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1 The motion is fully briefed, ECF Nos. 27 ("Opp'n"), 32 ("Reply"),
2 and suitable for decision without oral argument, Civ. L.R. 7-1(b).
3 For the reasons discussed below, Defendants' motion is GRANTED, and
4 Plaintiffs' claims are DISMISSED WITH PREJUDICE.

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6 **II. BACKGROUND**

7 Yogurt is a dairy product made by combining milk with certain
8 food-grade bacteria. FAC ¶¶ 16-18. The bacteria ferment the
9 milk's lactose to produce lactic acid. Id. This fermentation
10 process causes the milk to coagulate and thicken into a liquid-
11 solid mixture. Id. "Regular" yogurt maintains both the liquid and
12 solid portions of the yogurt manufacturing process, while Greek
13 yogurt keeps only the solid. Id. ¶¶ 19-20. As a result it is
14 thicker, higher in protein, and lower in sugar than regular yogurt.
15 Id. ¶ 20. It also tends to be more expensive than regular yogurt.
16 Id. ¶ 5.

17 Cabot markets "Cabot Greek," the product at issue in the
18 instant matter, as "Greek-Style YOGURT." Id. ¶ 22. Cabot Greek
19 contains whey protein concentrate ("WPC") and milk protein
20 concentrate ("MPC"). Id. ¶ 26. WPC and MPC are concentrated
21 protein powders that are essentially byproducts of cheese
22 manufacturing. Id. ¶ 28. If the protein powder contains mostly
23 whey protein, it is WPC. Id. ¶ 29. If it contains whey and casein
24 proteins in the same proportion as they appear in cow's milk, it is
25 MPC. Id. Plaintiffs allege that Cabot uses WPC and MPC as "filler
26 material" to thicken Cabot Greek and increase its protein content,
27 instead of making Greek yogurt the "authentic" way, which involves
28 filtering the liquid whey byproduct during the manufacturing

1 process and keeping only the protein-rich solid portion. Id. ¶¶ 1-
2 2, 20-21, 27-29, 32.

3 Plaintiffs are all consumers who purchased Cabot Greek
4 believing it to be yogurt. FAC ¶ 6. According to Plaintiffs, the
5 problem with Cabot Greek's manufacturing process arises from the
6 Food and Drug Administration's ("FDA") strict guidelines, called
7 Standards of Identity ("SOI(s)"), which define what may legally be
8 called "yogurt." Id. ¶¶ 37-40. Plaintiffs allege that Cabot Greek
9 is not "yogurt" under FDA regulations and the Food, Drug, and
10 Cosmetic Act ("FDCA"), 21 U.S.C. § 341, because it contains MPC and
11 WPC, which Plaintiffs claims the FDA forbids as ingredients in
12 yogurt. Id. ¶¶ 35-36, 43-44. Plaintiffs allege that Cabot's
13 branding misled them into believing that they were purchasing
14 genuine Greek yogurt and thereby paying a premium for it, which
15 they would not have done if it were not so branded. See id. ¶¶ 5-
16 6, 36.

17 Per these allegations, Plaintiffs bring the following causes
18 of action against Cabot: (1) breach of express warranty; (2) breach
19 of the implied warranty of merchantability; (3) breach of the
20 implied warranty of fitness for a particular purpose; (4) unjust
21 enrichment; (5) violation of California's Consumer Legal Remedies
22 Act ("CLRA"), Cal. Civ. Code sections 1751 et seq.; (6) violation
23 of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof.
24 Code sections 17200 et seq.; (7) violation of California's False
25 Advertising Law ("FAL"), Cal. Bus. & Prof. Code sections 17500 et
26 seq.; (8) negligent misrepresentation; and (9) fraud.

27 Defendants now move to dismiss Plaintiffs' FAC, arguing
28 primarily that the FDA permits the addition of MPC and WPC to

1 yogurt, thereby rendering all of Plaintiffs' claims baseless
2 because they are predicated on the FDA's purported prohibition of
3 those ingredients. MTD at 6-15.¹

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5 **III. LEGAL STANDARD**

6 A motion to dismiss under Federal Rule of Civil Procedure
7 12(b)(6) "tests the legal sufficiency of a claim." Navarro v.
8 Block, 250 F.3d 729, 732 (9th Cir. 2001). "Dismissal can be based
9 on the lack of a cognizable legal theory or the absence of
10 sufficient facts alleged under a cognizable legal theory."
11 Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir.
12 1988). "When there are well-pleaded factual allegations, a court
13 should assume their veracity and then determine whether they
14 plausibly give rise to an entitlement to relief." Ashcroft v.
15 Iqbal, 556 U.S. 662, 679 (2009). However, "the tenet that a court
16 must accept as true all of the allegations contained in a complaint
17 is inapplicable to legal conclusions. Threadbare recitals of the
18 elements of a cause of action, supported by mere conclusory
19 statements, do not suffice." Id. (citing Bell Atl. Corp. v.
20 Twombly, 550 U.S. 544, 555 (2007)). A court's review is generally
21 "limited to the complaint, materials incorporated into the
22 complaint by reference, and matters of which the court may take
23 judicial notice." See Kourtis v. Cameron, 419 F.3d 989, 994 n.2
24 (9th Cir. 2005).

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¹ Defendants assert a variety of other grounds for the FAC's
28 dismissal, MTD at 15-18, but since the Court resolves the instant
matter on Defendants' main argument, the Court need not and does
not address Defendants' remaining arguments.

1 **IV. DISCUSSION**

2 The parties' dispute is ultimately based on one predicate
3 issue: whether FDA regulations forbid cultured dairy products
4 containing WPC and MPC from being called "yogurt." Plaintiffs say
5 they do. Defendants say they do not. Defendants are right. Since
6 all of Plaintiffs' claims are premised on the FDA forbidding the
7 addition of WPC and MPC to yogurt, all of Plaintiffs' claims fail.

8 **A. The Relevant FDA Regulations**

9 The FDA promulgated its first SOIs for yogurt in 1981. 21
10 C.F.R. §§ 131.200 (yogurt), 131.203 (lowfat yogurt), 131.206
11 (nonfat yogurt). These SOIs became effective July 1, 1983. 46
12 Fed. Reg. 9924; 47 Fed. Reg. 41519. The yogurt SOI specifies:

13 Yogurt is the food produced by culturing one
14 or more of the optional dairy ingredients
15 specified in paragraph (c) of this section
16 with a characterizing bacterial culture that
17 contains the lactic acid-producing bacteria,
18 Lactobacillus bulgaricus and Streptococcus
19 thermophilus. One or more of the other
20 optional ingredients specified in paragraphs
21 (b) and (d) of this section may also be
22 added. When one or more of the ingredients
23 specified in paragraph (d)(1) of this
24 section are used, they shall be included in
25 the culturing process. All ingredients used
26 are safe and suitable.

21 C.F.R. § 131.200(a).

22 The "optional dairy ingredients" that may be cultured per
23 paragraph (c) of the yogurt SOI are "cream, milk, partially skimmed
24 milk, or skim milk, used alone or in combination." Id. §
25 131.200(c). Paragraph (b) permits the addition of Vitamins A and
26 D. Id. § 131.200(b). Paragraph (d) permits the addition of "other
27 optional ingredients," including (1) "[c]oncentrated skim milk,
28 nonfat dry milk, buttermilk, whey, lactose, lactalbumins,

1 lactoglobulins, or whey modified by partial or complete removal of
2 lactose and/or minerals . . . , " as well as (2) nutritive
3 carbohydrate sweeteners, (3) flavoring ingredients, (4) color
4 additives, and (5) stabilizers. Id. § 131.200(d)(1)-(5). Notably,
5 this list of other ingredients does not include MPC or WPC. See
6 id. § 131.200(d)(1)-5). However, in 1982, the FDA stayed paragraph
7 (d)(1) of the SOI, and so despite being published that portion is
8 not in effect. Stay of Effective Date of Certain Provisions, 47
9 Fed. Reg. 41519-01 (Sept. 21, 1982) ("1982 Stay").

10 Plaintiffs allege that the SOI for yogurt, absent the stayed
11 provision, "is an exclusive list of ingredients that may be added
12 to yogurt," and that "if 'yogurt' contains any ingredient not on
13 that list, as a matter of federal law it is not yogurt"
14 FAC ¶ 43. Plaintiffs further claim that since the yogurt SOI does
15 not include WPC or MPC, those ingredients are prohibited. Id. ¶
16 44. Therefore, Plaintiffs aver, Cabot Greek is not yogurt at all
17 and is misbranded per FDA regulations and the FDCA. See id. ¶¶ 35-
18 36, 43-44. This allegation is the basis for all of Plaintiffs'
19 claims. See id. ¶¶ 68-70, 76-83, 86-89, 92-94, 97-102, 109-113,
20 116-120, 123-28, 131-33.

21 Defendants' primary argument in moving to dismiss the FAC is
22 that Plaintiffs' claims all fail because the FDA actually permits
23 WPC and MPC as optional ingredients in yogurt. In support of this
24 argument, Defendants point to several FDA statements, made
25 consistently over the last thirty years, in which the agency has
26 interpreted the effect of the stay and the remaining parts of the
27 yogurt SOI. MTD at 6-11.

28 In 1982, the FDA stated, "[The FDA] is staying the effective

1 date of the provision[] of [§ 131.200(d)(1)] that restricts the
2 kinds of safe and suitable milk-derived ingredients that may be
3 used as optional ingredients to increase the nonfat solid contents
4 of [yogurts]" 1982 Stay at 41519. Defendants note that
5 this was the earliest date on which the FDA explained the effect of
6 the 1982 Stay, which was not -- as Plaintiffs allege -- to render
7 the remaining provisions of the yogurt SOI exclusive lists of
8 ingredients, but rather to remove a restriction on what could be
9 added to yogurt. Id.; see Reply at 2-3.

10 In 2004, the FDA published a Memorandum of Information on its
11 website, which included the following question and answer:

12 Q: May whey protein concentrate (WPC)
13 and/or milk protein concentrate (MPC) be
14 used as ingredients in yogurt to increase
the nonfat solids content?

15 A: Yes. 21 C.F.R. 131.200(d), which would
16 have precluded WPC or MPC use, was one of
17 several provisions of the standard of
identity for yogurt that were stayed in
18 1982, 47 F.R. 41519, September 21, 1982.

19 NOTE: If WPC and MPC are used in Grade "A"
20 yogurt product, they must be Grade "A" and
come from an IMS Listed Source.

21 ECF No. 33, ("RJN") Ex. A ("2004 Interpretation").²

22 In 2009, the FDA proposed amendments to the yogurt SOI.
23 Proposal to Revoke the Standards for Lowfat and Nonfat Yogurt and
24 to Amend the Standard for Yogurt, 74 Fed. Reg. 2443-02 (Jan. 15,
25 2009) ("2009 Proposal"). In the 2009 Proposal, the FDA noted that
it had stayed parts of the yogurt SOI that "restricted the type of

26
27 ² Defendants submitted a Request for Judicial Notice ("RJN"), ECF
28 No. 33, in support of their motion to dismiss. Plaintiffs do not
oppose the request and the documents contained in the RJN are
public records. The Court GRANTS Defendants' request and takes
judicial notice of the documents.

1 milk-derived ingredients that may be used to increase the nonfat
2 solids content of cultured milk and yogurts." Id. at 2444 (citing
3 1982 Stay at 41523). As Defendants note, this was the same
4 construction -- removal of a restriction rather than the narrowing
5 of an exclusive list -- that the FDA offered in 1982. Compare id.
6 with 1982 Stay at 41519. The FDA elaborated, "To date, due to
7 competing priorities and limited resources, FDA has not held a
8 public hearing to resolve these issues and the effective date for
9 these provisions remains stayed. Therefore, these provisions were
10 never in effect." Id. Thus, the FDA concluded:

11 [C]ultured milk and yogurts may deviate from
12 the relevant standards in the previously
13 mentioned respects. For example, although
14 the current standards do not permit the use
15 of certain ingredients such as preservatives
16 or a reconstituted dairy ingredient as a
17 basic ingredient, because of the stayed
18 provisions, FDA has not taken enforcement
19 action against the use of these ingredients
20 in yogurt, lowfat yogurt, or nonfat yogurt.

21 Id.

22 Defendants claim that these express statements are controlling
23 interpretations of the FDA's own regulations, thereby clarifying
24 that WPC and MPC may lawfully be used as optional ingredients to
25 increase the nonfat solid content of yogurt, as Cabot did. See MTD
26 at 7-8, 10. To support this point, Defendants rely mainly on two
27 cases: PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575, reh'g denied,
28 132 S. Ct. 55 (2011), and Bassiri v. Xerox Corp., 463 F.3d 927, 930
(9th Cir. 2006).

29 In PLIVA, the parties disputed whether and to what extent
30 generic drug manufacturers could change their drugs' labels after
31 FDA approval. 131 S. Ct. at 2575. The defendants argued that FDA

1 regulations allowed them to change their drugs' labels without
2 waiting for preapproval, which is ordinarily necessary when a drug
3 company changes a label, but the FDA interpreted its regulations to
4 bar changes without preapproval. Id. The Supreme Court held on
5 this issue that "[t]he FDA's views are 'controlling unless plainly
6 erroneous or inconsistent with the regulation[s] or there is any
7 other reason to doubt that they reflect the FDA's fair and
8 considered judgment.'" Id. (quoting Auer v. Robbins, 519 U.S.
9 452, 461, 462, (1997)).

10 In Bassiri, the Ninth Circuit reviewed a district court's
11 decision to give deference to several Department of Labor letters
12 defining the term "normal compensation." 463 F.3d at 930. The
13 district court had given those letters deference under Skidmore v.
14 Swift & Co., 323 U.S. 134, 140 (1944), which sets the standard for
15 courts' deference to agency interpretations of statutes. Bassiri,
16 463 F.3d at 930. The Ninth Circuit held that because the
17 Department of Labor was interpreting regulations, not statutes, the
18 district court should have applied the Supreme Court's rule from
19 Auer (the same rule the Supreme Court applied in PLIVA, 132 S. Ct.
20 at 2575), which is that "where an agency interprets its own
21 regulation, even if through an informal process, its interpretation
22 of an ambiguous regulation is controlling under Auer unless
23 'plainly erroneous or inconsistent with the regulation.'" Id.
24 (quoting Auer, 519 U.S. at 461).

25 Plaintiffs do not grapple with these cases, but they attempt
26 to dull the effect of the FDA's 2004 Interpretation by arguing that
27 the source of the 2004 Interpretation -- a Q&A session at the 2004
28 Regional Milk Seminar -- renders the 2004 Interpretation merely

1 informal and, under Supreme Court precedent, "at most, informal
2 statements of policy," which Plaintiffs claim would not be binding
3 in the way a formal regulation would be. Opp'n at 12-13 (citing
4 Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,
5 467 U.S. 837 (1984)). This distinction is not relevant. Chevron
6 does not bar the Court from giving the FDA's clarifications
7 deference, and agencies are not bound to limit their pronouncements
8 to formal rulemaking, as the Supreme Court has made clear:
9 "[B]ecause agencies normally address problems in a detailed manner
10 and can speak through a variety of means, including regulations,
11 preambles, interpretative statements, and responses to comments, we
12 can expect that they will make their intentions clear if they
13 intend for their regulations to be exclusive." Hillsborough County
14 v. Automated Med. Labs., 471 U.S. 707, 718 (1984). PLIVA provides
15 further guidance: "Where an agency interprets its own regulation,
16 even if through an informal process, its interpretation of an
17 ambiguous regulation is controlling under Auer unless 'plainly
18 erroneous or inconsistent with the regulation.'" 132 S. Ct. at
19 2575 (quoting Auer, 519 U.S. at 461).

20 Defendants correctly note that the "informal comments" from
21 the meeting Plaintiffs mention were indeed formalized into a
22 Memorandum of Information from the FDA, directed to "All Regional
23 Food and Drug Directors." 2004 Interpretation. This renders those
24 comments far more compelling than Plaintiffs would suggest. In any
25 event, the FDA is permitted to clarify its regulations as it did in
26 the 2004 Interpretation, and those clarifications are entitled to
27 deference. See Hillsborough, 471 U.S. at 718. Further, the FDA's
28 guidance from the 2004 Interpretation indicates that the FDA

1 understands its own guidelines to allow WPC and MPC as optional
2 ingredients in yogurt.

3 Further, per Auer, the FDA's statements in 2004 and 2009 show
4 that it was interpreting its own ambiguous regulation regarding the
5 yogurt SOI. Plaintiffs' contention that "the regulations are
6 completely unambiguous," Opp'n at 12, is plainly false given the
7 posture of this case. The parties would likely not be engaged in
8 such heated argument over the effects of the yogurt SOIs and the
9 FDA's interpretation of them if the yogurt SOIs on their own were
10 as easy to interpret as Plaintiffs claim. Moreover, the regulation
11 is ambiguous by definition because the FDA's stay of the "optional
12 ingredients" provision could suggest either that "optional
13 ingredients" are excluded entirely from the yogurt SOI, or
14 potentially included by virtue of the stay.

15 The FDA clarified in the 2004 Interpretation and the 2009
16 Proposal that though it has not made a definitive ruling on the
17 subject, it considers WPC and MPC acceptable optional ingredients
18 in yogurt. These interpretations are entitled to deference, being
19 statements from the FDA about its own regulations. The Court
20 therefore finds that MPC and WPC are permissible optional
21 ingredients in yogurt under FDA regulations. Plaintiffs' claims
22 all fail because they are premised on the argument that those
23 ingredients are impermissible. Defendants' motion to dismiss is
24 GRANTED for these reasons.

25 **B. Plaintiffs' Other Arguments**

26 Plaintiffs provide four additional arguments for why the FDA
27 regulations do not actually allow WPC or MPC in yogurt. These
28 arguments are all unconvincing on their own.

1 First, Plaintiffs argue that the FDA has unambiguously stated
2 that WPC and MPC are forbidden in yogurt. Opp'n at 10-13. The
3 statements to which Plaintiffs refer actually concern the FDA's
4 clarification that WPC and MPC are not allowed as basic ingredients
5 in yogurt. See 2009 Proposal at 2452-53. This is irrelevant.
6 Defendants' argument is that the FDA permits WPC and MPC as
7 optional ingredients, which is how they are used in Cabot Greek.
8 The two categories of ingredients, basic and optional, are
9 factually and legally different and should not be conflated.³

10 Second, Plaintiffs' argument that the 1982 Stay renders the
11 yogurt SOI an "exclusive list" of acceptable ingredients fails
12 because the FDA, as discussed in Section IV.A supra, has stated
13 otherwise, and its interpretation of its regulation is binding.
14 Further, Plaintiffs' authority here is inapposite. Plaintiffs rely
15 on the following language from the Supreme Court's decision in
16 Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218,
17 232 (1943): "The announcements promulgating [the SOIs in question]
18 stated that they were so framed as to exclude substances not
19 mentioned in the definition." Opp'n at 6. But this language
20 actually undermines Plaintiffs' position. The FDA never stated
21 that substances not mentioned in the yogurt SOIs were excluded from

22
23 ³ In support of their argument on this point, Plaintiffs also cite
24 FDA statements regarding "cheese food" products, in which the FDA
25 stated clearly that MPC cannot be added to "cheese foods" as an
26 optional ingredient. FAC ¶ 45. These statements are irrelevant to
27 the instant matter. Cheese foods and yogurt have different SOIs,
28 and the FDA's statements on one should not be taken to apply to the
other. Plaintiffs disagree, claiming that the FDA explained that
its findings on WPC and yogurt were "consistent with the agency's
recent tentative decision not to permit [MPC] as a basic ingredient
in standardized cheese," but that quotation concerned basic
ingredients, not optional ingredients, and as the Court has noted,
the two categories are not to be conflated. See Opp'n at 12
(citing 2009 Proposal at 2452-53).

1 yogurt. As discussed in Section IV.A supra, it did the opposite.
2 Further, the SOIs in question in Quaker Oats specifically forbade
3 the food producer in that case from using the certain ingredients
4 in the product it produced. See Quaker Oats, 318 U.S. at 220-23.
5 That is not the issue here.

6 Third, Plaintiffs argue that the FDA's failure to enact any
7 rules explicitly permitting WPC and MPC in yogurt from the 2009
8 Proposal means that the FDA meant to indicate that WPC and MPC had
9 always been prohibited in yogurt. See Opp'n at 11. This is
10 unconvincing. The FDA had interpreted its regulations to permit
11 WPC and MPC in yogurt in 1982 and 2004, and even in the 2009
12 Proposal itself. See 2009 Proposal at 2444; see also Section IV.A,
13 supra (discussing the 2009 Proposal). Plaintiffs misleadingly cite
14 a section of the 2009 Proposal in which the FDA clarifies that WPC
15 and MPC are forbidden as basic ingredients, an argument the Court
16 rejected above. See Opp'n at 11 ("[The National Yogurt
17 Association] requested that FDA revise the yogurt standards to
18 allow the use of [WPC] as a basic ingredient") (citing 2009
19 Proposal at 2452-53) (emphasis added). But this section says
20 nothing at all about optional ingredients.

21 Finally, Plaintiffs allege that WPC and MPC render Cabot Greek
22 "adulterated" because they are food additives, and moreover, are
23 not Generally Recognized as Safe ("GRAS"), thereby violating the
24 FDCA. FAC ¶¶ 46-51. This argument is also unavailing. The FDA
25 has stated specifically that MPC and WPC are permissible optional
26 ingredients in yogurt. It would not have made this statement so
27 clearly if that same permissible addition would render the yogurt
28 illegally adulterated.

1 **V. CONCLUSION**

2 For the reasons discussed above, the Court GRANTS Defendants
3 Cabot Creamery Cooperative, Inc. and Agri-Mark, Inc.'s motion to
4 dismiss Plaintiffs Timothy Smith, Rohit Fedane, and Misty Johnson's
5 first amended complaint. Plaintiffs' complaint is DISMISSED WITH
6 PREJUDICE.

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8 IT IS SO ORDERED.

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10 Dated: February 25, 2013



11 UNITED STATES DISTRICT JUDGE
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