

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

O

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

GINA DELAROSA,

Plaintiff,

vs.

BOIRON, INC.

Defendant.

CASE NO. 8:10-CV-1569-JST (CWx)

**ORDER DENYING DEFENDANT'S
MOTION FOR JUDGMENT ON THE
PLEADINGS**

1 Plaintiff Gina Delarosa, individually and on behalf of all others similarly situated,
2 filed this action in California state court, alleging that Defendant Boiron, Inc.¹ defrauded
3 Californians by claiming that a tablet called “Children’s Coldcalm” would provide relief
4 from sneezing, runny nose, nasal congestion, sinus pain, headaches, and sore throat. (Doc.
5 1, Ex. 2.) Defendant removed the case pursuant to diversity as set forth under 28 U.S.C. §
6 1332(a), and pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). (Doc. 1 at
7 3-4.) On January 21, 2011, Defendant filed this Motion for Judgment on the Pleadings,
8 arguing that Plaintiff’s claims are preempted by federal law and that Plaintiff fails to state
9 a claim upon which relief can be granted. (Doc. 27-1.) For the reasons set forth below, the
10 Court DENIES Defendant’s Motion.

11 I. Legal Standard

12 A motion for judgment on the pleadings under Federal Rule of Civil Procedure
13 12(c) is “functionally identical” to a motion to dismiss under Federal Rule of Civil
14 Procedure 12(b)(6); therefore, the same legal standard applies to both motions. *Dworkin v.*
15 *Hustler Magazine, Inc.*, 867 F.2d 1188, 1192 (9th Cir. 1989). Dismissal of a complaint for
16 failure to state a claim is not proper where a plaintiff has alleged “enough facts to state a
17 claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570
18 (2007). When evaluating a Rule 12(b)(6) motion, the Court must accept as true all
19 allegations of material facts that are in the complaint, and must construe all inferences in
20 the light most favorable to the non-moving party. *Moyo v. Gomez*, 32 F.3d 1382, 1384
21 (9th Cir. 1994). Judgment on the pleadings is therefore appropriate only “when the
22 moving party clearly establishes on the face of the pleadings that no material issue of fact
23 remains to be resolved and that it is entitled to judgment as a matter of law.” *Enron Oil*
24 *Trading & Transp. Co. v. Walbrook Ins. Co.*, 132 F.3d 526, 529 (9th Cir. 1997) (citation
25 omitted).

26
27 ¹ Pursuant to a joint stipulation filed by the parties, the Court ordered the originally named
28 defendant, “Boiron USA, Inc.” stricken and “Boiron Inc.” interlineated. (Doc. 13.)

1 **II. Background**

2 **A. The Parties**

3 Defendant Boiron, Inc. is the manufacturer and distributor of Children’s Coldcalm
4 (“Coldcalm”). (Doc. 1, Ex. 2, Compl. ¶ 2.) Coldcalm belongs to a class of medicine
5 known as “natural” or “homeopathic,” and is described as such on its packaging. (*Id.* ¶ 11;
6 *id.* Ex. 2.) The homeopathic ingredients in Coldcalm include various flowers, vegetables,
7 insects, metals, and poison. (*Id.* ¶ 17.) Defendant advertises on the outside of the package
8 that ColdCalm will relieve symptoms of the common cold, including: sneezing, runny
9 nose, nasal congestion, sinus pain, headaches, and sore throat. (*Id.* ¶ 7.)

10 Plaintiff Gina Delarosa read Defendant’s advertisements on the outside of the
11 Coldcalm package and read about Coldcalm on a website. (*Id.* ¶ 8; *id.* Exs. 1, 2.) After
12 reading that Coldcalm relieved cold symptoms, Plaintiff purchased Coldcalm, and her
13 family used the drug as directed. (*Id.* ¶ 8.) Plaintiff’s family did not obtain the advertised
14 relief from the common cold, nor did they receive any benefits from using Coldcalm. (*Id.*)
15 Plaintiff filed a Complaint alleging three claims: (1) violation of the California Legal
16 Remedies Act (“CLRA”); (2) common-law fraud; and (3) violation of the California
17 Unfair Competition Law (“UCL”). (*Id.* ¶¶ 29-46.) Plaintiff seeks to represent persons
18 located within California who purchased Coldcalm for personal use at any time during the
19 four years preceding the filing of the Complaint. (*Id.* ¶ 22.) Plaintiff requests all available
20 legal and equitable remedies. (*Id.* at 11.)

21 **B. Regulatory Framework for Over-The-Counter Drugs**

22 Congress enacted the Federal Food, Drug, and Cosmetic Act (“FDCA”), ch. 675, 52
23 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.* in 1938, after Congress “became
24 increasingly concerned about unsafe drugs and fraudulent marketing.” *Wyeth v. Levine*,
25 129 S. Ct. 1187, 1198-99 (2009). Among other things, Congress prohibited the sale of
26 adulterated or misbranded drugs, and required manufacturers to apply to the U.S. Food and
27 Drug Administration (“FDA”) for premarket approval of new drugs. 21 U.S.C. § 331.
28 The FDCA defines “drug” to include articles, like Coldcalm, that are recognized in the

1 official Homœopathic Pharmacopœia of the United States (“HPUS”) and includes both
2 prescription and over-the-counter (“OTC”) drugs.² 21 U.S.C. § 321(g)(1). Although
3 homeopathic OTC drugs appear to be treated as a subset of OTC drugs by the FDCA and
4 its various regulations, the way in which they are evaluated and tested by the FDA differs
5 markedly from the ways in which non-homeopathic OTC drugs are evaluated.

6 **1. Regulation of Non-homeopathic OTC Drugs**

7 The FDA evaluates whether non-homeopathic OTC drugs are safe, effective and not
8 misbranded using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1,
9 330.10. In drafting the monographs, the FDA divided the non-homeopathic OTC drugs
10 into drug categories, such as antacids, laxatives, antidiarrheal products, emetics,
11 antiemetics, antiperspirants, etc. *Id.* § 330.5. Each category of drugs was then assigned an
12 advisory review panel of qualified experts who were appointed by the Commissioner of
13 the FDA. *Id.* § 330.10(a). The advisory review panels were tasked with evaluating the
14 safety and effectiveness of the non-homeopathic OTC drugs, reviewing the drugs’
15 labeling, and advising the Commissioner on the promulgation of monographs establishing
16 conditions under which non-homeopathic OTC drugs listed within each monograph are
17 generally recognized as safe, effective, and not misbranded. *Id.* § 330.10(a). To that end,
18 the panels reviewed clinical studies, explanations from manufacturers as to why clinical
19 studies may not exist, reports of documented side effects, as well as other pertinent
20 information. *See id.* § 330.10. Based on each panel’s recommendations, the
21 Commissioner engaged in a notice and comment period; the Commissioner published a
22 proposed monograph, received comments and sometimes further data, and ultimately
23 published a final monograph that established the conditions under which a non-
24 homeopathic OTC drug is safe, effective, and not misbranded. *Id.* Although any

25
26 ² Although Plaintiff does not allege in the Complaint that Coldcalm is listed in the HPUS, the
27 Court notes that the arguments from both parties appear to assume that Coldcalm (or the
28 ingredients in Coldcalm) can be found in the HPUS. Therefore, for purposes of this Order, the
Court will assume that Coldcalm is a homeopathic drug that is recognized in the HPUS.

1 interested person may petition for the amendment or repeal of any monograph pursuant to
2 21 C.F.R. § 10.30, a non-homeopathic OTC drug which fails to conform to its applicable
3 monograph after the date the final monograph became effective is liable to regulatory
4 action. *See id.* § 330.10(a)(12), (b).

5 A manufacturer seeking approval of a new non-homeopathic OTC drug must
6 submit a detailed new drug application in accordance with the requirements of the FDCA
7 and related regulations promulgated by the FDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. §§
8 314.1-314.3, 314.50. A new drug application must include:

9 [E]vidence consisting of adequate and well-controlled
10 investigations, including clinical investigations, by experts
11 qualified by scientific training and experience to evaluate the
12 effectiveness of the drug involved, on the basis of which it could
13 fairly and responsibly be concluded by such experts that the drug
14 will have the effect it purports or is represented to have under the
15 conditions of use prescribed, recommended, or suggested in the
16 labeling or proposed labeling thereof.

17
18 21 U.S.C. § 355. Similarly, after the FDA approves a new drug application, any change in
19 the drug’s labeling requires a supplement to the application, and further approval by the
20 FDA, either before or after the change. 21 C.F.R. §§ 314.70(b), (c), 314.71.

21 **2. Quasi-Regulation of Homeopathic OTC Drugs**

22 Unlike non-homeopathic OTC drugs, homeopathic OTC drugs, including the
23 Coldcalm product at issue here, are not evaluated by the FDA at all. The FDA defines a
24 homeopathic drug as any drug labeled as being homeopathic that is also listed in the
25 HPUS, an addendum, or its supplements. *See* 21 U.S.C. § 321(g)(1)(A); FDA,
26 Inspections, Compliance, Enforcement, and Criminal Investigations, Compliance Policy
27 Guides § 400.400, “Conditions Under Which Homeopathic Drugs May be Marketed”
28 (“CPG § 400.400”), available at <http://www.fda.gov/ICECI/ComplianceManuals/>

1 CompliancePolicyGuidanceManual/ucm074360.htm.³ According to the FDA, the HPUS
2 is “[a] compilation of standards for source, composition, and preparation of homeopathic
3 drugs. The HPUS contains monographs of drug ingredients used in homeopathic
4 treatment.” CPG § 400.400. Although the HPUS describes how these ingredients are
5 prepared for homeopathic use, it does not list the drugs as fit to treat specific symptoms,
6 ailments, or conditions. (Compl. ¶ 14.) Instead, the HPUS allows the practitioner or
7 manufacturer to set forth the substance’s indications for use. (*Id.*)

8 Drug substances are included in the HPUS after having been subjected to
9 “provings.” (*Id.*) “Provings,” conducted in the 1800’s and early 1900’s, established what
10 types of symptoms resulted from the use of a homeopathic substance in a healthy person.
11 (*Id.* ¶ 13.) Use of homeopathic remedies relies on the “law of similars,” i.e., “a notion that
12 the symptoms of disease, ailment or condition can be cured by extremely small amounts of
13 substances that produce similar symptoms in healthy people when administered in large
14 amounts.” (*Id.* ¶ 14.) *See* CPG § 400.400 (“The practice of homeopathy is based on the
15 belief that disease symptoms can be cured by small doses of substances which produce
16

17 ³ Defendant requested the Court take judicial notice of CPG § 400.400, pursuant to Federal
18 Rule of Evidence 201. (Doc. 28.) Although the Court may take judicial notice of entire
19 documents, the consequences of taking judicial notice are significant. *See Rivera v. Philip Morris,*
20 *Inc.*, 395 F.3d 1142, 1151 (9th Cir. 2005). Thus the Ninth Circuit has urged district courts to be
cautious in taking judicial notice and do so only when the “fact is beyond controversy.” *Id.*
(citation omitted).

21 A Compliance Policy Guide (“CPG”) “may derive from a request for an advisory opinion,
22 from a petition from outside the Agency, or from a perceived need for policy clarification by FDA
23 personnel.” FDA, CPG, “Foreword,” available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm>. The Court may take judicial notice of the
24 fact that this document exist, however, it would be inappropriate to accept all of the contents
25 within the document as facts beyond reasonable dispute. Defendant is free to cite to these public
records and make arguments in its brief regarding the appropriate level of deference that the Court
should give to the documents; judicial notice is unnecessary and therefore, the Court will not take
judicial notice of the entirety of these documents.

26 The Court also notes that Defendant argues that “a CPG constitutes a formal FDA ‘advisory
27 opinion,’ which FDA is obligated to follow unless or until it is amended or revoked.” (Mot. at 7
n.6.) The Court concludes that this argument is not supported by the regulation cited, and is in
28 fact contradicted by the language previously quoted from the CPG “Foreword.”

1 similar symptoms in healthy people.”). Homeopathic remedies are prepared through
2 repeated dilution of a homeopathic substance, which also includes repeated shaking and
3 striking of the substance. (Compl. ¶ 17.) “This process is posited to increase the
4 effectiveness of the substance even if after the dilutions none of the original substance
5 remains.” (*Id.*) For example, the dilution of Coldcalm is between 3C and 6C; a 6C
6 dilution consists of 1 part ingredient to 1 trillion parts solution. (*Id.* ¶¶ 17-18.) Dilutions
7 of this level leave the solution with no trace of the original ingredient. (*Id.* ¶ 18.)

8 The Court is unaware of what standards, if any, exist to ensure that homeopathic
9 OTC drugs are safe and effective. The FDA does not impose additional standards for
10 strength, purity, quality, safety, or efficacy on homeopathic OTC remedies. Indeed, the
11 FDA has advised that unless a homeopathic remedy is “being offered for use (or promoted)
12 significantly beyond recognized or customary practice of homeopathy,” federal policies on
13 health fraud do not apply. CPG § 400.400. And perhaps most significant, “[a] product’s
14 compliance with requirements of the HPUS . . . does *not* establish that it has been shown
15 by appropriate means to be safe, effective, and not misbranded for its intended use.” *Id.*
16 (emphasis added).

17 **Discussion**

18 Defendant argues that Plaintiff’s claims are precluded under the doctrines of
19 express and implied preemption. (Mot. at 8-10.) In the alternative, Defendant argues that
20 the Court should exercise judicial restraint and abstain from hearing the case in deference
21 to the government’s enforcement powers. (*Id.* at 12.) Finally, Defendant argues that
22 Plaintiff fails to state a claim upon which relief can be granted, because (1) “safe harbor
23 provisions” preclude Plaintiff’s consumer protection claims; (2) Plaintiff fails to state fraud
24 with particularity; and (3) Plaintiff failed to comply with the CLRA’s notice requirements.
25 (*Id.* at 14-16.) The Court addresses each of these arguments in turn.

26 **C. Express Preemption**

27 Under Article VI of the Constitution, “the Laws of the United States . . . shall be the
28 supreme Law of the Land” U.S. Const. art. VI, cl. 2. Thus, the Supreme Court has

1 long held that under the Supremacy Clause, “state law that conflicts with federal law is
2 ‘without effect.’” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting
3 *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). “Consideration of issues arising under
4 the Supremacy Clause ‘start[s] with the assumption that the historic police powers of the
5 States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest
6 purpose of Congress.’” *Id.* (alterations in original) (quoting *Rice v. Santa Fe Elevator*
7 *Corp.*, 331 U.S. 218, 230 (1947)). “Accordingly, [t]he purpose of Congress is the ultimate
8 touchstone of pre-emption analysis.” *Id.* (alteration in original) (internal quotation marks
9 and citation omitted).

10 “Congress’ intent may be ‘explicitly stated in the statute’s language or implicitly
11 contained in its structure and purpose.’” *Id.* (quoting *Jones v. Rath Packing Co.*, 430 U.S.
12 519, 525 (1977)). “If the statute contains an express pre-emption clause, the task of
13 statutory construction must in the first instance focus on the plain wording of the clause,
14 which necessarily contains the best evidence of Congress’ pre-emptive intent.” *CSX*
15 *Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

16 Under section 379r of the FDCA, “no State or political subdivision of a State may
17 establish or continue in effect any requirement (1) that relates to the regulation of a
18 drug . . . and (2) that is different from or in addition to, or that is otherwise not identical
19 with, a requirement under this chapter” 21 U.S.C. § 379r(a). In adding this
20 provision to the FDCA,⁴ “Congress pre-empted certain state requirements concerning
21 over-the-counter medications and cosmetics,” and did so expressly. *See Wyeth*, 129 S. Ct.
22 at 1200 n.8; *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1279 n.13
23 (C.D. Cal. 2008) (“The express preemption clause for the regulation of nonprescription
24 drugs was added to the FDCA”); *Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr. 2d
25 72, 80 (Cal. Ct. App. 2002) (“Under the heading ‘National uniformity for nonprescription
26

27 ⁴ This provision was added to the FDCA by the Food and Drug Administration Modernization
28 Act of 1997, Pub. L. No. 105-115 (Nov. 21, 1997) 111 Stat. 2296.

1 drugs,' the FDAMA includes an express preemption provision relating to nonprescription
2 or over-the-counter drugs . . .”).

3 **1. Homeopathic OTC Drugs Are Excepted from the Express**
4 **Preemption Clause**

5 As an initial matter, the Court must determine if the express preemption clause
6 found in section 379r is applicable to the case at hand. “Our preemption analysis is also
7 guided by the presumption that ‘because the States are independent sovereigns in our
8 federal system, . . . Congress does not cavalierly preempt state-law causes of action.’”
9 *Ventress v. Japan Airlines*, 603 F.3d 676, 682 (9th Cir. 2010) (quoting *Medtronic, Inc. v.*
10 *Lohr*, 518 U.S. 470, 485 (1996)). As noted earlier, the FDCA’s definition of drug includes
11 homeopathic remedies, like Coldcalm, which are recognized in the HPUS. *See* 21 U.S.C.
12 § 321(g)(1). Therefore, at first glance, the express preemption clause set forth in section
13 379r would appear to apply.

14 This express preemption clause, however, also contains a few exemptions,
15 exceptions, and limitations. *See* 21 U.S.C. § 379r(b), (d), (e). Of relevance to this case is
16 section 379r(d), titled “Exceptions”⁵:

17 (1) In general

18 In the case of a drug described in subsection (a)(1) of this
19 section that is not the subject of an application approved
20 under section 355 of this title or section 357 of this title (as
21 in effect on the day before November 21, 1997) or a final
22 regulation promulgated by the Secretary establishing
23 conditions under which the drug is generally recognized as
24 safe and effective and not misbranded, subsection (a) of this

25
26 ⁵ Both parties were given the opportunity to submit a fifteen page supplemental brief on the
27 applicability of 21 U.S.C. § 379r(d)(1) to this case. (Doc. 58.) The parties’ supplemental briefs
28 were reviewed and considered by the Court in crafting this Order. (*See* Docs. 61, 62.)

1 section shall apply only with respect to a requirement of a
2 State or political subdivision of a State that relates to the
3 same subject as, but is different from or in addition to, or
4 that is otherwise not identical with –

5 (A) a regulation in effect with respect to the drug pursuant
6 to a statute described in subsection (a)(2) of this section;

7 or

8 (B) any other requirement in effect with respect to the
9 drug pursuant to an amendment to such a statute made
10 on or after November 21, 1997.

11 21 U.S.C. § 379r(d)(1). The Court concludes that the plain language, albeit dense,
12 establishes that a homeopathic drug like Coldcalm is subject to the exception set forth in
13 section 379r(d)(1).

14 First, Coldcalm is a “drug described in subsection (a)(1)” of section 379.

15 Second, section 355 addresses the application and approval process for new drugs.
16 *See, e.g., id.* § 355(b)-(j). It is undisputed that Coldcalm was not the subject of a new drug
17 application as set forth in section 355.

18 Third, the version of section 357 in effect the day before November 21, 1997,
19 addressed the regulation of drugs containing penicillin, streptomycin, chlortetracycline,
20 chloramphenicol, bacitracin or any other antibiotic drug. 21 U.S.C. § 357 (1994) (repealed
21 1997). Again, it is undisputed that Coldcalm was not the subject of an application
22 approved under section 357 prior to the section’s repeal.

23 Fourth, the Court previously noted that homeopathic drugs are not the subject of
24 any final regulation promulgated by the Secretary establishing conditions under which they
25 might be recognized as safe and effective and not misbranded. *See* CPG § 400.400 (“A
26 product’s compliance with requirements of the HPUS . . . does not establish that it has
27 been shown by appropriate means to be safe, effective, and not misbranded for its intended
28 use.”). Thus, it would appear that the express preemption clause found in “subsection (a)

1 of this section” should only apply to Coldcalm with respect to a state requirement that
2 relates to *the same subject as*, but is different from either (A) a regulation in effect with
3 respect to Coldcalm pursuant to the FDCA, the Poison Prevention Packing Act of 1970, or
4 the Fair Packaging and Labeling Act or (B) any other requirement in effect with respect to
5 Coldcalm pursuant to an amendment made to the FDCA. *See* 21 U.S.C. § 379r(d)(1)(A)-
6 (B).

7 The key difference between the language used in 379r(a) and 379r(d)(1) appears to
8 be the use of the phrase “the same subject as.” *Compare id.* § 379r(a) *with id.* §
9 379r(d)(1). It is without question that this phrase is vague, ambiguous, and seemingly
10 open to multiple meanings. In the supplemental briefing regarding the application of
11 section 379r(d)(1) to the case at hand, neither party presented the Court with any binding
12 or even persuasive authority discussing section 379r(d)(1). The Court independently
13 searched for case law, legislative history, treatises, and law reviews, and could find no
14 information on section 379r(d)(1)’s purpose or usage in other cases. As far as the Court
15 can see, this subsection of the FDCA has failed to make an appearance in history.

16 Defendant argues, without authority, that “even though the statutory heading for
17 this section is entitled ‘Exceptions,’ subsection 379r(d)(1) clearly establishes the
18 preemptive effect of all regulations and statutory requirements in effect with respect to
19 OTC drugs not subject to [New Drug Application] approval, or a final OTC drug
20 monograph, which unambiguously includes OTC homeopathic drugs.” (Def.’s Supp.
21 Mem., Doc. 62, at 1 n.2; *see also id.* at 8.) Confusingly, although Defendant states that
22 “379r(d)(1) provides for a more narrowly-tailored scope of coverage,” Defendant seems to
23 argue the exact opposite, i.e., drugs that are covered by 379r(d)(1) are still subject to the
24 same scope of coverage.⁶ (*See, e.g., id.* at 7.) This can only be the case if Defendant is
25 interpreting “the same subject as” to mean the general subject of drugs.

26
27 ⁶ Although Plaintiff submitted a supplemental brief, Plaintiff failed to address the issue for
28 which the brief was requested by the Court. (*See* Pl.’s Supp. Mem., Doc. 61.)

1 The Court finds that Defendant’s interpretation of section 379r(d)(1) would appear
2 to render nugatory the additional phrase “the same subject as,” and in so doing, make the
3 entire subsection superfluous. “Absent a statutory text or structure that requires us to
4 depart from normal rules of construction, we should not construe the statute in a manner
5 that is strained and, at the same time, would render a statutory term superfluous.” *Dole*
6 *Food Co. v. Patrickson*, 538 U.S. 468, 476-77 (2003) (internal quotation marks and
7 citations omitted). “The cardinal principle of statutory construction is to save and not to
8 destroy. It is our duty to give effect, if possible, to every clause and word of a statute,
9 rather than emasculate an entire section” *United States v. Menasche*, 348 U.S. 528,
10 538-39 (1955). Thus the Court rejects Defendant’s argument that 379r(d)(1) creates no
11 exceptions to the express preemption clause of 379r(a).

12 Instead, the Court concludes that the only way it can give effect to section
13 379r(d)(1), and indeed make the title of the subsection, “Exceptions,” accurately reflect its
14 purpose, is to more narrowly read the phrase “the same subject as,” so that it cannot mean
15 all drugs (or even all OTC drugs). Although it is overly broad to define the “the same
16 subject as” as all drugs, it would be overly narrow to define the phrase to mean the exact
17 drug, in this case Coldcalm (or even homeopathic cold relief remedies for children).
18 Indeed, as used in this context, it would be contrary to the plain meaning of the word
19 “subject,” which indicates a category.

20 As noted earlier, there were no prior cases, legislative history, or later guidance
21 from the FDA that addressed this exact issue. The Court has, however, examined a
22 number of Compliance Policy Guides (“CPG”), which “advise the field inspection and
23 compliance staffs as to the [FDA’s] standards and procedures to be applied when
24 determining industry compliance.” FDA, CPG, “Foreword,” *available at*
25 *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidance*
26 *Manual/ucm116271.htm*. The Court recognizes that “[t]he statements made in the CPG are
27 not intended to create or confer any rights, privileges, or benefit on or for any private
28 person, but are intended for internal guidance.” FDA, CPG, “Introduction,” *available at*

1 <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm1>
2 [16791.htm](http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm16791.htm). The Court looks at the CPG for further indications as to how the FDA is
3 reviewing the safety and efficacy of homeopathic remedies like Coldcalm.

4 As noted earlier, the FDA allows a private organization to designate which
5 homeopathic drugs meet certain (and unknown) standards for strength, quality, and purity
6 set forth in the HPUS. CPG § 400.400. In addition, the FDA did not review any studies or
7 information on homeopathic drugs when putting together the monographs, i.e., the “final
8 regulation[s] promulgated by the Secretary establishing conditions under which the drugs
9 [are] generally recognized as safe and effective and not misbranded.” 21 U.S.C. §
10 379r(d)(1). Moreover, as noted earlier, the FDA explicitly states in CPG § 400.400 that a
11 homeopathic drug’s compliance with the requirements of the HPUS “does *not* establish
12 that it has been shown by appropriate means to be safe, effective, and not misbranded for
13 its intended use.” CPG § 400.400 (emphasis added).

14 More generally, the FDA has “an interest in taking steps to either encourage the
15 manufacturers of [non-FDA approved] products to obtain the required evidence and
16 comply with the provisions of the [FDCA] or remove the products from the market.”
17 FDA, CPG § 440.100, available at [http://www.fda.gov/ICECI/ComplianceManuals/](http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm)
18 [CompliancePolicyGuidanceManual/ucm074382.htm](http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm). Products that lack FDA approval
19 include those such as homeopathic OTC drugs that have not provided the FDA with
20 evidence demonstrating safety and efficacy, as well as other non-homeopathic OTC drugs
21 that are not marketed in accordance with an OTC drug monograph.

22 Due to a lack of resources, the FDA employs a risk-based enforcement approach
23 with respect to marketed unapproved drugs, in which drugs that threaten human health
24 (either directly or indirectly because they are used in lieu of other drugs) are prioritized for
25 investigation above drugs that are simply ineffective. *Id.* Thus, the FDA recently
26 investigated the homeopathic remedy Zicam Cold Remedy, because the FDA found a
27 significant and growing body of evidence indicating that it could pose a serious risk to
28 consumers who use it, specifically, that consumers reported a loss of their sense of smell.

1 See Warning Letter to Matrixx Initiatives, Inc. from FDA, June 16, 2009, *available at*
2 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm166909.htm>.
3 The Court, however, could find no record of any investigation of homeopathic remedies
4 due to a reported lack of efficacy.

5 For all of these reasons, the Court concludes that in this case, “the same subject as”
6 should be construed to mean homeopathic drugs. The Court finds this to be particularly
7 appropriate because of the FDA’s decision to apply the labeling requirements of the FDCA
8 to homeopathic drugs while concurrently declining to vouch for, or even investigate,
9 homeopathic drugs’ safety and efficacy. *See supra* Part II (C). The Court’s interpretation
10 attaches practical consequences to subsection 379r(d)(1), whereas Defendant’s
11 interpretation “violates the settled rule that a statute must, if possible, be construed in such
12 fashion that every word has some operative effect.” *United States v. Nordic Vill. Inc.*, 503
13 U.S. 30, 36 (1992). Moreover, the Court notes that, should the FDA promulgate final
14 regulations to address the conditions under which homeopathic drugs could be generally
15 recognized as safe, effective, and not misbranded, or should Congress amend the FDCA to
16 address homeopathic drugs, homeopathic remedies such as Coldcalm would no longer fit
17 into section 379r(d)(1)’s exception to the express preemption clause set forth in section
18 379r(a).

19 **2. Plaintiff’s Claims Impose State Requirements that are Identical to**
20 **the FDCA’s**

21 In the alternative, the Court concludes that even if Coldcalm is not excepted from
22 379r(a)’s express preemption clause under 379r(d)(1), Plaintiff’s state claims are not
23 preempted by 379r(a) because they do not constitute state-imposed “requirements” that are
24 “different from or in addition to” the federal requirements.⁷ 21 U.S.C. § 379r(a). “The
25

26 ⁷ Plaintiff does not argue, nor could she, that her claims are brought under the savings clause
27 set forth under section 379r(e), which exempts actions brought “under the product liability law of
28 any State” from the express preemption of section 379r(a). “Under the product liability law of
(footnote continued)

1 Court looks to two sources in defining the scope of state ‘requirement[s]’ in § 379r(a):
2 Supreme Court precedent, and the additional statutory language in § 379r(c)(2).” *Carter*,
3 582 F. Supp. 2d at 1280 (alteration in original). In *Riegel v. Medtronic*, 552 U.S. 312
4 (2008), the plaintiff’s state law claims for strict product liability, implied warranty, and
5 negligent design, testing, inspection, distribution, labeling, marketing, and sale of a Class
6 III medical device were preempted by section 360k(a) of the FDCA. 552 U.S. at 330.
7 *Riegel* held that “reference to a State’s ‘requirements’ includes its common-law duties.”
8 *Id.* at 324. “[W]hile the common-law remedy is limited to damages, a liability award ‘can
9 be, indeed is designed to be, a potent method of governing conduct and controlling
10 policy.’” *Id.* (quoting *Cipollone*, 505 U.S. at 521). The Court is persuaded by the
11 reasoning set forth in *Carter v. Novartis Consumer Health, Inc.*, that “the structural
12 similarities between § 360k(a) and § 379r(a), and their close relation in the overall
13 regulatory context, compel the Court to adopt *Riegel’s* expansive reading of [a state]
14 ‘requirement.’” *Carter*, 582 F. Supp. 2d at 1281.

15

16 Taken together, *Riegel* and § 379r(c)(2) suggest that virtually
17 any state requirement that relates to the regulation of
18 nonprescription drugs can be preempted, regardless of the
19 common law theory under which it is brought. However, this
20 does not mean that preemption is without any limits. Again,
21 under the language of § 379r(a), state requirements are only
22 preempted to the extent that they differ from federal
23 requirements.

24

25 *Id.* at 1282.

26

27 _____
28 California, injury to the plaintiff from a defective product is an essential element of a cause of
action.” *Kanter*, 122 Cal. Rptr. 2d at 80.

1 Plaintiff's claims are premised on the allegation that Coldcalm's marketing,
2 advertising, and/or labeling were false and misleading, because the drug "did not work as
3 advertised, nor did Plaintiff experience any of the promised benefits." (Compl. ¶ 31.) The
4 FDCA prohibits the sale of misbranded drugs. *See generally* 21 U.S.C. § 331. Under the
5 FDCA, a drug will be deemed to be misbranded if the label is false or misleading. 21
6 U.S.C. § 352(a). The term "labeling" is defined to include "all labels and other written,
7 printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2)
8 accompanying such article." *Id.* § 321(m). As noted in *Carter*, "[t]he touchstone of
9 preemption under § 379r is the *effect* that a finding of liability on a particular claim would
10 have on the Defendants, and not the particular common law or state law theory upon which
11 that claim was brought." 582 F. Supp. 2d at 1283. The Court therefore concludes that any
12 claim about false or misleading labeling and advertising is expressly preempted by federal
13 law to the extent that the state requirements are not identical to those in the FDCA. Thus,
14 the Court reviews whether Plaintiff's claims are identical to the requirements as set forth in
15 the FDCA.

16 The FDCA requires the label of a homeopathic OTC drug to include adequate
17 directions for use, a statement of ingredients, the dilution, and at least one major OTC
18 indication for use. *See* 21 C.F.R. §§ 201.5, 201.10, 201.61, 201.62. In determining
19 whether the labeling or advertising is misleading, the Court should consider "not only
20 representations made or suggested by statement, word, design, device, or any combination
21 thereof, but also the extent to which the labeling or advertising fails to reveal facts
22 material." 21 U.S.C. § 321(n). Thus, if a label has an indication for use that is false, or by
23 virtue of being on the market, implies that an OTC drug is effective when it is not, the
24 label or advertising would be misleading and the drug would be misbranded.

25 Defendant contends that Plaintiff's requested relief would require Defendant to
26 change its labels and advertising, and thus constitute a requirement that is either different
27 from, or additional to, the requirements of the FDCA. Defendant's argument is premised
28 on the underlying assumption that, so long as a homeopathic OTC drug is included in the

1 HPUS, “the general efficacy and safety of the remedy has been substantiated to the extent
2 required by federal law.” (Mot. at 11 (quoting *Nat’l Council Against Health Fraud, Inc. v.*
3 *King Bio Pharm., Inc.*, 133 Cal Rptr. 2d 207, 216 (Cal Ct. App. 2003)).)

4 The Court is not persuaded by the reasoning set forth in *King Bio Pharmaceuticals*
5 that inclusion in the HPUS is sufficient to guarantee the efficacy and safety of a
6 homeopathic OTC drug. As previously noted, unlike with non-homeopathic OTC drugs,
7 the FDA has not set up a comprehensive process to evaluate the safety or efficacy of
8 homeopathic OTC remedies. *See* CPG § 400.400. More importantly, the FDA explicitly
9 acknowledges that “[a] product’s compliance with requirements of the HPUS . . . does *not*
10 establish that it has been shown by appropriate means to be safe, effective, and not
11 misbranded for its intended use.” *Id.* (emphasis added).

12 Thus, this action differs from the cases cited by Defendant, specifically *Kanter* and
13 *Carter*. In both of those cases, the courts concluded that the plaintiffs’ common-law tort
14 claims regarding the lack of efficacy of the non-homeopathic OTC drugs at issue were
15 preempted by a combination of the monograph system and labeling requirements of the
16 FDCA. In both cases, the plaintiffs’ requested relief would require defendants to modify
17 the labels with which they were required to comply under the FDCA. The courts’ decision
18 to defer to the FDA’s labeling regulations relied in no small part on the FDA’s
19 comprehensive process that tested the safety and efficacy of the drugs which it regulated.
20 Therefore, the Court is not persuaded that the cases cited by Defendant, which deal with
21 non-homeopathic OTC drugs, are controlling in this case.

22 Indeed, under Defendant’s arguments, Defendant could state that Coldcalm would
23 relieve symptoms of allergies, lessen headaches and back pain, improve a person’s visage,
24 and eliminate the occurrence of body odor, regardless of whether the drug did any of these
25 things, without violating the FDCA. This would create the perverse effect that Coldcalm
26 would not violate the FDCA if it set forth indications for use that were false, but it would
27 violate the FDCA if it was completely ineffective, yet did not contain an indication for use.
28 This reading of the regulations is contrary to Congress’ purpose—in this instance, to give

1 truthful and helpful information to consumers about OTC drugs. Instead, the Court
2 concludes that Plaintiff’s claims, if proven to be true, would simply require Defendant to
3 truthfully state its efficacy or not sell its products; such relief would not impose a state
4 requirement that is “different from or in addition to, or that is otherwise not identical with”
5 that of the FDCA. *See* 21 U.S.C. § 379r(a)(2). Therefore the Court concludes that the
6 FDCA does not expressly preempt Plaintiff’s claims.⁸

7 **D. Implied Preemption**

8 Although an express preemption clause “does not categorically preclude courts
9 from applying principles of implied preemption,” it does “support[] an inference that
10 Congress did not intend to preempt matters *beyond* the reach of the provision.”

11 *Metrophones Telecomms. Inc. v. Global Crossing Telecomms., Inc.*, 423 F.3d 1056, 1072
12 (9th Cir. 2005) (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995)).

13 [The Supreme Court] recognized at least two types of implied
14 pre-emption: field pre-emption, where the scheme of federal
15 regulation is so pervasive as to make reasonable the inference
16 that Congress left no room for the States to supplement it, and
17 conflict pre-emption, where compliance with both federal and
18 state regulations is a physical impossibility, or where state law
19 stands as an obstacle to the accomplishment and execution of
20 the full purposes and objectives of Congress.

21
22 *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (internal quotation marks
23 and citations omitted); *see also Cipollone*, 505 U.S. at 516.

24
25 ⁸ Defendant argues that, because it complied with federally-imposed requirements for labeling
26 homeopathic drugs, a “safe harbor” shields it from liability under the CLRA and the UCL.
27 (Opp’n, Doc. 27-1, at 14-15.) Because the Court concludes that federal regulations do not
28 explicitly sanction or require the “business practice complained of,” in this case Coldcalm’s
alleged misleading labeling, the Court concludes that Defendant is not shielded from Plaintiff’s
consumer protection claims.

1 First, the Court concludes that, even without inferring the absence of implied
2 preemption due to the express preemption clause set forth in section 379r(a), there is no
3 field preemption here. Although section 379r(a) requires that all state requirements on
4 OTC drugs be identical with those set forth in the FDCA, as set forth previously by this
5 Order, section 379r(d) creates exceptions that apply to drugs which have not been the
6 subject of FDA review. *See generally*, 21 U.S.C. § 379r(d). In addition, section 379r(f)
7 explicitly states that “[n]othing in this section shall prevent a State or political subdivision
8 thereof from enforcing, under any relevant civil or other enforcement authority, a
9 requirement that is identical to a requirement in this chapter.” *Id.* § 379r(f); *cf.*
10 *Metrophones Telecomms.*, 423 F.3d at 1072 (holding a savings clause permitting the
11 continuation of limited state remedies was persuasive in finding no field preemption).

12 Second, the Court concludes that the principle of implied conflict preemption, i.e.,
13 whether “state law stands as an obstacle to the accomplishment and execution of the full
14 purposes and objectives of Congress,” *Gade*, 505 U.S. at 98, is largely identical to the
15 analysis of whether the state requirements in this action were identical to the federal
16 requirements of the FDCA. *See Metrophones Telecomms.*, 423 F.3d at 1073. As noted in
17 the previous section, the FDA has explicitly acknowledged that compliance with
18 requirements of the HPUS does not establish that a product is either effective or correctly
19 labeled. Therefore, for the same reasons as set forth above, the Court rejects this
20 argument.

21 **E. Abstention and Deference to FDA Regulatory Authority**

22 Defendant argues that the Court has discretion to abstain from hearing this action,
23 “in deference to the government’s enforcement powers.” (Mot. at 12.) Defendant also
24 argues that the FDA has “primary jurisdiction” and that the Court should thus leave claims
25 such as this one for the FDA to address. (Reply, Doc. 39, at 13.) As evidenced by the
26 FDA guidance documents described above, the Court concludes that the FDA has largely
27 abdicated any role it might have had in creating standards for homeopathic OTC drugs,
28 and has instead attempted to delegate this authority to the non-governmental organization

1 that determines whether homeopathic substances should be included in the HPUS. In
2 addition, the FDA explicitly states that it makes no guarantee about the safety or efficacy
3 of homeopathic OTC drugs, even if they meet the unknown standards for inclusion in the
4 HPUS. Moreover, in this case, there does not appear to be a large body of scientific
5 evidence requiring an expertise that is beyond the abilities of the judiciary. Therefore, to
6 the extent the Court has discretion to abstain from hearing this action, it does not so
7 choose.

8 **F. Fraud Pleading Standards**

9 Defendant argues that Plaintiff does not satisfy the heightened pleading standards
10 that Federal Rule of Civil Procedure 9(b) requires of claims sounding in fraud, and that
11 Plaintiff fails to address all of the elements of her fraud claim. (Mot. at 15-16.) The
12 requirement for specificity for claims sounding in fraud is meant “to allow defendant to
13 understand fully the nature of the charge made.” *Tarmann v. State Farm Mut. Auto. Ins.*
14 *Co.*, 2 Cal. Rptr. 2d 861, 862 (Cal. Ct. App. 1991) (internal quotation marks and citation
15 omitted). “The elements of fraud are: (1) a misrepresentation (false representation,
16 concealment, or nondisclosure); (2) knowledge of falsity (or scienter); (3) intent to
17 defraud, i.e., to induce reliance; (4) justifiable reliance; and (5) resulting damage.”
18 *Robinson Helicopter Co. v. Dana Corp.*, 102 P.3d 268, 274 (Cal. 2004). Plaintiff must not
19 only allege each element of fraud, but because she is alleging fraud against a corporation,
20 she must also specify: (1) the names of people who made representations; (2) their
21 authority to speak; (3) to whom they spoke; (4) what they said; (5) and when it was said.
22 *Tarmann*, 2 Cal. Rptr. 2d at 862-63.

23 The Court concludes that Plaintiff not only addresses each element of her fraud
24 claim, but also states her claims that sound in fraud with sufficient particularity. Plaintiff
25 alleges that Defendant states on the packaging for Coldcalm that it “will relieve the
26 common cold, including: sneezing, runny nose, nasal congestion, sinus pain, headaches,
27 and sore throat.” (Compl. ¶ 7.) Plaintiff alleges that this is a misrepresentation, because
28 she “consumed Children’s Coldcalm as directed, but it did not work as advertised, nor did

1 Plaintiff experience any of the promised benefits.” (*Id.* ¶ 31.) Therefore, Plaintiff alleges
2 that the advertising was “false and misleading.” (*Id.*) Plaintiff next alleges that
3 “Defendant knew when it began making claims about Children’s Coldcalm, and knows
4 now, that its claims regarding Children’s Coldcalm were false, contrary to established
5 medical authority, and were likely to mislead consumers.” (*Id.* ¶ 38.) Plaintiff alleges that
6 Defendant displayed the alleged misrepresentations “prominently” on Coldcalm’s
7 packaging, knowing that Plaintiff would rely on the misrepresentations in choosing to
8 purchase the product. (*Id.*) Plaintiff alleges that she “expressly relied on the
9 representations of Defendant and had no reason to doubt or dispute those representations.”
10 (*Id.* ¶ 40.) Finally, Plaintiff argues that she, and those in the class she seeks to represent,
11 “have suffered actual damages in an amount not presently known . . . including incidental
12 and consequential damages, interest, and reasonable attorneys’ fees.” (*Id.* ¶ 41.) Thus,
13 Plaintiff alleges each of the required elements of “fraud” with sufficient specificity that
14 Defendant can understand fully the nature of the charge made. The underlying facts set
15 forth in Plaintiff’s fraud claim are the same in her other claims sounding in fraud,
16 therefore, the Court concludes that they, too, meet the requirements for specificity.

17 **G. Compliance with California Civil Code Section 1782(a)**

18 Defendant argues that Plaintiff fails to allege compliance with the notice
19 requirements of the CLRA.⁹ The CLRA requires that:

20
21 Thirty days or more prior to the commencement of an action for
22 damages pursuant to this title, the consumer shall do the
23 following:
24

25
26 ⁹ Contrary to Defendant’s claims, the notice provisions are not jurisdictional, but do require
27 compliance in order to state a claim. *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 949
28 (S.D. Cal. 2007) (citing *Outboard Marine Corp. v. Superior Court*, 124 Cal. Rptr. 852, 858-59 (1975)).

1 (1) Notify the person alleged to have employed or committed
2 methods, acts, or practices declared unlawful by Section 1770 of
3 the particular alleged violations of Section 1770.

4
5 (2) Demand that the person correct, repair, replace, or otherwise
6 rectify the goods or services alleged to be in violation of Section
7 1770.

8
9 The notice shall be in writing and shall be sent by certified or
10 registered mail, return receipt requested, to the place where the
11 transaction occurred or to the person's principal place of business
12 within California.

13
14 Cal. Civ. Code. § 1782(a). California courts require “a literal application of the notice
15 provisions.” *Outboard Marine Corp. v. Superior Court*, 124 Cal. Rptr. 852, 859 (1975).

16 Here, Plaintiff alleges that she “mailed to Defendants, by certified mail, return
17 receipt requested, the written notice required by Civil Code Section 1782(a).” (Compl. ¶
18 32.) Plaintiff also attached the letter, which fulfilled the requirements of section 1782(a)
19 and was mailed more than thirty days prior to the filing of Plaintiff’s Complaint. (Compl.,
20 Ex. 3.) Thus, the Court concludes that Plaintiff complied with the literal notice
21 requirements of the CLRA. Defendant contends that the statute requires Plaintiff to allege
22 that Defendant “actually received the notice, or that [Defendant] even knew of and had the
23 opportunity to correct the behavior before a suit for damages was filed.” (Reply at 17.)
24 Defendant does not provide, and the Court has not found, any authority to support these
25 contentions. The Court additionally concludes that a determination as to whether the letter
26 was sent to the wrong address or whether Defendant refused receipt would require the
27 Court to look beyond the face of the pleadings, which is not permitted in a Rule 12(c)

28

1 motion. Therefore, the Court concludes that Plaintiff has alleged sufficient compliance
2 with the CLRA notice requirements to maintain this claim.

3 **III. Conclusion**

4 For the foregoing reasons, the Court DENIES Defendant's Motion for Judgment on
5 the Pleadings.

6
7
8 DATED: July 25, 2011

9
10 **JOSEPHINE STATON TUCKER**
11 **UNITED STATES DISTRICT JUDGE**
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28