek/> [<https://perma.cc/KVN4-NVFT>]. See also Joanne Hawana, *What's in a Name? When You're Selling a Food with an Established Federal Standard of Identity, a Whole Lot!*, (Sept. 8, 2015), <https://www.consumerproductmatters.com/2015/09/whats-in-a-name-when-youre-selling-a-food-with-an-established-federal-standard-of-identity-a-whole-lot/> [<https://perma.cc/FWW4-LATJ>].

Unilever has decided to withdraw its lawsuit against Hampton Creek so that Hampton Creek can address its label directly with industry groups and appropriate regulatory authorities. . . . We applaud Hampton Creek's commitment to innovation and its inspired corporate purpose. We share a vision with Hampton Creek of a more sustainable world. It is for these reasons that we believe Hampton Creek will take the appropriate steps in labelling its products going forward.

*Id.*



tion.<sup>116</sup> In the eyes of the public, the suit was a horrible move on Unilever's part, as consumers viewed the attack on Hampton Creek as analogous to a David and Goliath battle.<sup>117</sup> While Hampton Creek's legal battle with Unilever was over, the relief was short lived. The Just Mayo producer now faced the FDA.

On August 12, 2015, the FDA sent Hampton Creek a letter stating that "Just Mayo products were 'misbranded' because they do not meet the legal definition of mayonnaise."<sup>118</sup> Specifically, Hampton Creek's products:

do not qualify as the standardized food mayonnaise as described under 21 CFR 169.140. Mayonnaise is a food for which a definition and standard of identity has been prescribed by regulation (see 21 CFR 169.140). According to the standard of identity for mayonnaise, egg is a required ingredient (21 CFR 169.140(c); however, based on the ingredient information on the labels, these products do not contain eggs.<sup>119</sup>

The FDA concluded their letter to Hampton Creek by including a provision indicating that Hampton Creek needs to let the FDA know their plan of action to correct the violations.<sup>120</sup>

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116. See Kowitz, *supra* note 107. A few years after dismissing its suit against Hampton Creek, Unilever came out with its own version of an eggless mayonnaise. However, to prevent any double standard stigma, Unilever did not use the term "mayo," but rather "dressing and sandwich spread." The reason given by Hellman's for the development of an egg-free "sandwich spread" came from "listening to our consumers."

117. Sarah Kaplan, *How little 'Just Mayo' took on Big Egg and Won*, WASH. POST (Dec. 18, 2015), [https://www.washingtonpost.com/news/morning-mix/wp/2015/12/18/how-little-just-mayo-took-on-big-egg-and-won/?utm\\_term=.c933cb2b6111](https://www.washingtonpost.com/news/morning-mix/wp/2015/12/18/how-little-just-mayo-took-on-big-egg-and-won/?utm_term=.c933cb2b6111) [<https://perma.cc/NVC5-LVSH>]. A Change.org petition was filed by consumers who wanted "Unilever to stop bullying sustainable food companies."

118. Warning letter from William A. Correll, Jr., Dir. Off. of Compliance Ctr. for Food Safety and Applied Nutrition, FDA, to Joshua Tetrick, CEO of Hampton Creek Foods, Inc. (Aug. 12, 2015) (on file with author). The letter also listed other violations, including that Just Mayo did not meet the requirements for a cholesterol-free claim, and heart-healthy claim. Just Mayo also had issues with their nutrition label, specifically that it did not meet the requirements of 21 C.F.R. § 101.9(d)(2), (d)(1)(i), and (d)(9). Finally, Just Mayo was in violation of 21 C.F.R. § 101.5(d) for not including their street address on their product, and 21 C.F.R. § 101.2(a) for not placing the information panel immediately contiguous and to the right of the principal display panel.

119. Warning letter from William A. Correll, Jr., Dir. Off. of Compliance Ctr. for Food Safety and Applied Nutrition, FDA, to Joshua Tetrick, CEO of Hampton Creek Foods, Inc., *supra* note 118.

120. *Id.* See also Strom, *infra* note 127 (Tetrick said that at his meeting with the FDA regarding the violations, the FDA were "thoughtful and engaging and really seemed to be trying to hear us out." Tetrick was not unnerved by FDA involvement—"This gives us the

The significance of this warning letter is that while the FDA stated Hampton Creek was violating their established guidelines, the FDA did not indicate to Hampton Creek that they had to stop selling Just Mayo, nor did they tell Hampton Creek that eggs needed to be added to their eggless mayo.<sup>121</sup> Finally, the FDA did not make any suggestions as to what Hampton Creek needed to do in order to comply with the guidelines.<sup>122</sup>

On December 18, 2015, only four months after receiving the initial letter, Hampton Creek was sent a close out letter from the FDA informing them that they successfully addressed the violations as stated in the initial letter.<sup>123</sup> The FDA also allowed to let Hampton Creek to continue to use the term “mayo,” despite not adding any eggs to their product.<sup>124</sup> So, exactly what changes did Hampton Creek have to make?

The product’s attributes, including egg-free, are now bigger, and the company’s logo of a cracked egg is smaller.<sup>125</sup>

The company has also added the words “spread and dressing” to the label.<sup>126</sup> [T]he label will define the word “just” in the brand name to mean “guided by reason, justice and fairness” instead of suggesting that it was an exact replica of mayonnaise.<sup>127</sup>

The decision by the FDA to allow Hampton Creek to continue to use the term “mayo” despite it not containing eggs was an important decision. While Just Mayo is in clear violation of the standard of identity for mayonnaise as set out in 21 C.F.R. § 169.140, the FDA has made the conscious

chance to tell the bigger story about what we're trying to accomplish with Hampton Creek in terms of changing the food system.”).

121. See U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY (2013). The FDA stated that they do not pre-approve labels for food products.

122. *Id.* The FDA maintains that “[i]t is the responsibility for the food industry to remain current with the legal requirements for food labeling.”

123. Close Out letter from William A. Correll, Jr., Dir. Off. of Compliance Ctr. for Food Safety and Applied Nutrition, FDA, to Joshua Tetrick, CEO of Hampton Creek Foods, Inc. (Dec. 18, 2015) (on file with author). See also Strom, *infra* note 127 (The FDA said that Hampton Creek “had promised to make changes to its labeling and that it would ensure it was truthful and not misleading.” From this, the FDA considered the issues to be resolved.).

124. Beth Kowitt, *The Mayo Wars Just Ended*, FORTUNE (Dec. 17, 2015), <http://fortune.com/2015/12/17/hampton-creek-just-mayo-fda/> [https://perma.cc/6KT5-VAVK].

125. *Id.*

126. *Id.* The decision to require the words “spread and dressing” could indicate that the FDA was not willing to amend the definition of mayonnaise to include Just Mayo’s eggless ingredients.

127. Stephanie Strom, *F.D.A. Allows Maker of Just Mayo to Keep Product’s Name*, N.Y. TIMES (Dec. 17, 2015), <https://www.nytimes.com/2015/12/18/business/fda-allows-maker-of-just-mayo-to-keep-products-name.html> [https://perma.cc/V67W-WZPC].

decision not to enforce their own guidelines. It would appear that it will now be difficult for any egg-based mayonnaise company to try and stop Hampton Creek, or any other eggless brand of mayonnaise for that matter, from using the term “mayo” in direct violation of FDA guidelines. This determination can also be used as support for other plant-based alternative companies who want to use generic, familiar terms traditionally used with animal products, such as “cheese” “yogurt” and even “milk.”<sup>128</sup>

For instance, in 2008 and 2012, the FDA had sent warning letters to manufacturers Lifesoy, Inc.<sup>129</sup> and Fong Kee Tofu Company, Inc.<sup>130</sup> regarding their use of the term “milk” in association with “soy milk,” however the FDA “[u]ltimately did not utilize its enforcement powers to prohibit the use of the term ‘milk’ on the products in question.”<sup>131</sup>

In June 2011, the FDA sent a warning letter to CytoSport, Inc., the makers of the popular protein shake, Muscle Milk, as the company uses the term “milk” as part of the name for their product in violation of 21 C.F.R. § 131.110, as Muscle Milk in fact contains no milk.<sup>132</sup> On November 29, 2016, the FDA sent a close out letter to CytoSport, Inc. informing them that their product Muscle Milk had “addressed the violations in the warning

128. See, e.g., Health Claims; Soy Protein and Coronary Heart Disease, 63 Fed. Reg. 62977, 62978 (Nov. 10, 1998) (to be codified at 21 C.F.R. pt. 101) (showing how the FDA itself has referred to soy products as soy milk, soy yogurt, and soy cheese).

129. Warning Letter from Alonza Cruse, FDA Dist. Dir., to Long H. Lai, Lifesoy, Inc. (Aug. 8, 2008) (on file with author), <https://wayback.archiveit.org/7993/20170112200226/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm> [https://perma.cc/YY8G-QGR7] (“[w]e do not consider ‘soy milk’ to be an appropriate common or usual name because it does not contain ‘milk.’”).

130. Warning Letter from Barbara Cassen, FDA Dist. Dir., to Yan Hui Fang, CEO of Fong Kee Tofu Company, Inc. (Mar. 7, 2012) (on file with author), <https://wayback.archiveit.org/7993/20170112192606/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm295239.htm> [https://perma.cc/YY8G-QGR7] (“[w]e do not consider ‘soy milk’ to be an appropriate common or usual name because your product does not contain ‘milk.’”).

131. Katie Gates Calderon, Elizabeth Fessler & Lindsey Heinz, *Dairy Vs. Plant-Based ‘Milks’: A Regulatory Standoff*, LAW 360: A LEXISNEXIS Co. (Aug. 24, 2017).

132. Warning Letter from Barbara Cassen, FDA Dist. Dir., to Michael Pickett, CEO of CytoSport, Inc. (June 29, 2011) (on file with author), [http://fda-warning-letters.blogspot.com/2011/06/department-of-health-and-human-services\\_29.html](http://fda-warning-letters.blogspot.com/2011/06/department-of-health-and-human-services_29.html) [https://perma.cc/6YZG-EXPA].

Your “Chocolate Muscle Milk Protein Nutrition Shake” and “Vanilla Crème Muscle Milk Light Nutritional Shake” products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labels are false or misleading. For example: These product labels prominently feature the word “MILK,” however these products contain no milk.

*Id.*

letter from 2011.”<sup>133</sup> So far, CytoSport is still using the word “milk” on their Muscle Milk beverage.<sup>134</sup>

### C. THE DAIRY PRIDE ACT

Defending Against Imitations and Replacements of Yogurt, milk, and cheese to Promote Regular Intake of Dairy Everyday Act, aptly referred to as the “Dairy Pride Act,” was introduced by Wisconsin Senator Tammy Baldwin (D-WI)<sup>135</sup> on January 12, 2017 to the Senate<sup>136</sup> and an identical version of the bill was introduced by Peter Welch (D-VT)<sup>137</sup> to the House.<sup>138</sup> Welch’s House version of the bill was co-sponsored by “Rep. Michael Simpson (R-ID); Rep. Sean Duffy (R-WI); Rep. Joe Courtney (D-CT); Rep. David Valadao (R-CA); and Rep. Suzan DelBene (D-WA).”<sup>139</sup> The Dairy Pride Act essentially claims that plant-based milks are misbranded because they use the term “milk” when they contain no milk that comes from a cow, as defined in 21 C.F.R. § 131.110 (2018).<sup>140</sup> The Act further claims that because these “imitations” are misbranded,<sup>141</sup> consumers are being misled<sup>142</sup> into thinking that plant-based dairy products have the nutri-

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133. Close Out letter from Lawton W. Lum, Dir. Compliance Branch, S.F. Dist., FDA, to James P. Snee, CEO of Hormel Foods Corp. Servs., LLC (Nov. 29, 2016) (on file with author), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm530973.htm> [<https://perma.cc/DCT3-XU4P>].

134. MUSCLE MILK, <http://www.muscle milk.com/products/> [<https://perma.cc/SL36-HV8N>].

135. Tammy Baldwin was born in 1962 in Madison, WI. She received her J.D. from the Univ. of WI at Madison in 1989. In 1998, she was the first woman from WI elected to the U.S. House of Representatives and in 2012 she was elected to the U.S. Senate. She serves on the Senate Appropriations Committee, the Senate Committee on Health, Education, Labor and Pensions (HELP), and the Senate Committee on Commerce, Science, and Transportation. See *About Tammy Baldwin*, <https://www.baldwin.senate.gov/about> [<https://perma.cc/44WY-GFZC>].

136. The Dairy Pride Act, S. 130, 115th Cong. (2017).

137. Peter Welch was born in Springfield, Mass. He received his J.D. from the Univ. of CA at Berkeley. He was elected to Congress in 2006 for Vt.’s seat in the House of Representatives. He serves on the Committee on Energy and Commerce and the Committee on Oversight and Government Reform. See *Peter Welch Biography*, <https://welch.house.gov/about/biography> [<https://perma.cc/GHQ3-2C4X>].

138. The Dairy Pride Act, H.R. 778, 115th Cong. (2017).

139. Steve Brachmann, *Dairy Pride Act Would Clear Up Consumer Milk Confusion Between Dairy Products and Plant-Based Beverages*, IPWATCHDOG (Sept. 21, 2017), <http://www.ipwatchdog.com/2017/09/21/dairy-pride-act-would-clear-consumer-milk-confusion/id=87950/> [<https://perma.cc/9W44-DYXT>].

140. Dairy Pride Act, S. 130, 115th Cong. § 2(7) (2017).

141. *Id.* at § 2(8).

142. *Id.* at § 2(6).

tional equivalency of animal-based dairy products,<sup>143</sup> and that consumers are therefore becoming nutrient deficient by drinking and eating these plant-based products instead of animal-based products.<sup>144</sup> As expected, the Dairy Pride Act calls for enforcement of the FDA's definition of milk.<sup>145</sup>

It should come as no surprise that the Dairy Pride Act has gained support from dairy farmers and producers across the country.<sup>146</sup> Wisconsin, where Baldwin is from, is known as "America's Dairyland."<sup>147</sup> "Dairy is the largest segment of Wisconsin agriculture,<sup>148</sup> contributing \$43.4 billion annually to Wisconsin's economy."<sup>149</sup> In 2016 alone, Wisconsin produced more than 30 billion pounds of milk.<sup>150</sup> Many farmers see the Dairy Pride Act as a way to help boost sales of dairy products and guarantee work.<sup>151</sup> Several farmers who have made comments supporting the Dairy Pride Act,<sup>152</sup> have mentioned that the FDA should be enforcing their regulation,<sup>153</sup> and address what the farmers refer to as plant-based "imitations."<sup>154</sup>

143. *Id.* at § 2(5).

144. *Id.* at § 2(3-4).

145. Dairy Pride Act, S. 130, 115th Cong. § 2(8) (2017).

146. See Dan Charles, *Soy, Almond, Coconut: If It's Not From A Cow, Can You Legally Call It Milk?*, THE SALT: NPR (Dec. 21, 2016), <https://www.npr.org/sections/thesalt/2016/12/21/506319408/soy-almond-coconut-if-its-not-from-a-cow-can-you-legally-call-it-milk> [https://perma.cc/4CBE-MG2C]; Editorial Board, *Sour Milk From The Dairy Industry*, CHI. TRIB. (Apr. 7, 2017), <http://www.chicagotribune.com/news/opinion/editorials/ct-milk-almond-soy-dairy-fda-edit-0410-md-20170407-story.html> [https://perma.cc/A2PE-ZC2B]; Associated Press, *Stop Calling Almond, Soy, and Rice Milks 'Milk,' 25 Members of Congress Say*, L.A. TIMES (Dec. 23, 2016), <http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html> [https://perma.cc/E9H9-YSBG].

147. Associated Press, *No more 'America's Dairyland' on Wisconsin license plates?* WIS. STATE FARMER (Oct. 17, 2017), <http://www.wisfarmer.com/story/news/state/2017/10/17/no-more-americas-dairyland-wisconsin-license-plates/770903001/> [https://perma.cc/MLQ9-D467] (Wisconsin's license plate has had the phrase "America's Dairyland" on it since 1940 due to its voluminous dairy production).

148. Wisc. Milk Marketing Board, *2017 Dairy Data: A Review of the Wisc. Dairy Industry*, WMMB (2017), <http://www.wmmb.com/assets/images/pdf/WisconsinDairyData.pdf> [https://perma.cc/77JB-H7WH].

149. *Id.*

150. *Id.* Interestingly, California produced more pounds of milk than Wisconsin, at over forty billion pounds.

151. Support for Senator Baldwin's Dairy Pride Act, BALDWIN SENATE GOV, <https://www.baldwin.senate.gov/imo/media/doc/011217%20DAIRY%20PRIDE%20Act%20Quotes.pdf> [https://perma.cc/5MM9-Q65S].

152. *Id.* For example, one farmer said, "Finally after all these years, it's about time someone stands up for the American Dairy farmer."

153. *Id.* Many of the comments from the farmers and groups that support the Dairy Pride Act referenced the FDA's lack of involvement in enforcing their own regulations. For example, one farmer said, "Milk is clearly defined by the FDA, and this definition should

Support for the Dairy Pride Act has also come from organizations that have a stake in the dairy industry.<sup>155</sup> The National Milk Producers Federation (NMPF) has said that “[They] are going to be looking for every opportunity to help move forward the DAIRY PRIDE Act.”<sup>156</sup> Agri-Mark Inc.,<sup>157</sup> who in the early months of 2017 alone, spent \$20,000 in lobbying,<sup>158</sup> has publicly voiced their support for the Dairy Pride Act, with a spokesman stating, “We are a dairy farmer-owned co-op so we firmly believe milk comes from cows.”<sup>159</sup> These organizations that support the Dairy Pride Act are actively lobbying Congress, with approximately \$300,000 spent in the first half of 2017.<sup>160</sup> As one can see, the organizations that have a stake in dairy profits lobby Congress hard to make sure their interests are protected.<sup>161</sup>

Opponents of the Dairy Pride Act have criticized the Act as bullying plant-based companies in an attempt to eliminate the competition.<sup>162</sup> As one article puts it, “[a]s the alternative forms of milk have become more popular, they've taken sales away from dairy producers. Regular milk sales are off by 20 percent since 2011. So the industry wants the federal government to intervene, while claiming to uphold the interests of grocery shoppers.”<sup>163</sup> Plant-based dairy also appeals to those who have concerns regarding health,

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also be enforced. It's about time the FDA upheld its responsibility of enforcing existing labeling requirements, especially when it comes to dairy.”

154. *Id.*

155. See The Dairy Pride Act, National Milk Producer's Federation, <http://www.nmpf.org/files/DAIRY%20PRIDE%20Act%20-%20One%20Pager.pdf> [<https://perma.cc/78EQ-A8HH>]; Teaganne Finn, *Dairy Cries Over 'Soy milk' as Lobbying Spills Into Legislation*, BLOOMBERG NEWS (Sept. 7, 2017), <https://www.bna.com/dairy-cries-soymilk-n73014464218/> [<https://perma.cc/5LAL-5WJB>].

156. *Id.*

157. Agri-Mark, Inc. is a dairy farmer cooperative in the northeastern region of the United States of America. See *The Northeast's Premier Dairy Farmer Cooperative*, AGRI-MARK FAMILY DAIRY FARMS, <https://www.agrimark.coop/> [<https://perma.cc/7UBY-XGXM>].

158. See Finn, *supra* note 155.

159. *Id.*

160. *Id.* This amount was for all issues, not solely the Dairy Pride Act.

161. See Editorial Board, *Sour Milk From The Dairy Industry*, CHI. TRIB. (Apr. 7, 2017), <http://www.chicagotribune.com/news/opinion/editorials/ct-milk-almond-soy-dairy-fda-edit-0410-md-20170407-story.html> [<https://perma.cc/A2PE-ZC2B>] (“27 members of Congress who got donations have signed a letter demanding that the federal Food and Drug Administration investigate the issue.”).

162. *Act Now to Fight a Dangerous Bill Pushed by Dairy Industry*, ANIMAL LEGAL DEFENSE FUND (Feb. 27, 2017), <http://aldf.org/blog/act-now-to-fight-a-dangerous-bill-pushed-by-dairy-industry/> [<https://perma.cc/WAM2-86K8>].

163. See Editorial Board, *supra* note 161.

animal welfare,<sup>164</sup> and the environment.<sup>165</sup> The groups that oppose the bill spent approximately \$40,000 in lobbying in the first half of 2017.<sup>166</sup>

The Dairy Pride Act does have a valid point in stating that plant-based milks use the term “milk” in violation of milk’s standard of identity.<sup>167</sup> The state of New Jersey even proposed legislation similar to the Dairy Pride Act in an attempt to enforce its regulations.<sup>168</sup> However, most of the sections of the bill can be argued to illustrate how the Dairy Pride Act is flawed. For instance, section 2(1) states, “[d]airy products are an important part of a healthy diet for both children and adults, according to the 2015-2020 Dietary Guidelines for Americans . . . published by the Department of Health and Human Services and the Department of Agriculture.”<sup>169</sup> However, a study funded by the National Dairy Council found that “the high protein content of dairy leaches calcium from the body.”<sup>170</sup> Section (2) states “dairy foods contribute about 67 percent of calcium, 64 percent of vitamin D, and 17 percent of magnesium.”<sup>171</sup> But it has also been argued that one can easily get higher levels of calcium and magnesium from fruits, vegetables, nuts, seeds, tofu, and simple sunlight aides in vitamin D absorption.<sup>172</sup>

Section 2(3) of the Dairy Pride Act states that most people, particularly females, do not meet the required daily dairy intake.<sup>173</sup> But there is no proof that passage of the Dairy Pride Act would increase dairy intake.<sup>174</sup> Section 2(6) states “[p]lant-based products labeled as milk are misleading to

164. For an in-depth discussion regarding animal welfare for dairy cows, see The Humane Society of the United States, *An HSUS Report: The Welfare of Cows in the Dairy Industry*, THE HUMANE SOCIETY OF THE UNITED STATES, <http://www.humanesociety.org/assets/pdfs/farm/hsus-the-welfare-of-cows-in-the-dairy-industry.pdf> [https://perma.cc/PFS9-TCZT] (last visited Feb. 6, 2019).

165. Anahad O’Connor, *Got Almond Milk? Dairy Farms Protest Milk Label on Nondairy Drinks*, N.Y. TIMES (Feb. 13, 2017), <https://www.nytimes.com/2017/02/13/well/eat/got-almond-milk-dairy-farms-protest-milk-label-on-nondairy-drinks.html> [https://perma.cc/AEZ7-H5PD].

166. See Finn, *supra* note 155 (this amount was for all issues, not solely the Dairy Pride Act).

167. The Dairy Pride Act, S. 130, 115th Cong. (2017) at 2(7-8); 21 C.F.R. § 131.110.

168. Assemb. Res. 235, 217 Leg. (N.J. 2017).

169. The Dairy Pride Act, S. 130, 115th Cong. (2017) at 2(1).

170. RORY FREEDMAN & KIM BARNOUIN, *SKINNY BITCH: A NO-NONSENSE, TOUGH-LOVE GUIDE FOR SAVVY GIRLS WHO WANT TO STOP EATING CRAP AND START LOOKING FABULOUS!* 54 (2005).

171. The Dairy Pride Act, S. 130, 115th Cong. (2017) at 2(2).

172. See FREEDMAN, *supra* note 170 at 57.

173. The Dairy Pride Act, S. 130, 115th Cong. (2017) at 2(3).

174. See e.g. The Times Editorial Board, *Got ‘Milk’? Dairy Farmers Rage Against Imitators But Consumers Know What They Want*, L.A. TIMES (Jan. 4, 2017), <http://latimes.com/opinion/editorials/la-ed-plant-milk-fda-20170104-story.html> [https://perma.cc/E9H9-YSBG] (“There’s no evidence that consumers have been tricked into buying a less nutritious plant-based alternative or that they’re unaware of the difference.”).

consumers.”<sup>175</sup> However, “the term ‘soymilk’ has been used on products for more than 100 years.”<sup>176</sup> According to one article, “[t]he status quo serves consumers just fine, offering them a range of beverage options that they have no trouble understanding.”<sup>177</sup>

What’s more, the Dairy Pride Act is arguably an unconstitutional restriction on commercial speech.<sup>178</sup> The famous Supreme Court case *Central Hudson Gas & Electric v. Public Service Commission of New York* put forth a four-part test for determining whether the government may regulate commercial speech: (1) is the speech protected (meaning it involves a lawful activity and is not misleading)?; (2) is there a substantial state interest?; (3) does the regulation directly advance that interest?; and (4) is the regulation no more extensive than necessary to protect the interest?<sup>179</sup> “Only when speech is inherently misleading will it fall outside of the protection of the First Amendment.”<sup>180</sup> Manufacturers using the term “milk,” attached to terms such as “almond” or “soy,” is a clear indication that they are not trying to mislead consumers into thinking their plant-based product is the same as cow’s milk.<sup>181</sup> Further, while some may say the government has a substantial interest in preventing consumer confusion, there really isn’t much consumer confusion out there to begin with.<sup>182</sup> Regarding the third prong of the *Central Hudson* test, the Dairy Pride Act does not further a government interest in preventing consumer confusion, as “banning the use of an already well-established name would result in more consumer confusion, and so would hardly serve the government’s interest in preventing

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175. The Dairy Pride Act, S. 130, 115th Cong. (2017) at 2(6).

176. Associated Press, *Stop Calling Almond, Soy, and Rice Milks ‘Milk,’ 25 Members of Congress Say*, L.A. TIMES (Dec. 23, 2016), <http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html> [<https://perma.cc/E9H9-YSBG>].

177. Editorial Board, *Sour Milk From The Dairy Industry*, CHI. TRIB. (Apr. 7, 2017), <http://www.chicagotribune.com/news/opinion/editorials/ct-milk-almond-soy-dairy-fda-edit-0410-md-20170407-story.html> [<https://perma.cc/A2PE-ZC2B>].

178. See Constantine Spyrou, *The Dairy Pride Act is Poorly Written, Big Dairy Propaganda*, FOODBEAST (Mar. 31, 2017), <https://www.foodbeast.com/news/dairy-pride-act/> [<https://perma.cc/8DQL-NX7Z>]; Emily Byrd, *Lawyers Find Pro Dairy Law Unconstitutional*, THE GOOD FOOD INSTITUTE, GOOD FOOD INSTITUTE (Mar. 2, 2017), <http://www.gfi.org/lawyers-find-pro-dairy-law-unconstitutional> [<https://perma.cc/5YTC-9PWP>]. For an in-depth look at commercial speech, see Scott Wellikoff, *Mixed Speech: Inequities That Result From An Ambiguous Doctrine*, 19 St. John's J.L. Comm. 159 (2004).

179. Scott Wellikoff, *Mixed Speech: Inequities That Result From An Ambiguous Doctrine*, 19 St. John's J.L. Comm. 159, 170-171 (2004).

180. Nigel Barrella, *Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food*, GOOD FOOD INSTITUTE (Mar. 2, 2017), <http://www.gfi.org/images/uploads/2017/03/GFIpetitionFinal.pdf> [<https://perma.cc/Y7RH-WS3H>].

181. *Id.*

182. *Id.* at 29-30.



confusion.”<sup>183</sup> Finally, the Dairy Pride Act is more extensive than is necessary in preventing consumer confusion;<sup>184</sup> in fact, the Dairy Pride Act itself is quite simply unnecessary. “[M]andatory nutritional labeling already suffices to inform consumers not just that the products are distinct, but exactly how they are distinct nutritionally — and this comprehensive disclosure is more than enough to protect against any supposed risk of deception.”<sup>185</sup>

Should the Dairy Pride Act pass into law, opponents can also fight to have it overturned on the grounds that the law is content-based and therefore unconstitutional.<sup>186</sup> A law will be an unconstitutional restriction on free speech if it “target[s] speech based on its communicative content . . . and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.”<sup>187</sup> “Restricting the common names of dairy alternatives, such as soymilk, would be a content-based restriction on speech, because such restrictions cannot be justified without reference to the content of such speech — to wit, the fact that such names reference dairy products specifically.”<sup>188</sup> Even if the government had a content-neutral solution that would lessen the level of scrutiny applied, “[t]he government could offer no content-neutral justification for banning outright the names of ‘soymilk’ or ‘almond milk,’ while allowing other products named in similar fashion to keep their names.”<sup>189</sup>

Taking another legal approach to the Dairy Pride Act could be to analyze it from an intellectual property standpoint. The Dairy Pride Act is trying to prevent plant-based dairy products from using terms like “milk,” “yogurt,” and “cheese;” however, these terms are generic and therefore cannot be claimed.<sup>190</sup> These generic terms cannot be owned by anyone, and therefore all are free to use them.<sup>191</sup>

183. *Id.* at 31.

184. *Id.* at 31. The petition states “[t]here are many alternative narrowly-drawn ways to dispel potential deception. . . .”

185. Nigel Barrella, Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food, GOOD FOOD INSTITUTE (Mar. 2, 2017), <http://www.gfi.org/images/uploads/2017/03/GFIpetitionFinal.pdf> [<https://perma.cc/Y7RH-WS3H>].

186. *Id.*

187. *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015).

188. Barrella, *supra* note 180.

189. *Id.* Specifically, Barrella mentions “[r]ice noodles, the name of which does not declare up-front whether it contains egg or wheat, as required of ‘noodles’ under FDA’s standard of identity.”

190. JAMES G. SAMMATARO, *FILM AND MULTIMEDIA AND THE LAW* § 4:6. GENERIC MARKS (2017 ed. 2017) (“a generic term names the item, ‘milk,’ ‘Yo-Yo,’ ‘drum,’ and ‘soap. Generic terms can never be trademarked, because they neither identify the user’s goods nor distinguish them from another’s goods.”). For a discussion on trademark terms, see *Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4, 9-10 (2d Cir. 1975); Jake Linford,

The Dairy Pride Act would also take away power from the FDA, because instead of having the FDA regulate the terms used to describe “milk” and “mayo,” the legislature would control. Because the FDA operates under the Federal Food, Drug, and Cosmetic Act enacted by Congress under 21 U.S.C. § 301,<sup>192</sup> regulation of foods listed under that Act are within the jurisdiction of the FDA and not legislators such as Tammy Baldwin (D-WI) and Peter Welch (D-VT).

Currently, the Dairy Pride Act is with the Committee on Health, Education, Labor, and Pensions,<sup>193</sup> where it has sat for most of 2017.

#### IV. PROPOSED SOLUTION

If the Dairy Pride Act were to pass into law, it would prohibit plant-based companies from using terms like “milk” and “mayo” when labeling their products.<sup>194</sup> The Act would further interfere with the FDA’s ability to regulate and enforce FDA regulations. The issues presented in this article have been going on for over twenty years, and it is time for the FDA to step in, take control, and make a decision on whether plant-based companies may use terms that have an established standard of identity. Interestingly, many of the FDA’s actions have supported plant-based companies rather than hinder their ability to use terms like “milk” and “mayo.”<sup>195</sup> A proposed solution that is viable, cost-effective, and achievable is for the FDA to amend their current guidelines to allow for plant-based companies to use terms such as “milk” and “mayo.”

The process for amending a regulation is not as tedious as one might think. Usually, the FDA will publish a rule and/or regulation in the Federal Register.<sup>196</sup> The proposed rule is open to comments from the public,<sup>197</sup> including businesses and consumers. The FDA takes public comments under advisement and uses the feedback they have received to help adjust the specific policy to be put in place.<sup>198</sup> The FDA can then either close the process

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*A Linguistic Justification for Protecting "Generic" Trademarks*, 17 Yale J. L. & Tech. 110 (2015).

191. See Times Editorial Board, *supra* note 174 (“Milk . . . is a relatively generic term that can’t easily be controlled through trademarks and copyrights.”).

192. See 21 C.F.R. § 131.110, *supra* note 34.

193. The Dairy Pride Act, S. 130, 115th Cong. (2017)

194. *Id.* at § 2.8.

195. *But see* Calderon, *supra* note 131 (“The FDA has not taken any action to affirmatively approve the use of the term ‘milk’ on plant-based products, either.”).

196. *FDA Rules and Regulations*, FOOD & DRUG ADMIN. (Last updated Mar. 28, 2018), <https://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm> [<https://perma.cc/C564-FGES>].

197. *Id.*

198. *Id.*

or determine if any further action is needed, such as issuing a new proposed rule or issuing a final rule.<sup>199</sup> The final rule is published under Title 21 of the Federal Register and is codified into law.<sup>200</sup> Sometimes, the FDA will issue an amendment without notice or comment.<sup>201</sup>

One option would be for the FDA to amend the descriptions in Title 21 that list animal products and to modify them to also include for plant-based alternatives. For example, the description in 21 C.F.R. § 131.110 can be amended to: milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows *or is manufactured from plants*. 21 C.F.R. § 169.140 can be amended to: mayonnaise is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, and *it is optional to add* one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section. Yes, the FDA would have to amend the guidelines for all animal-based products that can be made with plant-based alternatives, such as butter, yogurt, cheeses, etc. However, amending guidelines is a normal part of any administrative agency's scope of duties and would likely not be an undue burden on the FDA.

Another way for the FDA to amend their guidelines is to follow the Good Foods Institute's suggestion as laid out in their citizen petition. The Good Foods Institute suggests the FDA amend 21 C.F.R. § 102.5 to include for "the common or usual name of another food preceded by a qualifying word or phrase that identifies (i) an alternative plant or animal source that replaces the main characterizing ingredient(s) or component(s) of such other food . . . ."<sup>202</sup> Here, the Good Foods Institute has already given the FDA the tools they need in order to make the proposed amendment. Even if the FDA does not approve of the exact language used, the Good Foods Institute has given them a starting point. The FDA can then publish the proposed amendment on the Federal Register and open it up for comments. Obtaining the public's reaction as to whether or not this amendment would be practical is vital for the FDA, as it is the public at large who are the driving force behind current food trends.<sup>203</sup>

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199. *Id.*

200. *Id.*

201. See Humanitarian Use Devices; 21st Century Cures Act; Technical Amendment, 82 Fed. Reg. 26348, 26349 (June 7, 2017) (to be codified at 21 C.F.R. pt. 814) ("FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only updates the implementing regulation to restate the statute in light of amendments recently enacted into law . . . .").

202. Nigel Barrella, Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food, GOOD FOOD INSTITUTE (Mar. 2, 2017), <http://www.gfi.org/images/uploads/2017/03/GFIpetitionFinal.pdf> [<https://perma.cc/Y7RH-WS3H>].

203. See Kamila, *supra* note 63.

The FDA has amended its guidelines in the past in response to consumer concerns.<sup>204</sup> The chemical Bisphenol A (BPA) was approved for use in plastics and aluminum cans by the FDA back in the 1960s.<sup>205</sup> Its use went widely unquestioned until the 21st century, when studies and reports declared BPA as potentially harmful on the human body, possibly affecting “the brain, behavior and prostate gland of fetuses, infants and children.”<sup>206</sup> While the FDA has maintained that low level exposure to BPA is safe, public concern over the potential for BPA to leach into foods and beverages has prompted the FDA to take action.<sup>207</sup> In response to citizen petitions filed by both the American Chemistry Council and Congressman Edward Markey of Massachusetts, the FDA amended its regulations to no longer include BPA resins in baby bottles, sippy cups, and infant formula packaging.<sup>208</sup>

If the FDA chooses to instead enforce their own guidelines and prohibit plant-based companies from using traditional nomenclatures associated with those products, it is going to cause a chain reaction forcing the FDA to spend time and resources, which they likely do not have, to enforce all food items that are using terms in violation of the established guidelines. For example, peanut butter does not contain any butter, goats milk does not come from cows, and there is no cream in cream of wheat.<sup>209</sup> Expecting the FDA to make sure all of these other products are using names in accordance with the established guidelines is unrealistic and quite frankly, ridiculous.<sup>210</sup>

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204. See FSMA Final Rule: *Amendments to Registration of Food Facilities*, FOOD AND DRUG ADMIN. (Feb. 17, 2018), <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm440988.htm>; *Bisphenol A (BPA): Use in Food Contact Application*, FOOD AND DRUG ADMIN. (February 17, 2018), <https://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm> [<https://perma.cc/4TTG-DXYH>].

205. *Bisphenol A (BPA): Use in Food Contact Application*, FOOD AND DRUG ADMIN. (Feb. 17, 2018), <https://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm> [<https://perma.cc/4TTG-DXYH>].

206. Brent A. Bauer, M.D., *What is BPA, and what are the concerns about BPA?* MAYO CLINIC: HEALTHY LIFESTYLE, NUTRITION AND HEALTHY EATING, (Mar. 11, 2016), <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/expert-answers/bpa/faq-20058331> [<https://perma.cc/DT2R-TJG2>].

207. Bisphenol A (BPA), *supra* note 205.

208. *Id.*

209. See Anahad O'Connor, *Got Almond Milk? Dairy Farms Protest Milk Label on Nondairy Drinks*, N.Y. TIMES (Feb. 13, 2017), <https://www.nytimes.com/2017/02/13/well/eat/got-almond-milk-dairy-farms-protest-milk-label-on-nondairy-drinks.html> [<https://perma.cc/AEZ7-H5PD>].

210. See Nigel Barrella, *Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food*, GOOD FOOD INSTITUTE (Mar. 2, 2017), <http://www.gfi.org/images/uploads/2017/03/GFIpetitionFinal.pdf> [<https://perma.cc/Y7RH-WS3H>] (The Good Food Institute’s petition lists several examples of foods the do not contain what their name says they should: “herbal teas (like peppermint, chamomile, or ginger teas) that contain no tea. . . [and] root beer, which contains no beer. . .”).

Not to mention the vast amount of consumer confusion it would cause to no longer call peanut butter, “peanut butter.” “Nor is it clear if a crackdown would stop the word ‘milk’ from being used in labeling.”<sup>211</sup> The FDA should be able to focus their time and resources on keeping the public safe from dangerous drugs and tainted food, not waste it on playing referee for the right to use terms like “milk” and “mayo.” An amendment to the current guidelines is a simple, cost-effective way for the FDA to wash their hands of an issue that has been going on for more than twenty years and shows no signs of slowing down.

## V. CONCLUSION

Over the past several years, consumers have steadily been shifting away from traditional animal-based food products and have instead taken an interest in plant-based alternatives. With the rise in popularity of such animal-free items, plant-based alternative companies have developed products to fit this new consumer demand. As a result, plant-based food companies started to use terms such as “milk” and “mayo” despite their products’ noncompliance with the FDA regulations. For decades, the FDA has not enforced their own guidelines regarding use of the terms “milk” and “mayo.”

When the FDA has gotten involved with plant-based food companies using terms like “mayo” on their label even though the mayo contains no eggs, the FDA has allowed the company to modify their label and keep the name Just Mayo. The FDA has also allowed the brand Muscle Milk as well as makers of soymilk to use the term “milk” despite sending them warning letters not to do so. As more funding is put towards the development of plant-based alternatives to traditional animal products, the FDA, on a continual basis, will keep getting pushed by both plant-based companies and animal-based companies to make a decision regarding the enforcement of established guidelines. After neglecting to enforce their guidelines for over twenty years, the FDA would expose itself to civil liability if they alter its treatment now. Dealing with these lawsuits would force the FDA to spend funding and resources on issues that it does not have time for.

This is why the FDA should amend their current guidelines to allow for plant-based alternatives to use common nomenclatures associated with traditional animal-based foods such as milk, mayo, cheese, yogurt, etc. This is not an issue that the FDA is unfamiliar with—for over twenty years,

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211. The Times Editorial Board, *Got ‘Milk’? Dairy Farmers Rage Against Imitators But Consumers Know What They Want*, L.A. TIMES (Jan. 4, 2017), <http://latimes.com/opinion/editorials/la-ed-plant-milk-fda-20170104-story.html> [<https://perma.cc/E9H9-YSBG>].

the FDA has been receiving literature and resources from interested parties on both sides of the issue. The FDA has the resources to make an amendment; all it has to do is follow the procedures they use over and over again: proposing the amendment in the Federal Register, obtaining public commentary, and making any necessary adjustments before the amendment is made final.

The Good Foods Institute has already stated they would file suit should the FDA decide to enforce its regulations and prohibit plant-based companies from using terms like “milk” and “mayo.”<sup>212</sup> The FDA has repeatedly claimed the reason for its inaction concerning this issue is due to a lack of resources.<sup>213</sup> However, a more feasible solution for the FDA would be to simply amend their guidelines. The FDA has been aware of the issue of plant-based companies using terms like “milk” and “mayo” for decades,<sup>214</sup> and the amount of research in support of letting these companies do so is exorbitant.<sup>215</sup> Amending the FDA’s current guidelines for plant-based alternatives is much easier than dealing with constant hounding from the dairy industry and plant-based companies, from the threat of legislators enacting acts that would take away FDA power, and from looming litigation should the FDA not allow plant-based companies to use these terms.

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212. See Barrella *supra* note 180.

213. See Letter from Scarbrough, *supra* note 77.

214. See GOLBITZ, *supra* note 75.

215. See Barrella *supra* note 180.