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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

FLOYD LUMAN and JOEL AMKRAUT,
individually and on behalf of all others
similarly situated,

Plaintiffs,

v.

NAC MARKETING COMPANY, LLC
d/b/a NEW VITALITY and JOE
THEISMANN,

Defendants.

No. 2:13-cv-00656-KJM-AC

ORDER

Plaintiffs Joel Amkraut and Floyd Luman brought a class action against NAC Marketing Company, LLC (“NAC”) and Joe Theisman, alleging defendants falsely advertised NAC’s product would treat symptoms of benign prostate hyperplasia (“BPH”), a progressive disease caused by an enlarged prostate. This court dismissed plaintiffs’ claims in full on February 4, 2014. On April 8, 2016, the Ninth Circuit (1) affirmed dismissal of Luman’s claims; (2) affirmed dismissal of any claims against Theisman; but (3) reversed dismissal of Amkraut’s claims against NAC and remanded the case back to this court. Now on remand, NAC has moved to dismiss Amkraut’s complaint. As discussed below, NAC’s motion is GRANTED.

1 I. FACTUAL ALLEGATIONS AND PROCEDURAL HISTORY

2 A. Original District Court Proceedings

3 On May 10, 2013, plaintiffs Amkraut and Luman filed the operative first amended
4 complaint, bringing eight claims against defendants NAC and Joe Theismann: (i) violation of the
5 Magnuson-Moss Warranty Act, (ii) breach of express warranty, (iii) breach of implied warranty
6 of merchantability, (iv) breach of implied warranty of fitness for a particular purpose, (v) unjust
7 enrichment, (vi) violation of the California Consumers Legal Remedies Act (“CLRA”), (vii)
8 violation of California Unfair Competition Law (“UCL”), and (viii) violation of California’s
9 False Advertising Law (“FAL”) in connection with NAC’s sales of its Super Beta Prostate
10 (“SBP”) product. *See generally* FAC, ECF No. 12. To support their claims, plaintiffs alleged
11 NAC’s sales of its SBP product misbranded it as a dietary supplement designed to treat symptoms
12 of BPH.¹ The product, plaintiffs alleged, should have been characterized as a “new drug” under
13 the Food, Drug, and Cosmetic Act (“FDCA”) because it “is not generally recognized among
14 experts . . . as safe and effective for use under the condition prescribed, recommended, or
15 suggested,” namely to treat BPH. *Id.* ¶¶ 55 (citing 21 U.S.C. § 321(p)(1)), 58. Plaintiffs further
16 alleged Theismann, a former NFL quarterback who publicly endorsed the SBP product, adopted
17 and disseminated misrepresentations regarding the product’s effectiveness. *Id.* ¶ 10. Plaintiffs
18 request monetary and injunctive relief. *Id.* ¶ 122 (a)–(h).

19 On February 4, 2014, this court held plaintiffs’ individual claims for monetary
20 relief were rendered moot when NAC refunded plaintiffs’ money for their purchases of SBP.
21 Prior Order 7, ECF No. 48. The court further held that plaintiffs lacked standing to pursue
22 injunctive relief because they could not demonstrate a likelihood of future injury. *Id.* at 10. The
23 court dismissed plaintiffs’ claims in full and closed the case. *Id.* at 13. On February 28, 2014,
24 plaintiffs appealed this court’s judgment to the Ninth Circuit. ECF No. 51.

25 _____
26 ¹ BPH is a progressive disease caused by an enlarged prostate, which can cause
27 bothersome urinary symptoms such as difficulty in urination, inability to completely empty the
28 bladder during urination, the need to urinate frequently, increased risk of urinary tract infections,
and painful urination. FAC ¶¶ 18–21.

1 B. Ninth Circuit Proceedings on Appeal

2 On appeal, the Ninth Circuit affirmed dismissal of all claims against Theismann
3 because he was merely a celebrity spokesperson for NAC and not a seller of SBP. *Luman v.*
4 *Theismann*, 647 F. App'x 804, 807 (9th Cir. 2016). The Circuit affirmed this court's dismissal of
5 plaintiffs' claims for injunctive relief, holding plaintiffs had not alleged they intended to purchase
6 SBP in the future and therefore "cannot demonstrate a likelihood of future injury." *Id.* (citing
7 *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1113–14 (9th Cir. 2013)).

8 The Ninth Circuit also affirmed this district court's dismissal of Luman's claim for
9 monetary relief, but on grounds of standing rather than mootness. *Id.* at 806–07. Because NAC
10 issued a refund two months before Luman filed the complaint, the Ninth Circuit held Luman did
11 not meet "the injury-in-fact requirement for standing at the time he filed his complaint." *Id.*
12 (citing *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 732–33 (2008)). Because Luman never
13 had standing to begin with, his claims could not be mooted. *Id.*

14 The Ninth Circuit reversed this court's dismissal of Amkraut's claims for
15 monetary damages. *Id.* at 807. The Ninth Circuit concluded that because Amkraut received the
16 refund after he filed his complaint, he had standing to request monetary relief. *Id.* It noted there
17 remained a question whether defendants' providing the refund mooted Amkraut's claims, in light
18 of the Supreme Court's recent decision in *Campbell-Ewald Co. v. Gomez*, holding that "an
19 unaccepted settlement offer or offer of judgment does not moot a plaintiff's case." *Id.* (citing 136
20 S. Ct. 663, 672 (2016)). The Ninth Circuit remanded the case with instructions to review the
21 effect of *Campbell-Ewald* on Amkraut's claim for monetary relief against NAC. *Id.* at 808.

22 C. Proceedings on Remand

23 On remand, NAC and Amkraut briefed whether Amkraut's claim for monetary
24 relief was moot. Def.'s Suppl. Mot., ECF No. 61; Pl.'s Suppl. Opp'n, ECF No. 65; Def.'s Suppl.
25 Reply, ECF No. 66. The court held a hearing on the mootness issue, ECF No. 67, at which it also
26 heard argument on NAC's original motion to dismiss and Amkraut's original opposition,
27 supplemented following the Ninth Circuit's remand. *See id.*; *see also* Mot., ECF No. 16; Opp'n,
28

1 ECF No. 24, Reply, ECF No. 25. L. Timothy Fisher appeared for Amkraut and Brad Seiling
2 appeared for NAC. ECF No. 67.

3 II. MOOTNESS

4 In *Campbell-Ewald*, the Supreme Court held an unaccepted offer to satisfy a
5 named plaintiff's claims cannot render the case moot. *Campbell-Ewald*, 136 S. Ct. at 669.
6 Relying on basic contract principles, the Supreme Court concluded that like an "unaccepted
7 contract offer[]," an unaccepted settlement offer "creates no lasting right or obligation." *Id.* at
8 670. Accordingly, "an unaccepted settlement offer has no force," and the parties thereby remain
9 in the same place they were before the offer, in adversity over the claims at issue. *Id.*

10 Here, NAC did more than simply offer to repay Amkraut; NAC deposited the
11 money into Amkraut's account, thereby precluding Amkraut from declining the offer. *See* Prior
12 Order at 3; Mayer Decl. ¶ 11, ECF No. 16-4. The Supreme Court explicitly declined to consider
13 these circumstances, holding, "we need not, and do not, now decide whether the result would be
14 different if a defendant deposits the full amount of the plaintiff's individual claim in an account
15 payable to the plaintiff, and the court then enters judgment for the plaintiff in that amount."
16 *Campbell-Ewald*, 136 S. Ct. at 672. Accordingly, the court looks to *Campbell-Ewald*'s progeny
17 to ascertain whether the law has filled this gap.

18 In *Chen v. Allstate Ins. Co.*, the Ninth Circuit addressed the question left open in
19 *Campbell-Ewald*, 819 F.3d 1136, 1142 (9th Cir. 2016). In *Chen*, after the plaintiff brought a class
20 action against defendant for monetary and injunctive relief under the Telephone Consumer
21 Protection Act ("TCPA"), the defendant deposited \$20,000 into an escrow account, agreed to the
22 requested injunction, and moved to dismiss the case as moot. *Id.* at 1138. The Ninth Circuit
23 declined to direct that the district court dismiss plaintiff's case, saying the named plaintiff did not
24 receive "complete relief" on his TCPA claim. *Id.* at 1144. The Circuit first defined complete
25 relief as "all of the relief [a plaintiff] could receive on the claim through further litigation." *Id.*
26 To determine what "all the relief" entailed, the appellate court looked to the relief plaintiff
27 requested in the operative complaint. *Id.* at 1142. Plaintiff's complaint requested statutory
28 damages and injunctive relief. *Id.*

1 The court then looked to the defendant’s escrow deposit and injunction agreement
2 to compare it against plaintiff’s requested relief. *Id.* at 1144. While the court held the
3 defendant’s agreement mooted plaintiff’s request for injunctive relief, the escrow deposit did not
4 moot the plaintiff’s claim for damages. *Id.* The court noted plaintiff did not “actually or
5 constructively” receive the \$20,000 because the defendant “neither deposited the \$20,000 in the
6 court nor unconditionally relinquished its interest in the \$20,000 to [the plaintiff].” *Id.* at 1146.
7 Instead, the defendant retained an interest in the funds unless or until the court dismissed the
8 entire action as moot. *Id.* Because plaintiff did not “actually receive[]” the funds, there was not
9 “complete relief” sufficient to moot plaintiff’s claim. *Id.* at 1146. Accordingly, the Ninth Circuit
10 found plaintiff should have a “fair opportunity to show [class] certification is warranted.” *Id.* at
11 1147.

12 Following *Chen*, the court first looks to the operative complaint to determine the
13 relief requested. *Chen*, 819 F.3d at 1142. Amkraut requests monetary damages, injunctive relief,
14 attorneys’ fees and costs. FAC ¶¶ 122(a)–(h). NAC has refunded the money Amkraut paid for
15 the SBP product, including shipping charges. Mayer Decl. ¶ 11. It has not agreed to the
16 injunctive relief Amkraut requests, paid his attorneys’ fees, or reimbursed his litigation related
17 costs. *See generally id.* Accordingly, defendant has not afforded plaintiff “complete relief,” and
18 plaintiff’s claims are therefore not moot. *Chen*, 819 F.3d at 1146.

19 III. DISMISSAL UNDER RULE 12(b)(6)

20 A. Legal Standards

21 A party may move to dismiss for “failure to state a claim upon which relief can be
22 granted.” Fed. R. Civ. P. 12(b)(6). The motion may be granted only if the complaint lacks a
23 “cognizable legal theory” or if its factual allegations do not support a cognizable legal theory.
24 *Hartmann v. Cal. Dep’t of Corr. & Rehab.*, 707 F.3d 1114, 1122 (9th Cir. 2013). The court
25 assumes these factual allegations are true and draws reasonable inferences from them. *Ashcroft*,
26 556 U.S. at 678. In making this context-specific evaluation, this court must construe the
27 complaint in the light most favorable to the plaintiff and accept as true the factual allegations of
28 the complaint. *Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007).

1 A complaint need contain only a “short and plain statement of the claim showing
2 that the pleader is entitled to relief,” Fed. R. Civ. P. 8(a)(2), not “detailed factual allegations,”
3 *Twombly*, 550 U.S. at 555. But this rule demands more than unadorned accusations; “sufficient
4 factual matter” must make the claim at least plausible. *Iqbal*, 556 U.S. at 678. Accordingly,
5 conclusory or formulaic recitations of a cause’s elements do not alone suffice. *Id.* (quoting
6 *Twombly*, 550 U.S. at 555).

7 Evaluation under Rule 12(b)(6) is a context-specific task drawing on “judicial
8 experience and common sense.” *Id.* at 679. Aside from the complaint, district courts have
9 discretion to examine documents incorporated by reference, *Davis v. HSBC Bank Nev., N.A.*,
10 691 F.3d 1152, 1160 (9th Cir. 2012); affirmative defenses based on the complaint’s allegations,
11 *Sams v. Yahoo! Inc.*, 713 F.3d 1175, 1179 (9th Cir. 2013); and proper subjects of judicial notice,
12 *W. Radio Servs. Co. v. Qwest Corp.*, 678 F.3d 970, 976 (9th Cir. 2012).

13 B. Analysis

14 NAC argues the operative complaint should be dismissed because the FDA has
15 primary jurisdiction to resolve the dispositive question it raises: whether NAC’s product is
16 misbranded as a dietary supplement and should instead be labeled a “new drug.” Mot. at 17.
17 Amkraut contends because the “new drug” determination is simple and straightforward, the court
18 can resolve the issue. Opp’n at 18.

19 “Primary jurisdiction is properly invoked when a claim is cognizable in federal
20 court but requires resolution of . . . a particularly complicated issue that Congress has committed
21 to a regulatory agency.” *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172
22 (9th Cir. 2002). “The doctrine applies when protection of the integrity of a regulatory scheme
23 dictates preliminary resort to the agency which administers the scheme.” *Id.* (citing *United*
24 *States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1361 (9th Cir. 1987)). The doctrine is not
25 designed to “secure expert advice” from agencies “every time a court is presented with an issue
26 conceivably within the agency’s ambit.” *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th
27 Cir. 2008). Rather, the doctrine is “properly invoked when a case presents a far-reaching
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1 question that requires expertise or uniformity in administration.” *Brown*, 277 F.3d at 1172
2 (internal quotation marks omitted).

3 When properly invoked, the primary jurisdiction doctrine provides for courts to
4 stay proceedings or dismiss a complaint without prejudice pending the resolution of an issue by
5 the administrative agency with special competence. *Clark*, 523 F.3d at 1114. A court’s reliance
6 on the doctrine does not indicate it lacks jurisdiction. *Id.* Rather, the doctrine is a “prudential”
7 one, under which a court determines that an otherwise cognizable claim implicates technical and
8 policy questions that should be addressed in the first instance by the agency with regulatory
9 authority over the relevant industry rather than by the judicial branch. *Id.*

10 When a district court determines primary jurisdiction applies, it enables a
11 “referral” of the issue to the relevant agency. *Id.* at 1115. “[T]here is no formal transfer
12 mechanism between the courts and the agency”; rather, the parties are responsible for initiating
13 administrative proceedings themselves. *Id.*

14 Here, all of Amkraut’s claims rely on the court’s resolving one primary question:
15 whether Super Beta Prostate is properly characterized as a “new drug” under the FDCA rather
16 than as a “dietary supplement.” FAC ¶¶ 5, 56, 66–122. Under the FDCA, “new drug” means:
17 “[a]ny drug . . . not generally recognized, among experts qualified by scientific training and
18 experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under
19 the conditions prescribed.” 21 U.S.C.A. § 321(p)(1); *Weinberger v. Bentex Pharm., Inc.*,
20 412 U.S. 645, 652 (1973). Amkraut contends Super Beta Prostate is properly characterized as a
21 “new drug” rather than a dietary supplement because it is not recognized as effective for its
22 purportedly intended purpose of treating BPH. Opp’n at 21.

23 Determining whether a product is properly characterized as a “new drug” requires
24 the FDA’s expertise. *Weinberger*, 412 U.S. at 652. In *Weinberger*, the Supreme Court held
25 whether a particular drug is a “new drug” depends in part on “expert knowledge and experience
26 of scientists based on controlled clinical experimentation and backed by substantial support in
27 scientific literature.” *Id.* This issue, the Supreme Court observed, is “peculiarly suited to initial
28 determination by the FDA” because “[e]valuation of conflicting reports as to the reputation of

1 drugs among experts in the field is not a matter well left to a court without chemical or medical
2 background.” *Id.* at 653–54. Accordingly, “where no . . . administrative determination has been
3 made and the issue ar[ose] in a district court . . . , it would be commonplace for the court to await
4 an appropriate administrative declaration before it acted.” *Id.* This conclusion, the Supreme
5 Court said, was in line with Congress’s desire to have the administrative agency make this
6 determination. *Id.*

7 Amkraut contends he should not be precluded from bringing his private action,
8 which is “consistent” with the FDCA, Opp’n at 21, but his argument misrepresents his complaint.
9 Amkraut’s claims are not merely “consistent” with the FDCA; each one requires the court to
10 interpret the definition of “new drug” under the FDCA. *See* FAC ¶¶ 66–122.² Plaintiff
11 essentially asks the court to do two things: (1) determine an issue better suited for an
12 administrative agency with the proper expertise, and (2) allow plaintiff a backdoor private right of
13 action to challenge defendant’s alleged violation of the FDCA, which is contrary to Congress’s
14 intent. *See* 21 U.S.C. § 337(a) (“all such proceedings for the enforcement, or to restrain
15 violations, of [the FDCA] shall be by and in the name of the United States,” with a limited
16 exception for state enforcement); *Buckman Co. v. Plfs.’ Legal Comm.*, 531 U.S. 341, 349 n.4
17 (2001) (“[t]he FDCA leaves no doubt that it is the Federal Government rather than private
18 litigants who are authorized to file suit for noncompliance with the [FDCA]”).

19 Plaintiff’s cited cases do not support his argument. In *Medtronic, Inc. v. Lohr*,
20 518 U.S. 470 (1996), while the Supreme Court allowed plaintiffs to bring private claims
21 complaining about a device regulated by the Medical Device Amendments Act of 1976, the issue
22 of primary jurisdiction was never raised, and resolving the private claims did not trespass into a
23 realm “peculiarly suited to initial determination by” an administrative agency. *Weinberger*, 412
24 U.S. at 653–54. Similarly primary jurisdiction was not involved in *Khasin v. Hershey Co.*, 2012

25 ² For example, Amkraut’s alleges “Super Beta Prostate does not, in fact, treat the
26 symptoms of BPH,” FAC ¶ 72, SBP is not “fit for its intended purpose,” *id.* ¶ 77, and SBP is
27 “unfit for [its] intended and ordinary purpose because there is no competent and reliable scientific
28 evidence that Super Beta Prostate is a safe and effective treatment for the symptoms of BPH,” *id.*
¶ 83.

1 WL 5471153, at *1 (N.D. Cal. Nov. 9, 2012), *Mut. Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp.
2 2d 925, 935 (C.D. Cal. 2006), or *Grove Fresh Distribs., Inc. v. The Flavor of Fresh Foods, Inc.*,
3 720 F. Supp. 714, 716 (N.D. Ill. 1989), and the courts in these cases did not otherwise address
4 whether an administrative agency should resolve the matters at bar. In *Axcan Scandipharm*
5 *Incorporated v. Ethex Corporation*, in which primary jurisdiction was discussed, the court held
6 the plaintiff could bring its private Lanham Act claim because it did not rely on an interpretation
7 or application of the FDCA. 585 F. Supp. 2d 1067, 1075 (D. Minn. 2007) (“Axcan seeks to
8 proffer evidence of the generally understood meanings of the terms ‘generic equivalence’ and
9 ‘substitute,’ and not the FDA’s definition of ‘equivalence,’ in order to establish the falsity of the
10 Defendants’ advertisements”).

11 Here, because plaintiff’s claims require a determination of whether defendant’s
12 product is a “new drug,” the primary jurisdiction doctrine applies. The court defers to the Federal
13 Drug Administration’s determination of this question. *Clark*, 523 F.3d at 1115.

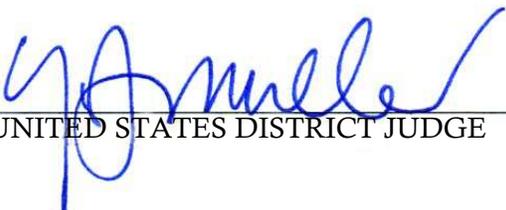
14 IV. CONCLUSION

15 Because NAC has not provided “complete relief” to plaintiff, plaintiff’s private
16 claims are not moot. The court DISMISSES plaintiff’s claims, however, in light of the FDA’s
17 primary jurisdiction. Plaintiff’s case is dismissed without prejudice pending the FDA’s resolution
18 of the “new drug” question.

19 This order resolves ECF Nos. 16-1 and 61.

20 IT IS SO ORDERED.

21 DATED: August 8, 2017.

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25 UNITED STATES DISTRICT JUDGE
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