UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' MOTION TO DISMISS

Defendants, the United States Department of Health and Human Services, Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, the United States Food and Drug Administration, and Margaret Hamburg, in her official capacity as Commissioner of Food and Drugs, respectfully move to dismiss this case pursuant to Rules 12(b)(1) and (6) of the Federal Rules of Civil Procedure based upon lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

The grounds for this motion are fully set forth in the accompanying Memorandum in Support of Defendants' Motion to Dismiss filed herewith.

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Respectfully submitted,

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Dated June 10, 2010

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INTRODUCTION

The United States Department of Health and Human Services ("HHS"), Kathleen Sebelius, in her official capacity as Secretary of HHS, the U.S. Food and Drug Administration ("FDA"), and Margaret Hamburg, in her official capacity as Commissioner of Food and Drugs, (collectively, "Defendants") submit this memorandum in support of their motion to dismiss plaintiffs' complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

Plaintiffs seek injunctive and declaratory relief related to ear candle products, which are hollow cones made from a fabric tube soaked in beeswax or paraffin. The ear candles are placed into the ear and set on fire with an open flame. Plaintiffs claim that these pyrotechnic devices, which are often marketed to children and infants, are useful for a variety of conditions, including ear aches, vision disorders (such as astigmatism), depression, attention deficit disorder, allergies, headaches, colds, and the flu. Not surprisingly, FDA has never determined that these devices are safe and effective for any indication, and has particular concerns about the use of these products for young children.

On February 17, 2010, FDA issued Warning Letters to fifteen different manufacturers and/or distributors of ear candle products, advising them that their ear candle products were medical devices based on the intended uses indicated in the labeling. The letters warned that the devices, as labeled, were marketed in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and referred the companies to FDA's website for information on how to obtain approval or clearance of the devices. The letters further stated that "FDA will evaluate the information you submit and decide whether your product may be legally marketed."

FDA noted that it was aware of adverse event reports for these devices and expressed its

concern that the devices are promoted for use in children and babies, who are at an increased risk of injury. FDA further advised the companies to take prompt action to correct the violations, and warned that failure to do so "may result in regulatory action." After FDA sent the letters, FDA met with two of the companies, including one of the plaintiffs. Several of the companies have voluntarily agreed to stop marketing the devices or to remove certain health-related claims in their promotional literature. To date, FDA has not brought an enforcement action against any of the entities that received the February 17 Warning Letters, or against any of the plaintiffs.

Plaintiffs allege that FDA has "effectively outlaw[ed]" ear candles, relying solely on the agency's issuance of Warning Letters for that charge. Compl. ¶ 3. But under settled law, an FDA advisory letter stating that FDA "may" initiate an enforcement action is not a final agency action. Plaintiffs have no standing to challenge FDA's issuance of such letters, which have caused them no injury. Similarly, plaintiffs' request for judicial intervention before FDA has made any final determination is unripe.

To the extent that plaintiffs' complaint can be characterized as a preenforcement challenge to any action that FDA may take in the future, long standing Supreme Court precedent establishes that FDA enforcement actions may not be enjoined. Moreover, plaintiffs' claims are insufficient as a matter of law because plaintiffs failed to exhaust their administrative remedies before bringing suit, and because FDA appropriately exercised its regulatory authority when it issued the Warning Letters. Finally, plaintiffs' assertions that FDA has violated various constitutional and religious rights lack any support in law. Plaintiffs' complaint should therefore be dismissed for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

BACKGROUND

I. Statutory and Regulatory Background

A. Classification of Medical Devices

In 1976, Congress extended the regulatory authority of the FDA to include premarket regulation of medical devices, thereby enabling the agency to "provide for the safety and effectiveness of medical device[s] intended for human use." *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. §§ 360c-360k); *see also Riegel v. Medtronic*, 552 U.S. 312, 322 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996); *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 593 (D.C. Cir. 1985); 21 U.S.C. § 371(a) (granting FDA authority to issue regulations to implement the FDCA).

Under the FDCA, as amended, all medical devices are categorized in three classes, based upon the degree of regulation that the agency determines is necessary to reasonably assure their safety and effectiveness. *See* 21 U.S.C. § 360c(a). In making that determination, the agency must consider, among other things, "the conditions of use prescribed, recommended, or suggested in the labeling of the device," and "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2).

Class I devices are subject to the least amount of regulation and are defined as those devices for which the "general controls" provided by the FDCA are sufficient to provide a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(A). The "general controls" include, *inter alia*, prohibitions on adulteration (21 U.S.C. § 351) and misbranding (which includes false or misleading labeling) (21 U.S.C. § 352), and requirements that device

manufacturers register with the FDA (21 U.S.C. § 360) and maintain such records as the agency may require to assure a device's safety and effectiveness (21 U.S.C. § 360i). 21 U.S.C. § 360c(a)(1)(A). Most general controls apply to all devices, regardless of the class in which they are placed, except for class I devices for which the FDA has determined that certain requirements need not apply. *See* 21 U.S.C. § 360c(d)(2)(A). Moreover, the general controls apply to all devices whether or not they have already been classified. *See* H.R. Rep. No. 94-853, at 17 (1976) (noting that the "general controls" include the pre-existing FDCA adulteration and misbranding provisions and that "certain of the general controls," such as registration of device manufacturers, became applicable to all devices "immediately upon enactment of the . . . [Medical Device Amendments of 1976]").

Class II covers those devices for which the general controls alone would be insufficient to reasonably assure the device's safety and effectiveness, but which may be marketed if "special controls," in addition to the general controls, would provide adequate assurance of the device's safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(B). Special controls include performance standards, postmarket surveillance, patient registries, guidelines, or other actions the agency determines are necessary to reasonably assure a device's safety and effectiveness. *Id.*

Class III encompasses those devices that potentially pose the greatest risk. A device is placed in class III if the general controls alone, or general controls along with special controls, are insufficient to provide reasonable assurance of the device's safety and effectiveness and the device is represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury. *See* 21 U.S.C. § 360c(a)(1)(C).

The FDCA requires FDA to classify all medical devices that were in interstate commerce prior to the 1976 amendments (*i.e.*, "pre-amendment devices"). *See* 21 U.S.C. § 360c(a), (b)(1). Post-amendment devices (*i.e.*, those that entered commerce only after the 1976 amendments) are automatically classified by statute in class III, without any rulemaking, unless and until the FDA issues an order finding that the device is "substantially equivalent" to a pre-amendment device of the same type that has not yet been classified or to a device previously classified in class I or II, or the agency reclassifies the device into class I or II. *See* 21 U.S.C. § 360c(f)(1)-(3); *see also* H.R. Conf. Rep. No. 94-1090 at 56 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 1103, 1108-09.

Because of the degree of safety risk, class III devices, unlike class I and II devices, must be approved by FDA (pursuant to a premarket approval application, or "PMA") before they may permissibly enter interstate commerce. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e. Pre-amendment devices that have been classified as class III devices can generally remain on the market without an approved PMA until FDA issues a final regulation requiring premarket approval. *See* 21 U.S.C. §§ 351(f)(2)(B) & 360e(b)(1)(A); *see also Medtronic, Inc.*, 518 U.S. at 477-78; 67 Fed. Reg. at 7,621.

By contrast, class I and II devices require only premarket *notification* to FDA (known as a section 510(k) notice), not premarket *approval*.[1] FDA reviews 510(k) submissions to determine whether such devices are "substantially equivalent" to a legally marketed device that is not subject to a PMA, but does not determine whether there is a reasonable assurance they are safe

[1] *See* Device Classification, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm. Most class I and a few class II devices are exempt from the premarket notification requirements, as described in Class I/II Exemptions, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm.

and effective as in a PMA.[2] If FDA determines that the device is substantially equivalent, FDA "clears" the device for commercial distribution. *Id.* Thus, in order to begin marketing a device, a manufacturer generally must submit either a premarket notification (section 510(k) notice) or a premarket approval application. FDA provides extensive information to prospective device manufacturers regarding how to obtain clearance or approval of devices.[3]

FDA has not issued any order for ear candles finding them to be "substantially equivalent" to a legally marketed device, or any regulation classifying the devices as class I or II. All ear candle devices first marketed after 1976 are therefore automatically placed into class III. *See* 21 U.S.C. § 360c(f)(1)-(3). If a manufacturer wants to establish that its device was marketed before 1976 and may therefore be marketed without FDA premarket review until FDA classifies the device (and, if it is in class III, issues a regulation calling for PMAs for the device), the manufacturer must be the same owner of the device that was sold before 1976, and the device must be marketed for the same intended uses.[4] No manufacturer of ear candle devices has provided sufficient evidence to FDA to establish that its device is such a pre-amendments device. Even if such devices were commercially marketed prior to 1976, they would nevertheless be subject to general controls under the FDCA, including the prohibitions against misbranding and

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[2] *See* Premarket Notification (510k), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

[3] *See* How to Market Your Device, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm.

[4] *See* Premarket Notification (510k), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

adulteration.

B. Warning Letters

When FDA becomes aware that a regulated entity is violating the FDCA, the agency may issue a "Warning Letter" to give the company an opportunity to take voluntary corrective action before any enforcement is undertaken. FDA describes Warning Letters as "the agency's principal means of achieving prompt voluntary compliance with the [FDCA]." FDA *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (Mar. 2010) *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176860.htm. Warning Letters are "informal and advisory." *Id.* As such, a Warning Letter "communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued." *Id.* And, as discussed the case law establishes that Warning Letters are not final agency action. *See infra* at 17-18.

II. Factual Background

A. Background on Ear Candles and Previous Enforcement Activities

None of the plaintiffs has sought FDA approval or premarket clearance for an ear candle device, or sought to provide FDA in the first instance with evidence supporting the safety or effectiveness of these devices for *any* medical claims or benefits. Nor is FDA aware of any such evidence.[5] To the contrary, FDA has received six adverse event reports for ear candles since

[5] *See* Advice for Patients: Ear Candles, *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm (citing Seely DR, Quigley SM, Langman AW. Ear Candles-Efficacy and Safety. *Laryngoscope*. October 1996; 106: 1226-9).

1992. *See* Adverse Event Reports (attached hereto as Exhibit A).[6] Five of these reports describe injuries to people who have used these devices, such as burns, ruptured tympanic membranes, and hearing loss. *Id.* One injury required surgery. *Id.* In addition, a survey of ear, nose and throat physicians published in 1996 reported 13 cases of burnt ears, seven cases of wax occlusion in the ear canal, and one case of a perforated eardrum.[7] Because these injuries are attributed to ear candles and because use of these products involves an open flame near the face and hair of adults, young children, and infants, FDA has warned consumers not to use ear candles. *Id.*[8]

FDA has taken enforcement actions against ear candle manufacturers in the past, including seizures of the devices in 1993 from two companies, Awareness and Health Unlimited[9] and Quality Health Products/Marilyn Jarzembski. Ms. Jarzembski was ultimately enjoined from further manufacture and distribution of these devices in 1997. *See United States v. Jarzebski*, No. 97-7573 (N.D. Ohio) (consent decree of permanent injunction entered Dec. 30, 1997). FDA has also issued import alerts for these devices,[10] as well as Warning Letters to companies other

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[6] These reports may also be obtained on FDA's website. *See* MAUDE – Manufacturer and User Facility Device Experience, *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm (simple searches for "ear candle" and "earwax candle") (last visited June 9, 2010).

[7] *See* Advice for Patients: Ear Candles, *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

[8] In addition, Health Canada has determined that ear candles produce no measurable effect in the ear and have no therapeutic value. *Id.*

[9] The seizure against Awareness and Health Unlimited involved only a small amount of inventory and did not result in an injunction against the company.

[10] *See, e.g.,* Import Alert 77-01, Detention Without Physical Examination of Ear Candles (published Oct. 2, 2009), *available at* http://www.accessdata.fda.gov/cms_ia/importalert_225.html.

than the plaintiffs, in 1998 and earlier.[11] In those proceedings, FDA has asserted, *inter alia*, that the products are devices that were marketed in violation of the FDCA because they are dangerous to health when used in accordance with the labeling (21 U.S.C. § 352(j)), that they fail to contain adequate directions for use (21 U.S.C. § 352(f)(1)), and that they were adulterated because the companies had failed to submit premarket approval applications for their devices before marketing them (21 U.S.C. § 352(o)).

B. FDA's February 17, 2010 Warning Letters

Out of increasing concern that these products are being marketed for use on young children, FDA issued 15 Warning Letters to various manufacturers and distributors of ear candles on February 17, 2010, including four letters to five of the plaintiffs in this case: Harmony Cone, King Cone Intl, Betty Lee, Home Remedy Solutions,[12] and Wholistic Health Solutions. These four letters are attached hereto as Exhibit B.[13]

In each of these Warning Letters, FDA stated that the products were "devices" under 21 U.S.C. § 321(h) because they are "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or [are] intended to affect the

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[11] Three of the 1998 Warning Letters may be accessed from FDA's website. *See* 1998 Warning Letters, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/1998/default.htm (Jan. 20, 1998 letter to Earth Care; Apr. 24, 1998 letter to Coyote Found Candles; and Nov. 18, 1998 letter to Nature's Way).

[12] FDA sent one Warning Letter to plaintiff Betty Lee as the owner of Home Remedy Solutions, both of whom are plaintiffs in this case.

[13] All fifteen letters are publicly available on FDA's website. *See* FDA's Electronic Reading Room – Warning Letters, *available at* http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?qryStr=ear+candle (simple search for "ear candle").

structure or function of the body."[14] For each particular company's ear candle product, FDA described certain claims that caused the ear candles to be considered "devices."[15] FDA determined that the devices violated the FDCA in that they are:

- adulterated under 21 U.S.C. § 351(f)(1)(B) because the companies did not have an approved PMA or application for an investigational device exemption; and
- misbranded under 21 U.S.C. § 352(o) because the companies did not notify the agency of their intent to distribute the devices.

FDA referred the companies to the agency's website for information on how to obtain approval or clearance of the devices and stated that "FDA will evaluate the information you submit and decide whether your product may be legally marketed."

In three of the fifteen letters, FDA described additional violations, including that the devices are:

- misbranded under 21 U.S.C. § 352(o) because the companies were not registered as required under 21 U.S.C. § 360, and the devices were not included in a list required by 21 U.S.C. § 360(j);

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[14] An article is a "device" and subject to regulation under the FDCA if it is "intended to affect the structure of any function of the body," or "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." *See* 21 U.S.C. § 321(h). The agency can establish intended use on the basis of objective evidence, such as claims in a product's labeling. *See* 21 C.F.R. § 801.4 (intended use regulation for devices); *see also Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) ("[I]t is well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.") (internal citations and quotation marks omitted).

[15] For example, FDA determined from their labeling that Harmony Cone candles "are intended to mitigate or treat allergies, headaches, colds, flu, sinus congestion, sore throat, ear infections, swollen glands, sinus infections, balance and equilibrium, migraines and vertigo." *See* Ex. B.

- misbranded under 21 U.S.C. § 352(a) because the labeling represents the devices as safe and effective for their intended uses;
- misbranded under 21 U.S.C. § 352(f)(1) because the labeling fails to bear adequate directions for use; and
- misbranded under 21 U.S.C. § 352(j) because the devices are dangerous to health when used in accordance with the labeling.[16]

At the end of each letter, FDA advised the companies as follows:

> You should take prompt action to correct these deviations. FDA requests that [the company] immediately cease marketing, promoting and distributing [the company's] ear candles. . . . Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. * * * Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter.

More than fifteen business days have passed since FDA issued the letters. Two of the companies, including one of the plaintiffs in this case, Harmony Cone, wrote responses to the Warning Letters and met with FDA officials. None of the companies has presented FDA with any proposed "Disclaimers and Disclosures" for labeling its product. Several of the companies have voluntarily agreed to stop marketing the devices or to remove health claims in their promotional literature. FDA is now in the process of considering whether to take enforcement action against those companies that do not comply with its request to cease marketing and distributing the products at issue.

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[16] Some of the companies were cited for additional violations, such as failure to comply with requirements for Medical Device Reporting, 21 U.S.C. § 352(t)(2), and adulteration under 21 U.S.C. § 351(h) for failure to comply with the Current Good Manufacturing Practice regulations found at 21 C.F.R. Part 820.

C. Current Litigation

On April 9, 2010, less than two months after the Warning Letters issued, plaintiffs brought this suit challenging FDA's statement in the Warning Letters that ear candles are medical devices. Compl. ¶ 6. Plaintiffs assert that the Warning letters constitute final agency action and are thus subject to review under the Administrative Procedure Act. *Id.* ¶ 10. Plaintiffs request various forms of relief, including (1) an order "staying" FDA's determination that ear candles are unapproved medical devices, *id.* ¶ 42; (2) a declaration that FDA's determination is void, *id.*; (3) "an order that the judicial determination voiding the FDA action is contingent upon clear Disclaimers and Disclosures mandating informed consent and voluntary use of Holistic Candles solely as a traditional use holistic relaxation and comfort modality, and not as a 'treatment of disease' or other Medical Device use, so that the citizens' First and Fourteenth Amendment and other rights shall be preserved," *id.*; (4) "a Declaratory Judgment that does not limit the rights of Plaintiffs to manufacture, distribute, use or consume Holistic Candles in private associational or religious grounds," *id.* ¶ 48; and (5) "a Declaratory Judgment that the FDA determination that Holistic Candles are unapproved Medical Devices violates their Ninth Amendment rights," *id.* ¶ 53.

ARGUMENT

I. Plaintiffs' Complaint Should Be Dismissed for Lack of Jurisdiction

Federal judicial power is limited by Article III of the Constitution to the resolution of "cases" and "controversies." *See, e.g., Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982). To invoke federal court jurisdiction, a party must establish the existence of a "justiciable controversy" with the adverse

party – one that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). Under Rule 12(b)(1), the party seeking to invoke the jurisdiction of a federal court bears the burden of establishing that the court has jurisdiction. *U.S. Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000). In order to demonstrate that a plaintiff has standing to invoke jurisdiction, "a litigant must have suffered, or be 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) (citations omitted); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

A plaintiff's claim also must be ripe. "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). The ripeness doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 732-33 (1998).

Although plaintiffs seeks declaratory relief, such relief is only permitted if jurisdiction otherwise exists. 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction . . . any court . . . may declare the rights. . . ."); *Public Service Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 242 (1952) (Declaratory Judgment Act "applies . . . only to 'cases and controversies in the constitutional sense.'") (quoting *Aetna Life Ins. Co.*, 300 U.S. at 240); *Skelly Oil Co. v.*

Phillips Petroleum Co., 339 U.S. 667, 671-72 (1950) (the Declaratory Judgment Act provides a discretionary, procedural remedy that courts may award, but it does not confer or expand a court's jurisdiction).

Each of plaintiffs' claims for relief in this case is premised on the misguided notion that FDA's Warning Letters effectively outlaw ear candles, and thus constitute final agency action that plaintiffs have standing to challenge. But under settled law, FDA's Warning Letters are not final agency action, and plaintiffs have suffered no injury sufficient to confer standing. Similarly, plaintiffs' claims are unripe because they seek premature adjudication of a non-final agency action before its effects have been felt in a concrete way. Finally, plaintiffs' request for a declaration that "does not limit" their "rights" to market ear candles (Compl. ¶ 48) amounts to a preenforcement challenge to any action that FDA may take in the future, and is foreclosed by long-standing Supreme Court and appellate precedent.

A. Plaintiffs Lack Standing

"Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. To invoke the jurisdiction of a federal court, a litigant must have suffered, or be 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) (citations omitted); *see also Summers v. Earth Island Inst.*, __ U.S. __, __, 129 S. Ct. 1142, 1148 (2009); *Defenders of Wildlife*, 504 U.S. at 560; *Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1134 (D.C. Cir. 2005); *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Defenders of Wildlife*, 504 U.S. at 561.

The "actual injury" must be "concrete in both a qualitative and temporal sense." *Whitmore. v. Arkansas*, 495 U.S. 149, 155 (1990). The injury must be "distinct and palpable" and "actual or imminent," not "conjectural" or "hypothetical." *Id.* (citations omitted); *see also Defenders of Wildlife*, 504 U.S. at 560. To establish injury in fact, a "plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be affected by the agency's action." *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 688-89 (1973); *see also Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc) (plaintiff must show that a particularized injury is at least imminent). The requirement of injury in fact is not satisfied "simply because a chain of events can be hypothesized in which the action challenged eventually leads to actual injury." *Northwest Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986).

Here, none of the plaintiffs has alleged an injury sufficiently imminent and concrete to establish Article III standing. Plaintiffs state that they are "nongovernmental organizations and private associations that advocate natural alternatives to government-licensed health care (herein, the NGOs), various natural product manufacturers, distributors, practitioners and consumers who are all members of the NGOs." Compl. ¶ 2. Plaintiffs assert that they "stand in imminent peril of risk of health or life, loss of liberty, property, livelihood or licensure, or other public [sic]. Thus, they have been harmed by the acts of the Defendants." *Id.* ¶ 14. However, the only specific act by defendants that plaintiffs identify is FDA's issuance of Warning Letters on February 17, 2010. *See id.* ¶ ¶ 3, 9. Plaintiffs' contention that they face "imminent peril" because five of the fourteen plaintiffs have received Warning Letters falls far short of

establishing a "real and immediate" threat that FDA will institute an enforcement action against them. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974); *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (requiring a plaintiff to show that "the injury is certainly impending") (citation and quotation marks omitted).

Indeed, this was the conclusion of the court in *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1 (D.D.C. 1989), in which the court refused to hold that the issuance of an FDA regulatory letter (similar to a Warning Letter) imposed a "hardship" on the plaintiff sufficient to warrant judicial review. The court dismissed the case on ripeness grounds: "Because Lauder is seeking a pre-enforcement review of a projected agency position, the claimed hardship is no greater than any company confronted by an interpretation of a law it dislikes." 727 F. Supp. at 5; *see also Regenerative Sciences, Inc. v. FDA*, No. 09-411, 2010 WL 1258010, at *8 (D. Colo. Mar. 26, 2010) (rejecting claim of hardship based on Warning Letter, stating that "[t]he fact remains that [the 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. Therefore, the Court concludes that [the plaintiff's] risk of future FDA enforcement actions is too speculative to warrant judicial intervention . . . .").

So too here. Plaintiffs who manufacture ear candles cannot establish a threatened future injury sufficient to confer Article III standing because any future action by FDA is too speculative. Plaintiffs who only use or advocate the use of ear candles have even more speculative claims.[17] Even if FDA were to take enforcement action at some point in the future

[17] Plaintiffs do not even attempt to establish standing on behalf of the organizational plaintiffs, none of whom have suffered any cognizable injury in their own right from FDA's issuance of the Warning Letters. If an organization cannot demonstrate injury to itself, it may nevertheless be able to establish associational standing by showing that the organization's

against one or more ear candle manufacturers, it would not confer standing on the other plaintiffs in this case, any of whom could still obtain ear candles from the large number of remaining manufacturers of these products, and thus would suffer no cognizable injury in any event.[18]

As FDA has made clear, Warning Letters are "informal and advisory," and are intended to give recipients the opportunity to take voluntary corrective action. *See* FDA *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (Mar. 2010) *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176860.htm. Such letters "communicate[] the agency's position on a matter," but do not "commit FDA to taking enforcement action." *Id.* For this reason, courts have repeatedly and consistently held that such letters are not 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 where it

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members would have standing to sue, that the interests it seeks to protect are germane to the organization's purpose, and that participation of individual members in the lawsuit is not necessary. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 181, 120 S. Ct. 693, 704 (2000); *see also Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343, 97 S. Ct. 2434, 2441 (1977); *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1435 (D.C. Cir. 1995); *Wash. Legal Found. v. Leavitt*, 477 F. Supp. 2d 202, 207-08 (D.D.C. 2007). Plaintiffs' complaint, however, is devoid of facts demonstrating that any member of these organizations has suffered an injury, nor does it establish any of the other requisite elements of associational standing. Plaintiffs also include "John and Jane Doe," who are asserted to represent "all other consumers who wish to continue to use Holistic Candles." Compl. ¶ 15(f). The inclusion of such unnamed plaintiffs, however, runs afoul of Fed. R. of Civ. P. 10(a), which requires the complaint to "name all the parties." Similarly, LCvR 5.1(e)(1) requires that the "first filing by or on behalf of a party shall have in the caption the name and full residence address of the party. *See also* LCvR 11.1; *Qualls v. Rumsfeld*, 228 F.R.D. 8, 10 (D.D.C. 2005) ("Requiring parties to disclose their identities furthers the public's interest in knowing the facts surrounding judicial proceedings."). Regardless, even if pseudonymous litigation were allowed, any such unidentified consumers have not been injured by FDA's Warning Letters and thus lack standing to challenge their issuance in this action.

[18] FDA estimates that there are approximately 60 companies in the United States that manufacture ear candles.

served to "initiate further proceedings" and "was not the consummation of the agency's decisionmaking process"); *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (holding that FDA regulatory letters do not constitute final agency action); *Am. Fed'n of Gov't Employees v. O'Connor*, 747 F.2d 748, 752-53 (D.C. Cir. 1984) (dismissing claims challenging agency letter because it "binds neither the public nor any agency or officer of government. No precedent known to us sanctions court review of such nonbinding advisory expositions."); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (no jurisdiction to review action challenging FDA Warning Letters because "such letters do not commit the FDA to enforcement action").[19]

The Warning Letters in this case are no different. The ear candle manufacturers to whom FDA wrote were referred to FDA's website for information on how to obtain approval or clearance of their devices and were informed that "FDA will evaluate the information you submit and decide whether your product may be legally marketed." *See* Ex. B. Thus, the Warning Letters do not commit FDA to enforcement action, nor do they purport to express the agency's final word on whether these devices may ever be marketed legally. Contrary to plaintiffs' claims, Compl. ¶ 3, FDA has not "effectively outlaw[ed]" ear candle devices. *See* 21 U.S.C. § 360f

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[19] *See also Regenerative Sciences,* 2010 WL 1258010*; Perez v. Nidek Co.*, 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009) (FDA Warning Letters "do not constitute a final decision by the FDA") (citing *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996)); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 946 (E.D. Wis. 2008) (FDA letters expressing opinion of officials who wrote letter that defendants' products were misbranded were not final agency actions); *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992) ("Such letters do not bind the agency to the views expressed in them."), *aff'd in part, rev'd in part on other grounds*, 21 F.3d 1026 (10th Cir. 1994); *Estee Lauder,* 727 F. Supp. 1 (dismissing action challenging FDA regulatory letters as unripe because letters stating that certain cosmetics were drugs based on manufacturers' claims were not final agency actions) (citing *Public Citizen Health Research v. FDA,* 740 F.2d 21 (D.C. Cir. 1984)).

(requiring Secretary to initiate a proceeding to promulgate a regulation to ban a device after finding that it "presents substantial deception or an unreasonable and substantial risk of illness or injury," and that such risk cannot be corrected or eliminated by a change in labeling); *see also* 21 C.F.R. Part 895. Rather, the agency has stated only that it "may" take enforcement action against the recipients if they do not promptly correct their violations.[20] In these circumstances, plaintiffs have not been injured by FDA's Warning Letters, nor have they raised any cognizable claim of future injury sufficient to invoke this Court's jurisdiction. Because plaintiffs thus lack standing to maintain this action, their complaint should be dismissed.

B. Plaintiffs' Claims Are Not Ripe

Plaintiffs' claims are also not ripe for this Court's review. As the Supreme Court explained in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967), "injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution." The purpose of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 148-49.

To determine whether an agency decision is ripe for review, courts examine "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court

[20] FDA requested a response to the February 17 letters within 15 working days of their receipt. *See* Ex. B. Although more than 15 days have since elapsed, FDA has yet to bring an enforcement action against any of the letters' recipients.

consideration." *Id.* at 149. The fitness prong, in turn, depends upon (a) whether the claims raise purely legal questions, and (b) whether the challenge involves final agency action. *Id.* In evaluating the fitness of an issue for judicial review, courts consider whether the issue is "purely legal" and the agency action is final, or, on the other hand, whether "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998); *see Fla. Power & Light v. EPA*, 145 F.3d 1414, 1421 (D.C. Cir. 1998) ("Under the fitness prong, we inquire into whether the disputed claims raise purely legal, as opposed to factual, questions and 'whether the court or the agency would benefit from postponing review until the policy in question has sufficiently crystallized.'") (quoting *Cronin v. FAA*, 73 F.3d 1126, 1131 (D.C. Cir. 1996)). A court must stay its hand when "judicial intervention would inappropriately interfere with further administrative action." *Ohio Forestry Ass'n*, 523 U.S. at 733. Indeed, "[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*, 523 U.S. at 300 (internal quotation marks omitted).

Plaintiffs' complaint fails to satisfy any of the ripeness criteria. As explained above, FDA Warning Letters are "informal and advisory," and do not constitute final agency action. *See supra* at 17-18 (citing cases). The letters do not commit FDA to enforcement action, but state only that the agency "may" take enforcement action in the future if certain conditions are not met. *See Nevada v. DOE*, 457 F.3d 78, 84 (D.C. Cir. 2006) (finding plaintiff's claims unripe because the agency's statement of its plan was not a final determination, and was "replete with conditional phrases"); *Estee Lauder*, 727 F. Supp. at 5 ("This language [in FDA's regulatory letter] is equivocal – there is no definite plan of attack on the part of the Administration.").

Moreover, plaintiffs' own allegations establish that their claims are not purely legal, and that further factual development is necessary before judicial intervention might be appropriate. For example, plaintiffs seek an order voiding FDA's action "contingent upon clear Disclaimers and Disclosures mandating informed consent and voluntary use of Holistic Candles solely as a traditional use holistic relaxation and comfort modality." Compl. ¶ 42. But plaintiffs do not spell out the text of any such proposed "Disclaimer" or "Disclosure," nor have they sought approval or clearance for their products with any proposed labeling, let alone labeling with "Disclaimers and Disclosures" relating to "traditional use holistic relaxation and comfort modality." The judicial relief plaintiffs seek would thus displace the agency's primary jurisdiction to determine in the first instance whether plaintiffs' devices may be legally marketed and any appropriate labeling and disclaimers that could accompany these devices. Because FDA has never had an opportunity to address any such proposed "Disclaimers and Disclosures," its position has not "crystallized," and plaintiffs' claims are thus manifestly premature. *See Florida Power & Light,* 145 F.3d at 1421.

Nor have plaintiffs demonstrated that withholding judicial review now will cause them hardship – the second element of the ripeness test. "In order to outweigh institutional interests in the deferral of review, the hardship to those affected by the agency's action must be immediate and significant." *Devia v. NRC,* 492 F.3d 421, 427-28 (D.C. Cir. 2007) (citation omitted). Here, however, FDA has merely warned plaintiffs that failure to take corrective action "may" result in regulatory action. *Cf. Estee Lauder*, 727 F. Supp. at 5 (regulatory letter warning that FDA was "prepared" to take regulatory action imposed hardship "no greater than any company confronted by an interpretation of a law it dislikes"). Plaintiffs have not been harmed by the Warning

Letters themselves, and will not suffer any hardship if judicial review is postponed until such time as FDA takes concrete action against them or their products. To be sure, those plaintiffs who received Warning Letters court the risk of enforcement if they fail to heed FDA's written warnings, but plaintiffs cannot *now* challenge any enforcement action that FDA *may* take in the *future*. It takes little imagination to foresee the effect on court dockets if every person who feared an enforcement action could gain access to the courts to preempt it:

> The FDA . . . has a strong institutional interest in having this Court withhold its review. The administration issues approximately 450 regulatory letters and numerous opinion letters each year. If FDA were subject to suit each time it warned a company that its product violated the Act, the Administration would be inhibited from performing a valuable public service – the issuing of informal advisory opinions.

Id. at 5.

Only if and when FDA brings a specific enforcement action will review be appropriate, because only in the context of a specific action will FDA have gathered the necessary evidence, analyzed the relevant facts, and made the requisite administrative determinations to permit meaningful judicial review. In the absence of an actual enforcement action, plaintiffs' claims of any hardship "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300. For these reasons, plaintiffs' claims are not ripe for this Court's review.

C. FDA Enforcement Action May Not Be Enjoined

In addition to its other jurisdictional deficiencies, plaintiffs' attempt to preemptively bar future FDA enforcement action runs afoul of well-established Supreme Court and appellate precedent. Plaintiffs seek a stay of FDA's determination that ear candles are medical devices, and a declaratory judgment "that does not limit the rights of Plaintiffs" to manufacture ear

candles. Compl. ¶¶ 42, 48. This relief, if granted, would preempt any enforcement action that FDA may take in the future. Such preenforcement challenges are foreclosed by the Supreme Court's holding in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), wherein the plaintiff sought judicial review of FDA's determination that there was probable cause to believe that the plaintiff's products violated the FDCA – a necessary prerequisite to the government initiating a seizure of the products under the FDCA. The Supreme Court ruled that the district courted lacked jurisdiction to review FDA's pre-seizure probable cause determination 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]" envisioned by Congress in enacting the statute. *Id.* at 600-01 (observing that the plaintiff would have ample opportunity to litigate any constitutional, statutory, or factual claims in the enforcement action itself).

The Supreme Court reaffirmed the *Ewing* principle in *Abbott Laboratories v. Gardner*, calling it "clearly correct." *Abbott*, 387 U.S. at 147. As the Court observed, the "manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference 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]." *Id.* at 148. The rule articulated in *Ewing* has been "consistently and strictly observed" by the lower courts, which have held that the decision "precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v. Alcon Labs.*, 636 F.2d 876, 881-82 (1st Cir. 1981).[21]

[21] *See also Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 764 n.10 (5th Cir. 1980) (explaining that *Ewing* "expresses a total and complete proscription of the district court's power both to undertake a pre-enforcement review . . . and to enjoin federal officials from . . . seizing products or initiating enforcement proceedings under the [FDCA]"); *Parke, Davis & Co. v.*

If and when FDA decides that future enforcement action is warranted, it has the discretion to initiate a seizure or injunction for FDCA violations, or to seek civil money penalties. *See* 21 U.S.C. §§ 332-34. Because ear candle products are sold with unique labeling, each such action would present its own set of facts, and would be litigated accordingly. If and when FDA takes legal action against their products, plaintiffs would have a full opportunity to raise and litigate the claims that they advance in the present action. Then, and only then, may such claims properly be heard. But plaintiffs seek to preclude FDA from bringing any enforcement action against them or their products in the future, and this claim for relief is plainly foreclosed by *Ewing* and its progeny.

II. Plaintiffs' Complaint Fails to State a Claim Upon Which Relief Can be Granted

Even if plaintiffs could establish jurisdiction to pursue this action, their claims would still fail. To state a claim upon which relief may be granted under Rule 12(b)(6), the plaintiff must allege "any set of facts consistent with the allegations," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007), that "possess enough heft to 'sho[w] that the pleader is entitled to relief,'" *id.* at 557 (citations omitted); *see also Aktieselskabet AF 21. November 2001 v. Fame Jeans, Inc.*, 525 F.3d 8, 17 n. 4 (D.C. Cir. 2008). Under Rule 12(b)(6), the court must treat the complaint's factual allegations as true and draw all reasonable inferences therefrom in the plaintiff's favor. *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003). But the court need not accept as true legal conclusions cast as factual allegations or inferences unsupported by facts set out in the complaint. *Warren v. Dist. of Columbia*, 353 F.3d 36, 40

Califano, 564 F.2d 1200, 1205-06 (6th Cir. 1977) (reversing, on *Ewing* grounds, a district court's injunction against FDA); *Rockwell Int'l Corp. v. United States*, 723 F. Supp. 176, 178 (D.D.C. 1989) (stating that the proceedings were still in "flux" and were thus "inappropriate subjects for judicial intervention," following *Ewing*).

(D.C. Cir. 2004).

Even accepting the truth of plaintiffs' factual allegations in this case, their claims still fail as a matter of law. As an initial matter, plaintiffs failed to exhaust their administrative remedies prior to bringing suit, a failure that is particularly acute because they seek declaratory relief involving "Disclaimers and Disclosures" that have never been presented to, much less considered by, FDA in the first instance. In any event, FDA acted well within its statutory authority in issuing the Warning Letters plaintiffs seek to challenge, and their attempt to assert claims under the First, Ninth, Tenth, and Fourteenth Amendments, as well as the Religious Freedom Restoration Act, have no basis in law or fact. Because plaintiffs' allegations lack "enough heft" to show that they are entitled to relief, dismissal under Rule 12(b)(6) is appropriate. *Twombly*, 550 U.S. at 557.

A. Plaintiffs Have Failed To Exhaust Their Administrative Remedies

It is well established that exhaustion of administrative remedies is generally required before proceeding to federal court. *See Bowen v. New York*, 476 U.S. 467, 484 (1986); *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 160 (D.C. Cir. 2007). In addition, the APA authorizes judicial review only with respect to "final agency action," 5 U.S.C. § 704, and 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) (quotation marks omitted). Nevertheless, plaintiffs have made no attempt to avail themselves of, much less exhaust, the administrative remedies available to them.

Plaintiffs have failed to propose any "Disclosures or Disclaimers" for any ear candle device before the agency, or to seek approval or clearance of any of their devices. Nevertheless,

plaintiffs seek to end run FDA's formal process for clearing or approving devices by asking this Court to approve and even mandate their vague labeling proposal – before FDA has had the opportunity to consider the matter.

Plaintiffs could also have filed a citizen petition with FDA pursuant to 21 C.F.R. §§ 10.25 and 10.30. FDA regulations require that "before any legal action is filed in a court," a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action." *Id.* § 10.45(b). Through this process, plaintiffs could have properly raised before the agency the issues that they now seek to raise to this Court: whether their products are medical devices, whether they may be grandfathered, and the appropriate classification of the devices and resulting regulatory requirements (Class I, II, or III). *See, e.g.*, Compl. at ¶¶ 18, 19, 24.

One of the plaintiffs, Harmony Cone, responded to FDA's Warning Letter by a letter dated March 22, 2010, raising some (but not all) of the same issues as this lawsuit. That letter is attached as Exhibit C. FDA has responded by meeting with the company, but no resolution has been reached,[22] and no further response is required by FDA absent a formal citizen petition. By contrast, FDA's response to a citizen petition would constitute final agency action. *Id.* § 10.45(d).

In bypassing the available administrative process, plaintiffs have precluded meaningful and efficient judicial review. Requiring plaintiffs to propose labeling and raise potentially complex regulatory issues with the agency before seeking judicial recourse would allow FDA to

[22] Resolution has been difficult in part because Harmony Cone has been largely unresponsive to FDA's requests for information, including such basic information as the company's address.

consider and address plaintiffs' concerns and could potentially resolve the issues here at stake; at the very least, the administrative process might crystalize the issues in contention. *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972) ("The basic purpose of the exhaustion doctrine is to allow an administrative agency to perform functions within its special competence – to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies."). Because plaintiffs have failed to avail themselves of the administrative process, dismissal of their action is appropriate for this reason as well. *See Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 22 (D.D.C. 2008) (dismissing APA and constitutional claims under Rule 12(b)(6) where the plaintiffs neglected to file a citizen petition as "mandated" by FDA's regulations), *aff'd*, 2009 WL 5178484 (D.C. Cir. Nov. 27, 2009); *Estee Lauder*, 727 F. Supp. at 7 (concluding that Lauder had failed to exhaust its administrative remedies when it challenged an FDA regulatory letter, stating that "[t]he company will not be allowed to circumvent the administrative process in order to have its labeling dispute judicially resolved").

B. Plaintiffs' Claims Are Frivolous

Even if this Court were to reach plaintiffs' claims, they are plainly insubstantial as a matter of law and thus subject to dismissal under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

1. Count One

a. Device-Related Allegations

Plaintiffs assert that ear candles are not medical devices as defined by 21 U.S.C. § 321(h), but are instead a "natural holistic modality," and that they "are used for and intended to be used for relaxation, comfort, reduction of stress and for the natural furtherance of the well-being of the

user." Compl. ¶ 19. But FDA has not considered whether a product with any such claims would be a medical device, and plaintiffs' allegation fails to identify any specific language on the labeling of their products that would convey such claims. By contrast, in the Warning Letters, FDA evaluated the actual language contained in the labeling of the ear candles manufactured by plaintiffs and determined that the health-related claims therein rendered their products medical devices within the meaning of the Act. *See, e.g.*, Ex. B. Plaintiffs do not appear to challenge FDA's product-specific findings of disease claims in plaintiffs' labeling as described in the Warning Letters, *e.g.*, FDA's finding that Harmony Cone's ear candles "are intended to mitigate or treat allergies, headaches, colds, flu, sinus congestion, sore throat, ear infections, swollen glands, sinus infections, balance and equilibrium, migraines and vertigo." *See* Ex. B. Those *actual labeling* claims cause plaintiffs' ear candles to be considered medical devices under the law, notwithstanding plaintiffs' characterization of their products *in the complaint* as "natural" and "holistic."[23] Because plaintiffs' products are marketed and promoted for the treatment of disease, they are properly regulated as medical devices.

Plaintiffs further argue that, if their products are devices, they should be considered to be in class I, and not subject to premarket approval requirements. Compl. ¶ ¶ 24, 39. Under the FDCA, however, devices that were introduced into commerce after 1976 are automatically classified into class III, without any rulemaking, unless and until FDA issues an order finding that the device is "substantially equivalent" to a pre-amendment device of the same type that has

[23] *See* n.14, *supra*, (explaining that devices are defined by their intended use under 21 U.S.C. § 321(h)). Plaintiffs object to the FDCA's "vague and ambiguous" definition of "device," Compl. ¶ 36., but Congress is free to define such terms broadly in the interest of protecting public health. *See United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 792 (1969) (rejecting argument that articles were not drugs based on their intended use given the "broad, remedial purpose of the Act").

not yet been classified or to a device previously classified in class I or II, or the agency reclassifies the device into class I or II. *See* 21 U.S.C. § 360c(f)(1)-(3). FDA has not issued any such order or reclassified ear candles into class I or II; therefore, all ear candles first marketed after 1976 are considered to be in class III and subject to premarket approval requirements. *Id.* Moreover, despite plaintiffs' allegations that they have "in some cases" manufactured or distributed ear candles before 1974, Compl. ¶ 15(d), plaintiffs do not allege that any device marketed before 1976 is now marketed by the same manufacturer and that it is marketed for the same intended uses, as is required to be considered a preamendments device.[24] *See* Compl. Exhibit A. For all of these reasons, plaintiffs' device-related claims in Count One fail as a matter of law.

b. Freedom of Speech Claims

Plaintiffs seek an order voiding FDA's "action" – presumably the issuance of Warning Letters to certain of the plaintiffs and others – "so that the citizens' First and Fourteenth Amendment and other rights shall be preserved." Compl. ¶ 42. Their speech-related First Amendment claims rely on *Thompson v. W. States Med. Center*, 535 U.S. 357 (2002), in which the Supreme Court struck down a unique statutory provision, 21 U.S.C. § 353a, that allowed manufacturers to compound a drug (*i.e.*, mix two approved drug products together to make a new, unapproved drug) so long as they did not advertise or promote the compounded drug. *See* Compl. ¶ 5.

FDA's Warning Letters do not restrict commercial speech in any manner akin to the

[24] *See* Premarket Notification (510k), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

statute at issue in *Western States*. Rather, FDA determined that certain manufacturers and distributors of ear candles have made claims that cause those products to be medical devices under the law, a type of decision that easily withstands scrutiny under the First Amendment. *See Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) (upholding FDA's use of claims in a product's labeling as evidence of whether the product is a drug); *see also Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (holding that the use of speech to establish an element of a violation does not violate the First Amendment). FDA has asked these companies to voluntarily comply with requirements relating to FDA's traditional authority over misbranding and adulteration. *See* Warning Letters, attached as Ex. B. Thus, the Warning Letter recipients have been asked to remove violative products from the market – not to suppress truthful, promotional information about their products, as in *Western States*.

c. Fourteenth Amendment Claims

Although plaintiffs assert that relief is necessary to preserve their "Fourteenth Amendment" right, the 14th Amendment applies only to the actions of a state, not the federal government. *United Transp. Serv. Employees ex rel. Wash. v. Nat'l Mediation Bd.*, 179 F.2d 446, 453 (D.C. Cir. 1949) ("The guarantees of the Fourteenth Amendment . . . apply to state action only; the limitations of the Fifth Amendment, to action of the Federal Government."). Any asserted 14th Amendment claim for relief against the defendants must therefore fail.

d. Jurisdictional Allegations

Plaintiffs also assert that FDA has acted outside its jurisdiction, citing 21 U.S.C. § 331(g), which prohibits "[t]he manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." *Id.* Plaintiffs contend that FDA can only

regulate the manufacture of devices within a "Territory," and "the FDA cannot constitutionally or statutorily regulate the manufacture of devices within the jurisdiction of any particular State of the Union." Compl. ¶ 30; *see also* Compl. ¶ 35 (challenging registration requirements in 21 U.S.C. § 352(o) on the ground that "Congress was not vested with power to regulate production within any of the several States of the Union and that the assertion of regulatory powers by the FDA against Plainitffs was unconstitutional.").

But FDA has made no statement in the Warning Letters that implicates FDA's authority to regulate intrastate manufacturing. Rather, FDA has cited various Warning Letter recipients for adulteration and misbranding, which FDA has unquestioned authority to regulate as prohibited acts when violative products are introduced into interstate commerce, or made from components that have been received in interstate commerce. *See, e.g.*, 21 U.S.C. § 331(a) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."); 21 U.S.C. § 331(k) (prohibiting "[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded"). None of the recipients allege that their products are *not* introduced into interstate commerce, or not made from components received in interstate commerce, which is presumed under the FDCA in any event . *See* 21 U.S.C. § 379a.[25] Thus, plaintiffs' allegation that FDA

[25] Plaintiffs challenge FDA's exercise of its regulatory authority under 21 U.S.C. § 379a as unconstitutional "because the regulatory power belongs to the several States and to the people respectively as secured by the 10th Amendment." Compl. ¶ 26; *see also id.* ¶ 28 (asserting that FDA has acted outside its jurisdiction under 5 U.S.C. § 558). But Congress has full authority

lacks authority to regulate their products in intrastate commerce is baseless and Count One fails for this reason as well.

e. Miscellaneous Allegations

Plaintiffs fare no better with their contention that FDA is "bound by the Data Quality Act to produce and disseminate only truthful information to the people of the United States," and that it has "woefully failed in that duty." Compl. ¶ 8. Plaintiffs' allegations fail to state a claim because the Information Quality Act (also known as the Data Quality Act) at 44 U.S.C. § 3516 "does not create any legal right to information or its correctness." *See Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006).

Plaintiffs further assert that the reporting requirements in 21 U.S.C. § 360i, as set forth in the regulation at 21 C.F.R. Part 803, "have not been assigned and do not display OMB control numbers as required by 44 U.S.C. §§ 3501, et seq." Compl. ¶ 37. Plaintiffs thus appear to allege that the requirements to report adverse events in 21 U.S.C. § 360i and 21 C.F.R. Part 803 contravene certain requirements in the Paperwork Reduction Act at 44 U.S.C. §§ 3501 et seq. Such arguments have been soundly rejected by the courts, which have determined that "Congress did not enact the [Paperwork Reduction Act's] public protection provision [in 44 U.S.C. § 3512] to allow OMB to abrogate any duty imposed by Congress." *United States v. Neff*, 954 F.2d 698, 699-700 (11th Cir. 1992); *see also United States v. Patridge,* 507 F.3d 1092, 1094-95 (7th Cir. 2007).

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under the Constitution to regulate interstate commerce, and has done so countless times under the FDCA. *See, e.g., United States v. Sullivan*, 332 U.S. 689, 697-98 (1948) (tracing authority of Congress in FDCA provisions to the commerce clause, Art. I, § 8). Pursuant to the Supremacy Clause, Art. VI, cl. 2, Congress' exercise of these constitutional powers trumps any conflicting exercise of state authority.

Finally, plaintiffs purport to challenge the constitutionality of 21 U.S.C. § 360(k), alleging that it is "in contravention to the separation of powers mandated by the [10th Amendment]." Compl. ¶ 38. But FDA has not taken any action implicating this preemption provision in the FDCA, which is in any event constitutional under the Supremacy Clause and Congress' valid exercise of authority under the Commerce Clause. *See Riegel*, 552 U.S. at 330 (explaining scope of preemption under 21 U.S.C. § 360(k)). Accordingly, none of the various allegations in Count One of plaintiffs' complaint are sufficient to state a claim for relief and should be dismissed as a matter of law.

2. Count Two

Plaintiffs allege that they or "some of them" use ear candles as part of the ordinary activities of their religion, or as part of private expressive association activities, and that "[s]ome users of Plaintiff's products have such deep convictions that include a belief in and-use of natural alternative modalities such as [ear candles]." Compl. (Count Two) ¶¶ 44, 46. Plaintiffs contend that FDA's action imposes "arbitrary burdens" upon their religious or private associational beliefs in violation of the Free Exercise Clause, and that they have a right to use ear candles that is protected by the Religious Freedom Restoration Act ("RFRA"). *Id.* FDA's regulatory action to date – seeking manufacturers' voluntary compliance to remove violative products from the market – has not compelled any person or company to take any action, much less any action that would burden plaintiffs' alleged religious practices. But even if FDA were to take enforcement against the plaintiffs, such an action would not interfere with plaintiffs' religious use of ear candles. FDA has asserted its regulatory authority over ear candles only to the extent that they are determined to be medical devices based on the specific health-related claims made by the

companies marketing these devices. These companies remain free to make religious claims about the benefits of using ear candles, so long as those claims do not include claims that the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. *See* 21 U.S.C. § 321(h).

For all of these reasons, plaintiffs have no valid claim under either the Free Exercise Clause or the RFRA. In *Employment Div., Dep't of Human Resources v. Smith*, 494 U.S. 872 (1990), the Supreme Court held that enforcement of generally applicable laws is not subject to challenge under the Free Exercise clause, even if it incidentally burdens the practice of religion. *See* 494 U.S. at 886 n. 3 ("religion-neutral laws that have the effect of burdening a particular religious practice need not be justified by a compelling governmental interest"). In response to that decision, Congress enacted the RFRA, 42 U.S.C. § 2000bb, which prohibits the government from substantially burdening a person's exercise of religion, except when the government can demonstrate that it has a compelling government interest and is the least restrictive means of furthering that interest. *See Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006).

The RFRA, however, requires plaintiffs to show, *inter alia*, that FDA's action has substantially burdened their exercise of religion. *See Cockrell-El v. Dist. of Columbia*, 937 F. Supp. 18, 21 (D.D.C. 1996). Because FDA has not taken any final agency action with respect to plaintiffs' ear candles, or any action that removes ear candles from the market or otherwise interferes with plaintiffs' use of ear candles for religious purposes, plaintiffs' reliance on the RFRA is unavailing. Count Two of plaintiffs' complaint thus fails to state a valid claim for relief

under either the Free Exercise Clause of the First Amendment or the RFRA, and should be dismissed.

3. Count Three

Plaintiffs also assert that FDA's determination that ear candles are unapproved medical devices violates their Ninth Amendment rights.[26] *See* Compl. (Count Three) ¶¶ 50-53. But the Ninth Amendment does not withdraw rights expressly granted to the federal government. *See Ashwander v Tenn. Valley Auth.*, 297 U.S. 288, 330-31 (1936). FDA is empowered by Congress to regulate medical devices and has the authority to determine in the first instance whether a product is a medical device under 21 U.S.C. § 321(h); and, if so, whether that product is adulterated or misbranded. *See United States v. Sullivan*, 332 U.S. 689, 697-98 (1948) (tracing authority of Congress in FDCA provisions to the commerce clause, Art. I, § 8); *see also* 21 U.S.C. §§ 351, 352 (provisions for adulteration and misbranding). Plaintiffs' Ninth Amendment claim, like their other constitutional claims, thus fails as a matter of law. Accordingly, Count Three of the complaint should also be dismissed.

[26] The Ninth Amendment states: "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." Plaintiffs cite no authority for their novel assertion that the Amendment protects "private rights to communicate about, obtain, use and enjoy natural, alternative, choices that are inherent in man's natural tendency to seek and obtain a stable equilibrium between interdependent elements." Compl. ¶ 51.

CONCLUSION

For the foregoing reasons, plaintiffs' complaint should be dismissed for lack of subject matter jurisdiction or, in the alternative, failure to state a claim upon which relief can be granted.

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Dated June 10, 2010

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing Motion to Dismiss, Memorandum in Support of Defendants' Motion to Dismiss, and proposed Order to be served via the District Court's electronic filing (ECF) system upon:

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