UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HOLISTIC CANDLERS AND CONSUMER ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Case No. 10-582 (RJL)**
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION
(March 16, 2011) [#7]

Plaintiffs, the Holistic Candlers and Consumer Association and other individual manufacturers, consumers, and private associations ("plaintiffs"), bring this action against the U.S. Food and Drug Administration ("FDA" or the "agency") and other agencies and officials in the United States government (collectively, "defendants") alleging violations of plaintiffs' First, Ninth, Tenth, and Fourteenth Amendment rights; seeking injunctive relief staying the FDA's determination that plaintiffs' holistic candles are unapproved medical devices under 21 U.S.C. § 321; and seeking declaratory relief voiding the FDA's determination. Before this Court is defendants' Motion to Dismiss [Dkt. #7]. Upon consideration of the parties' pleadings, relevant law, and the entire record, the defendants' motion is GRANTED.

BACKGROUND

Plaintiffs are a collection of individuals, organizations, and associations who manufacture, distribute, consume, and advocate for the use of "holistic candles," commonly referred to as "ear candles." Pls.' Compl. ("Compl."), Apr. 12, 2010, ¶¶ 2-3, 15 [Dkt. #1]. Made of fabric soaked in beeswax or paraffin, ear candles are hollow cones placed into the ear and set on fire with an open flame. Defs.' Mot. to Dismiss, June 10, 2010, at 1 [Dkt. #7]. Certain of the plaintiff-manufacturers historically[1] marketed ear candles for uses such as "[h]elping people with . . . sinus congestion, colds, the flu, sore throats, earaches, ear infections, sinus infections, lymphatic congestion, swollen glands," (Defs.' Mot. to Dismiss, Ex. B at 3 [Dkt. #7-2]); obtaining relief from Meniere's Disease, tinnitus, sleep disorders, and vision disorders (*id.* at 5); and extracting wax and infectious fluid from a child's ear (*id.* at 7).

On February 17, 2010, the FDA issued Warning Letters to fifteen manufacturers and distributors of ear candles (Compl. ¶ 17; Defs.' Mot. to Dismiss at 1) – including five named plaintiffs[2] in this case (Defs.' Mot. to Dismiss at 15) – objecting to certain marketing claims the manufacturers made about ear candles.[3] In the letters, the FDA

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[1] Although the marketing claims contained on some of plaintiffs' websites appears to have changed, plaintiffs do not challenge the claims defendants identified and contested in 2010. *See generally* Compl.; Pls.' Opp'n, June 24, 2010 [Dkt. #8].

[2] Harmony Cone, King Cone International, Betty Lee, Home Remedy Solutions, and Wholistic Health Solutions. Defs.' Mot. to Dismiss at 9.

[3] According to internal documents, the FDA strives "to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action." FDA, REGULATORY PROCEDURES MANUAL § 4-1-1 (Mar. 2010),

explained that ear candles are considered "devices" under the Federal Food, Drug, and Cosmetic Act ("the FDCA" or "the Act"), and thus regulated by the FDA, because they are

> "an instrument, apparatus, [or] implement . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, . . . or intended to affect the structure or any function of the body of man."

21 U.S.C. § 321(h)(2), (3).

Further, the FDA advised the plaintiff-manufacturers that they had violated the FDCA by labeling and marketing devices (ear candles) without the agency's clearance or approval. Defs.' Mot. to Dismiss at 1.[4] The agency referred the manufacturers to the FDA website for information about how to obtain approval and clearance for devices and noted that the "FDA will evaluate the information you submit and decide whether your product may be legally marketed." *Id.* at 1.[5] The FDA requested that the manufacturers "cease marketing and distribution of ear candles . . . the same as or similar to those described [in the letter]" and stated that the failure to correct FDCA violations "may

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available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf. Warning Letters are issued to "achieve voluntary compliance." *Id.*

[4] Specifically, the FDA warned that the ear candles, as labeled and as marketed without clearance or approval, were adulterated under 21 U.S.C. § 351(f)(1)(B) (lack of premarket approval) and 21 U.S.C. § 352(o) (failure to notify FDA of intent to introduce device into commercial distribution) and misbranded under 21 U.S.C § 352(a), (f)(1), (j) (labeling deficiencies). Defs.' Mot. to Dismiss, Ex. B at 2-3.

[5] The FDA highlighted other specific concerns in its letters, such as manufacturers and distributors advertising ear candles for use on infants and small children. *See* Defs.' Mot. to Dismiss, Ex. B.

result in regulatory action." Defs.' Mot. to Dismiss, Ex. B at 6. Finally, the FDA asked recipients of the Warning Letters to submit, within fifteen business days, a written response outlining each recipient's intent to comply with the FDA's request. Defs.' Mot. to Dismiss at 19 n.20; Ex. B at 3. Some of the fifteen letter recipients – including Harmony Cone, a named plaintiff in this case – complied with the FDA's request for a written response; others agreed to voluntarily cease marketing ear cones or to remove health claims from promotional materials. Defs.' Mot. to Dismiss at 11. But no company presented the FDA with proposed labeling disclaimers or disclosures for the agency's evaluation. *Id.*

Notwithstanding their prior marketing and representations, plaintiffs now claim that ear cones "are not medical devices," Compl. ¶¶ 18-19, 29. Instead, they contend, ear candles are generic products used for "holistic . . . relaxation [and] comfort" and are thus exempt from FDA regulation. *Id.* ¶¶ 3, 19-23. Alleging that the FDA's issuance of Warning Letters constituted final agency action (Pls.' Opp'n at 5) and that the agency has "effectively outlaw[ed]" ear candles (Compl. ¶ 3), plaintiffs filed this suit against the FDA on April 9, 2010: less than two months after the FDA issued the February 17 Warning Letters. *See* Defs.' Mot. to Dismiss at 12.

To date, the FDA has not initiated enforcement action against any named plaintiff. *Id.* at 11.

ANALYSIS

I. *Standard of Review*

Defendants move to dismiss this action pursuant to FED. R. CIV. P. 12(b)(1). A Rule 12(b)(1) motion shall be granted if a plaintiff fails to establish subject-matter jurisdiction. A plaintiff bears the burden of proving subject-matter jurisdiction, and the standing required to invoke it. *See US Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000). In addition, a plaintiff's claim must also be ripe. Importantly, a "claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States,* 523 U.S. 296, 300 (1998) (citations omitted).

Defendants also move to dismiss plaintiffs' complaint under FED. R. CIV. P. 12(b)(6) for failure to state a claim upon which relief may be granted. To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must support its complaint with "any set of facts consistent with the allegations" such that the complaint "possess[es] enough heft to show that the pleader is entitled to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 563 (2007) (citations omitted).

Unfortunately for plaintiffs, even taking as true all allegations in the complaint, *see Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003), each of plaintiffs' claims must, for the following reasons, be dismissed.

II. *Rule 12(b)(1) Motion*

A. *Plaintiffs Lack Standing Because They Cannot Demonstrate Actual Injury.*

First, plaintiffs' claims must be dismissed for lack of subject-matter jurisdiction because plaintiffs cannot, and do not, demonstrate the actual injury required to establish standing. A litigant bears the burden of showing that is has "suffered, or be[en] threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477 (1990); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). But plaintiffs do not "allege that [they] ha[ve] been or will in fact be perceptibly harmed by the challenged agency action, not that [they] can *imagine* circumstances in which [they] could be affected by the agency's action." *United States v. Students Challenging Reg. Agency Procs. (SCRAP)*, 412 U.S. 669, 688-89 (1973) (emphasis added). In fact, despite plaintiffs' allegations of "imminent peril of risk of health or life, loss of liberty, property, [and] livelihood or licensure," Compl. ¶ 14, plaintiffs' case *is* one of imagined injury. Indeed, the FDA's only official action in this case occurred in February 2010, when it issued Warning Letters to some named plaintiffs.[6] Defs.' Mot. to Dismiss at 11, 15. That the FDA has taken no additional official action – enforcement or otherwise – undercuts

[6] Plaintiffs allude to a March 2010 meeting in which FDA officials allegedly stated the agency's disinclination to approve ear candles as a device. Pls.' Opp'n at 4-5, 11. To be sure, this allegation is in no way probative of injury, much less final agency action. *See infra*, Section II.B. To the contrary, it reinforces the fact that – because plaintiffs never presented the FDA with proposed disclosures and disclaimers – the agency never had an opportunity to evaluate such labeling. *See* Defs.' Reply Memo., July 9, 2010, at 7 n.5 [Dkt. #10].

plaintiffs' assertion that they have suffered real (much less imminent) harm. The mere allegation that the FDA "effectively outlaw[ed]" ear candles, Compl. ¶ 3, or that plaintiffs are "at imminent risk of loss of income," *id.* ¶ 8, does not suffice to prove actual injury where the FDA has initiated no enforcement action, seized no personal property, imposed no civil fine, and banned no device.[7] *See Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4 (D.D.C. 1989); *see also Regen. Scis., Inc. v. FDA*, No. 09-cv-00411, 2010 WL 1258010, at *8 (D. Colo. March 26, 2010) ("The fact remains that [plaintiff] has not shown any specific concrete action taken by the FDA that has harmed it or any specific losses it has suffered as a result of FDA action."). Accordingly, plaintiffs do not have standing to bring their declaratory and injunctive claims against the FDA.[8]

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[7] This is especially true where, as here, the FDA provided an opportunity for the plaintiff-manufacturers and distributors to obtain approval and clearance for its device. *See* Defs.' Mot. to Dismiss, Ex. B. Moreover, plaintiffs' alleged injuries – which are, at best, speculative – apply only to plaintiffs who manufacture or distribute ear candles, not to other named plaintiffs who simply advocate or use them. Because plaintiffs make no effort to establish associational standing, *see Friends of the Earth, Inc. v. Laidlaw Envt'l Servs., Inc.*, 528 U.S. 167, 181 (2000), this Court will not address the additional prudential deficiencies suffered by plaintiffs who neither manufacture nor distribute ear candles.

[8] Similarly unavailing is the assertion that standing is conferred by alleging violations of plaintiffs' First Amendment right to commercial speech. *See* Compl. ¶ 40; Pls.' Opp'n at 9-10, 16-17. It is well established that the FDA may evaluate speech contained in labeling to determine whether sale of a regulated product is lawful. *See Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004).

B. *Plaintiffs Lack Subject-Matter Jurisdiction Because There Has Been No Final Agency Action and Plaintiffs' Claims Are Not Ripe.*

Plaintiffs also lack subject-matter jurisdiction on a separate but related ground: ripeness. A claim is not ripe for review if "judicial intervention would inappropriately interfere with further administrative action," *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998), or if "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas,* 523 U.S. at 300 (internal quotations omitted). To determine whether a litigant's claims are ripe, courts look to two factors: "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967) (abrogated on other grounds). When evaluating the first factor, fitness, our Circuit makes three additional inquiries: "whether the issue raised is a purely legal one; whether immediate judicial review is calculated to avoid multiplicity of litigation; and whether the agency position is final and not likely to be reconsidered." *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4 (D.D.C. 1989) (citing *Indep. Bankers Ass'n of Am. v. Smith,* 534 F.2d 921, 927-29 (D.C. Cir.), *cert. denied,* 429 U.S. 862 (1976)). The "hardship" inquiry asks "whether the agency's position has a direct and immediate . . . effect on the day-to-day business[] of the complaining parties." *Estee Lauder*, 727 F. Supp. at 4 (internal citations and quotations omitted).

Here, plaintiffs meet none of the criterion for ripeness. Of the factors relevant to the ripeness inquiry, both parties agree that one is the lynchpin: whether the FDA's Warning Letters constitute final agency action. Here, they did not. How so?

Under the Administrative Procedure Act ("APA"), agency action is subject to judicial review when it is final and "there is no other adequate remedy in a court." 5 U.S.C. § 704. "A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action." *Id.* Plaintiffs argue that FDA Warning Letters generally – and the letters issued to certain plaintiffs in this case specifically – constitute final agency action. Compl. ¶ 10; Pls.' Opp'n at 11-12, 22-27. But the text of the Warning Letters plainly contradicts plaintiffs' claims of finality.[9] To wit, the letters indicate that further evaluation is required (*see* Defs.' Mot. to Dismiss, Ex. B at 3) ("The FDA will evaluate the information you submit and decide whether your product may be legally marketed.")), and that the FDA's instructions are not final demands, but rather intermediate requests for voluntary compliance. *See id.* ("FDA *requests* that Harmony Cone immediately cease marketing, promoting and distributing . . . ear candles. . . . Failure to promptly correct these deviations *may* result in regulatory action being initiated.") (emphasis added). Moreover, FDA policy is clear: Warning Letters are informal, advisory, and not intended to serve as final agency action. FDA, REGULATORY PROCEDURES MANUAL § 4-1-1 (Mar. 2010) ("A Warning Letter is informal and advisory. . . . *FDA does not consider Warning Letters to be final agency action* on which it can be sued.") (emphasis added).

Most importantly, the FDA's view that "[a Warning Letter] communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action,"

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[9] That the FDA's Warning Letters are *not* final is underscored by plaintiffs' own admissions that "there may be no real agency administrative record regarding this matter other than the offending letters." Pls.' Opp'n at 26-27.

id., also comports with the law of our Circuit. *See, e.g., Am. Fed'n of Gov't Emps. v. O'Connor*, 747 F.2d 748, 752-53 (D.C. Cir. 1984) (agency's informal advisory opinion unripe for judicial review because it "binds neither the public nor any agency or officer of the government"). Indeed, the analysis by another Judge on our Court in *Estee Lauder* is particularly instructive. 727 F. Supp. at 1. There, a cosmetic manufacturer sued the FDA based on a "regulatory letter" sent by an agency employee which outlined objections to the manufacturer's labeling of a skin cream and classified the cream as a drug under the FDCA. *Id.* at 2-3. Engaging in a six-factor analysis of finality, the court concluded that the FDA regulatory letter was "by its very nature informal and advisory" and determined that the letter did not constitute final agency action subject to judicial review. *Id.* at 4-5.[10] Simply put, these plaintiffs – just like the plaintiffs in *Estee Lauder* – fail to demonstrate that their claims are fit for review.[11] Because plaintiffs' claims are not ripe, this Court does not have subject-matter jurisdiction to review them.

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[10] Persuasive authority from other Circuits also supports the determination that FDA warning letters are not final and are not, therefore, subject to judicial review. *See, e.g., Mobil Exploration & Producing U.S., Inc. v. Dep't of Interior*, 180 F.3d 1192, 1198-99 (10th Cir. 1999) (agency letter not final); *Dietary Supp. Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (FDA regulatory letters do not constitute final agency action).

[11] Contrary to plaintiffs' assertions, *see* Pls.' Opp'n at 24-26, *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.D.C. 1986), does not control on the point of standing. In *Ciba-Geigy*, unlike here, the agency's follow-up letter was "definitive" and "reiterat[ed] the Agency position." *Id.* at 437. As a result, the court saw "not the slightest danger that judicial review will disrupt the orderly process of administrative decisionmaking." *Id.*

C. *This Court Has No Jurisdiction to Review Plaintiffs' Pre-Enforcement Challenge.*

In addition, plaintiffs' efforts to obtain injunctive relief (a stay of the FDA's determination that ear candles are medical devices) and declaratory relief (judgment that plaintiffs' rights to manufacture ear candles are not limited), Compl. ¶¶ 42, 48, is nothing more than a pre-enforcement challenge foreclosed by *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600 (1950) (district court lacked jurisdiction to review the FDA's pre-seizure determination of probable cause because "[j]udicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]"). *See also Abbott Labs.*, 387 U.S. at 148 (reaffirming the *Ewing* court's rejection of "an unheard-of form of relief which, if allowed, would have permitted inferences in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the [FDCA]"). Here, as in *Ewing*, plaintiffs ask this Court for relief which, if granted, would preempt future FDA enforcement action such as injunctions, civil penalties, or seizures under the FDCA. *See* 21 U.S.C. §§ 332-34. The determination of FDCA violations is, of course, a factual one that the FDA must conduct on a plaintiff-by-plaintiff basis, at a relevant time and in light of each plaintiff's unique products and labeling. Unless and until the FDA has completed such an inquiry and taken legal action, this Court does not have jurisdiction over plaintiffs' claims and may not review requests for injunctive or declaratory relief preventing the FDA from bringing enforcement actions against plaintiffs.

III. *Rule 12(b)(6) Motion*

Even taking as true all allegations in the complaint, *see Holy Land Found. for Relief & Dev.*, 333 F.3d at 165, plaintiffs' remaining claims fail as a matter of law because they have not exhausted their administrative remedies (here, the requirement of a "citizen petition"): a fact that plaintiffs admit. Compl. ¶ 17 ("The FDA determination was made without the prior petition of Citizens."). Indeed, final agency action is required for judicial review under the APA. 5 U.S.C. § 704. But an agency action is "final for the purposes of [the APA]" only after a plaintiff "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993). In this case, FDA regulations plainly state that "before any legal action is filed," a party's claim seeking action or inaction from the agency "must first be the subject of a final administrative decision based on a ['citizen'] petition submitted under § 10.25(a)." 21 C.F.R. § 10.45(b). Unfortunately, plaintiffs have not initiated the administrative-review process, let alone exhausted their administrative remedies.[12] By failing to challenge the Warning Letters through a citizen petition, *see* 21

[12] Defendants note that plaintiff Natural Solutions Foundations filed "Emergency Citizens Petitions" with various government officials on May 7, 2010, and June 5, 2010, seeking a stay of the FDA's determinations from the February 2010 Warning Letters. Defs.' Reply Memo., at 7 n.6. The petitions did not comply with relevant statutory requirements, *see* 21 C.F.R. § 10.30, a fact the FDA highlighted in a June 17, 2010, letter to Natural Solutions Foundation requesting that plaintiff resubmit the petition in compliance with § 10.30. Defs.' Reply at 7, n.6. Because plaintiff did not resubmit a proper citizen petition, the "emergency petitions" are insufficient to exhaust plaintiff's administrative remedies.

C.F.R. § 10.25, plaintiffs preclude, as a matter of law, judicial review of their claims.[13] *See Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21-22 (D.D.C. 2008) (dismissing under Rule 12(b)(6) plaintiffs' claims against the FDA for failure to exhaust administrative remedies including a citizen petition), *aff'd*, 358 F. Appx. 179 (D.C. Cir. 2009), *cert. denied*, 131 S. Ct. 1062 (2011).

Finally, even if plaintiffs had standing to sue the FDA – which they do not – and even if plaintiffs' claims were ripe and their administrative remedies exhausted – which they are not – the remaining statutory and constitutional claims would still fail as a matter of law. Some of these claims fail because they assert conclusory allegations without pleading the elements necessary to prevail as a matter of law.[14] Others claims are

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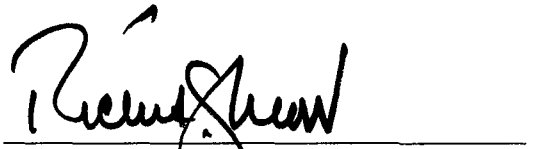
[13] Incidentally, the FDA's response to a citizen petition would constitute final agency action. 21 C.F.R. § 10.45(d). Suffice it to say that plaintiffs seek to circumvent administrative remedies with improper judicial review. As an initial matter, plaintiffs did not seek – at any point prior to or during this litigation – approval or clearance from the FDA for plaintiffs' ear candles or its labeling. Nor did plaintiffs respond to the FDA's request, stated in the February 2010 Warning Letters, to respond within fifteen days. Defs.' Mot. to Dismiss at 11; *see also* Compl. ¶ 11.

[14] *See* Count I, Compl. ¶¶ 19, 24, 39 (device-related claims under 21 U.S.C. § 321(h) do not challenge FDA's product-specific determinations); Count I, Compl. ¶ 15(d) (plaintiffs do not allege elements to rebut automatic class III classification and premarket approval requirements); Count II, Compl. ¶¶ 44, 46 (Free Exercise and Religious Freedom Restoration Act claims fail because FDA has not compelled action or interfered with religious use of ear candles, *see Emp't Div., Dep't of Human Res. of Or. v. Smith*, 494 U.S. 872 (1990), nor has the FDA substantially burdened plaintiffs' exercise of religion, *see Cockerell-El v. Dist. of Columbia*, 937 F. Supp. 18, 21 (D.D.C. 1996)); Pls.' Opp'n at 13-15 (Fourteenth Amendment claim not properly alleged and, in any event, applies only to states, not to federal government action, *United Transp. Serv. Emps. ex rel Wash. v. Nat'l Meditation Bd.*, 179 F.2d 446, 453 (D.C. Cir. 1949)).

insufficient as a matter of law.[15] Still others fail because no private right of action exists for the alleged violations.[16] In sum, plaintiffs' remaining claims are foreclosed by plaintiffs' failure to exhaust administrative remedies, or they fail simply as a matter of law.

CONCLUSION

For all of the foregoing reasons, the Court GRANTS the defendants' Motion to Dismiss [Dkt. #7] and DISMISSES the action without prejudice. An order consistent with this decision accompanies this Opinion.



RICHARD J. LEON
United States District Judge

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[15] *See* Count I, Compl. ¶¶ 5, 42 (freedom of speech claims foreclosed by settled law holding that use of speech to establish an element of a violation does not violate the First Amendment, *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)); Count I, Compl. ¶¶ 30, 35 (claims that FDA acted outside its jurisdiction by regulating devices within a particular state fail as a matter of law because FDA's Warning Letters pertained only to devices introduced into interstate commerce, *see* 21 U.S.C. § 331(a), (k) (granting authority to regulate devices in interstate commerce); Count I, Compl. ¶ 37 (claim that FDA regulations violate the Paperwork Reduction Act foreclosed by settled law, *see, e.g.*, *United States v. Neff*, 954 F.2d 698, 699-700 (11th Cir. 1992)); Count I, Compl. ¶¶ 26-27, 38 (Tenth Amendment claim fails as a matter of law because no state power at issue); Count III, Compl. ¶¶ 50-53 (Ninth Amendment claim fails because FDA still maintains rights – such as enforcement of the FDCA – expressly granted to the federal government, *see United States v. Sullivan*, 332 U.S. 689, 697-98 (1948)).

[16] *See* Count I, Compl. ¶ 8 (alleging that defendants are "bound by the Data Quality Act" even though the act, Pub. L. No. 106-554, § 1(a)(3), 114 Stat. 2763, 2763-153 (2000), "does not create a legal right to information or to correctness," *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006)).