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Defendants Merrick B. Garland, in his official capacity as U.S. Attorney General, and Anne M. Milgram, in her official capacity as Administrator, U.S. Drug Enforcement Administration (DEA), hereby move to dismiss Plaintiffs' Third Amended, Verified Complaint for Declaratory and Injunctive Relief Pursuant F.R.C.P. 15(a)(1) (Compl.), ECF No. 59, under Federal Rule of Civil Procedure 12(b)(1) or, in the alternative, Rule 12(b)(6).

MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

In the Controlled Substances Act (CSA), Congress gave the Attorney General authority to issue, deny, suspend, or revoke registrations for the importation, manufacture, and distribution of controlled substances. By regulation, the Attorney General delegated this authority to DEA. Pursuant to that authority, and in accordance with the Religious Freedom Restoration Act (RFRA), DEA considers requests for religious exemptions from the CSA. This suit challenges DEA's Final Determination that Plaintiffs were not entitled under RFRA, 42 U.S.C. §§ 2000bb *et seq.*, to a religious exemption from the CSA, and DEA's conclusions as to the framework for considering religious exemptions. By statute, jurisdiction over this dispute lies exclusively in the courts of appeals. 21 U.S.C. § 877. Section 877 vests the courts of appeals with exclusive jurisdiction over claims such as these relating to DEA's administration and application of the CSA. That provision bars district courts from exercising jurisdiction over challenges to final determinations under the CSA. Dismissal of the entire action is warranted for this reason alone.

Even if Plaintiffs could clear this jurisdictional bar, their constitutional and procedural claims must be dismissed under Rule 12(b)(6). Plaintiffs' Administrative

Procedure Act (APA) claim must be dismissed because DEA has statutory authority to consider an individual's request for a religious exemption to the CSA. And Plaintiffs' Free Exercise claim fails because the CSA is a neutral and generally applicable law, and the right of free exercise does not relieve an individual of the obligation to comply with such a law on the ground that the law proscribes what one's religion requires.

BACKGROUND

I. Statutory and Regulatory Background

By the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, Congress created a "comprehensive" federal scheme to regulate the handling of controlled substances. *Gonzales v. Raich*, 545 U.S. 1, 10, 12-13 (2005). Title II of that Act contains the statutory provisions known as the Controlled Substances Act, by which Congress established "a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Id.* at 12-13. Congress enacted the CSA based on a finding that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2); *Raich*, 545 U.S. at 12-13 (CSA enacted "to conquer drug abuse," "to control the legitimate and illegitimate traffic in controlled substances," and "to prevent the diversion of drugs from legitimate to illicit channels").

Subchapter I of the CSA vests in the Attorney General (and his delegees, 21 U.S.C. § 871(a)) regulatory and enforcement authority over controlled substances and their handling, including complete authority to determine who may manufacture, distribute, dispense, or possess any controlled substance and in what manner. *See, e.g.*,

21 U.S.C. §§ 811, 822-824, 831 & 841. The CSA also grants the Attorney General plenary authority to “promulgate rules and regulations ... relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.” *Id.* § 821; see also *id.* § 871(b) (“The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.”). The Attorney General has delegated this authority to DEA. *Id.* § 871(a); 28 C.F.R. § 0.100. DEA, in turn, has promulgated regulations related to controlled substances. See 21 C.F.R. §§ 1300-1316.

The CSA established five “schedules” of controlled substances, and placed “any material, compound, mixture, or preparation, which contains any quantity of ... Dimethyltryptamine [(DMT)]” in Schedule I. See *id.* § 812(a), (b)(1), (c) sched. I (c)(6). For placement in Schedule I, DEA must find that a substance: “has a high potential for abuse”; “has no currently accepted medical use in treatment in the United States”; and is one for which “[t]here is a lack of accepted safety for use ... under medical supervision.” *Id.* § 812(b)(1). Ayahuasca contains the Schedule I controlled substance DMT. See, e.g., *O Centro Espirita Beneficente Uniao Do Vegetal v. Ashcroft*, 282 F. Supp. 2d 1236, 1240 (D.N.M. 2002) (“‘Ayahuasca’ ... refers to a category of South American teas containing DMT and beta-carbolines.”), *aff’d*, 342 F.3d 1170 (10th Cir. 2003), *on reh’g en banc*, 389 F.3d 973 (10th Cir. 2004), *aff’d and remanded sub nom. Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006); Compl. ¶ 6 (“Ayahuasca contains small quantities of a Schedule I controlled substance, dimethyltryptamine (DMT).”).

By its terms, the CSA authorizes the Attorney General to create exemptions from the Act’s prohibitions related to handling controlled substances. See 21 U.S.C. § 822(d).

Pursuant to this authority, and corollary to the Attorney General's categorical authority to determine who may handle any controlled substance and in what manner, 21 C.F.R. § 1307.03 provides that "[a]ny person may apply for an exception to the application of any provision of [the DEA regulations]" by filing a written request with the DEA Administrator, who has delegated authority to grant such an exception.

In 1993, Congress passed the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb-1 *et seq.* RFRA provides that the Government "shall not substantially burden a person's exercise of religion" unless "it demonstrates that application of the burden to the person . . . is in furtherance of a compelling governmental interest; and . . . is the least restrictive means of furthering that compelling governmental interest." *Id.* § 2000bb-1(a)-(b). RFRA applies to "all Federal law, and the implementation of that law," *id.* § 2000bb-3(a), and authorizes persons whose religious exercise has been substantially burdened to "assert that violation as a claim . . . in a judicial proceeding," *id.* § 2000bb-1(c).

As of 2006, no process existed by which an individual who wished to use ayahuasca (or any controlled substance, other than peyote, see 21 CFR § 1307.31) for religious purposes could obtain permission to do so under the CSA. In *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006) (*O Centro*), however, the Supreme Court held that the Government must assess an individual's claims that provisions of the CSA burden religious exercise under RFRA. When the Government makes such RFRA assessments, RFRA's "compelling interest test is satisfied through application of the challenged law 'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened." 546 U.S. at 430-31.

Accordingly, following *O Centro*, DEA created a petition process for religious

exemption from the CSA pursuant to RFRA. The petition process is open to anyone who wishes to manufacture, distribute, import, export, use, or possess ayahuasca or another controlled substance for religious purposes. See *generally* Off. of Diversion Control, DEA, Guidance Regarding Petitions for Religious Exemption from the CSA Pursuant to the Religious Freedom Restoration Act (2009, updated Feb. 26, 2018) (“Guidance”), Compl. Ex. 11, ECF No. 59-11. That process remains in place today,¹ and directly responds to the Court’s concern in *O Centro* that the previous regulatory regime did not allow DEA to address “the harms posed by the particular use at issue.” *O Centro*, 546 U.S. at 432. This petition process now allows religious entities to raise religious objections that arise when the Government chooses to act. That process allows DEA, in accommodating religious beliefs, to at the same time ensure that the CSA’s compelling governmental interests are satisfied, including protecting against the risk of diversion of controlled substances.

II. Administrative Background

In August 2016, Plaintiff Christopher Young received a letter sent by DEA to Oklevueha Native American Church Somaveda of Soul Quest, Inc., at the business address of Plaintiff Soul Quest.² See Compl. ¶¶ 111-114, 139, 141; *id.* at Ex. 5 ¶ 22, ECF No. 59-5; *id.* at Ex. 2 at 4, ECF No. 59-2 (in August 2016, Soul Quest operated under the name Oklevueha Native American Church Somaveda of Soul Quest, Inc.); DEA Letter of August 1, 2016 (“DEA Letter”), ECF No. 13-3. The letter stated that it had “come to

¹ Diversion Control Division, DEA, Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised) (updated Nov. 20, 2020), <https://perma.cc/VE74-SQMH>.

² Plaintiffs refer to a letter from DEA dated August 22, 2016. See, e.g., Compl. ¶ 111. Plaintiffs presumably intend to refer to the August 1, 2016 letter from DEA attached to the First Amended Complaint. Compare Compl. ¶¶ 111-114, 139, 141 with ECF No. 13-3.

[DEA's] attention" that Soul Quest's predecessor entity was "involved in offering 'retreats' through [its] website, www.soulquest-retreat.com," at which ayahuasca, as well as Schedule I controlled substances ibogaine and mescaline, are provided to "clientele." DEA Letter at 1. Citing applicable statutory, regulatory, and caselaw authorities, the letter explained that, pursuant to RFRA, DEA considers religious-based petitions for exemption from the CSA. *Id.* DEA invited the recipient to submit an exemption petition for DEA to "consider ... based on the specific facts regarding [the recipient's] plans to distribute controlled substances," and attached a copy of the applicable Guidance. *Id.* at 1, 3-6.

By letter from counsel dated August 21, 2017, Soul Quest submitted to DEA a Request for Religious-Based Exemption to Controlled Substances Act ("Plaintiffs' Exemption Request"), "as it pertains to the ritual use by Soul Quest of ayahuasca for its sacramental activities." Compl. Ex. 10 at 1, ECF No. 59-10. As the basis for its eligibility for an exemption, Soul Quest cited RFRA and *O Centro*. *Id.* Plaintiffs' Exemption Request stated that "Soul Quest and its adherents hold a common set of beliefs regarding the cause, nature, and purpose of the universe ... Soul Quest and its adherents sanctify and uphold this core religious belief through its devotional and ritual observances." *Id.* The Request detailed the "common set of beliefs" held by "Soul Quest and its adherents," *id.* at 3-13, and stated that, as a "requirement for membership" in Soul Quest, an "individual must express a belief in the foundation principles of the Soul Quest Church," *id.* at 21. The Request also described protocols for "Safety and Security" and "Storage and Use" related to "Sacramental Use of Ayahuasca." *Id.* at 13-19.

On April 16, 2021, DEA responded to Plaintiffs' Exemption Request. Compl. Ex. 2, ECF No. 59-2 ("Final Determination"). The Final Determination stated that DEA had

“determined that the request must be denied” for two reasons based on DEA’s investigation of Soul Quest. *Id.* at 2. First, DEA’s investigation found that “Soul Quest has not satisfied its burden under RFRA of demonstrating that its use of ayahuasca is pursuant to a religious exercise and based on a sincerely held religious belief.” *Id.* at 4. DEA explained that “[i]n practice, Soul Quest ... promotes ayahuasca to the public for self-help and therapeutic reasons, rather than solely to fellow believers for ... religious ritual purposes,” *id.*, noting that language from Soul Quest’s website “supports a conclusion that Soul Quest understands and advertises the use and distribution of ayahuasca to the public as fundamentally medicinal,” *id.* at 3. Thus, DEA “conclude[d] that Soul Quest’s promotion of ayahuasca to the public in this manner does not constitute a sincere exercise of religion under RFRA.” *Id.* at 4. Second, “[b]ased upon a thorough review of the entire record,” DEA concluded that Soul Quest’s practices “cannot be accommodated in a manner that would allow DEA to preserve its compelling interests in public health and safety and in preventing illegal diversion of ayahuasca.” *Id.* at 8. DEA noted that “to the extent Soul Quest and its customers use ayahuasca for purposes other than sincere religious exercise, their own use constitutes unlawful diversion.” *Id.* Finally, DEA explained that “[t]his letter is a final determination under 21 U.S.C. § 877.” *Id.*

III. The Instant Litigation

The relevant litigation history is provided in ECF No. 57 at ¶¶ 1-12, and incorporated here by reference. On July 20, 2021, the Court granted Plaintiffs leave to amend their complaint for a third time. Minute Order, ECF No. 58. On July 22, 2021, Plaintiffs filed the Third Amended Complaint, ECF No. 59, asserting three claims against Defendants under: (1) RFRA, *id.* ¶¶ 118-30; (2) the APA, *id.* ¶ 131-42; and (3) the Free

Exercise Clause of the First Amendment to the U.S. Constitution, *id.* ¶¶ 143-53.

STANDARD OF REVIEW

A court “must have both statutory and constitutional jurisdiction before it may decide a case on the merits.” *See Friends of the Everglades v. EPA*, 699 F.3d 1280, 1288 (11th Cir. 2012). A Rule 12(b)(1) motion should be granted if the complaint fails to allege facts sufficient to establish subject matter jurisdiction or if evidence external to the complaint refutes the jurisdictional facts alleged. *See McElmurray v. Consol. Gov’t of Augusta-Richmond Cnty.*, 501 F.3d 1244, 1251 (11th Cir. 2007). Plaintiffs bear the burden of demonstrating jurisdiction by a preponderance of the evidence. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *McCormick v. Aderholt*, 293 F.3d 1254, 1257-58 (11th Cir. 2002). In addition, when considering a 12(b)(6) motion, courts are not required to accept inferences unsupported by the facts or legal conclusions that are cast as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

ARGUMENT

I. PURSUANT TO 21 U.S.C. § 877, THIS COURT LACKS JURISDICTION OVER PLAINTIFFS’ CLAIMS.

Federal courts “are courts of limited jurisdiction” that “possess only that power authorized by the Constitution and statute,” *Kokkonen*, 511 U.S. at 377, which “is not to be expanded by judicial decree,” *United States v. Salmona*, 810 F.3d 806, 810 (11th Cir. 2016) (quoting *Kokkonen*, 511 U.S. at 377). Congress has the power to “prescribe the procedures and conditions under which, and the courts in which, judicial review of administrative orders may be had.” *City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 335-36 (1958). For example, Congress may provide for exclusive review in a court of appeals of an administrative agency’s actions. *See id.*; *see also Mims v. Arrow Fin.*

Servs., LLC, 565 U.S. 368, 378-79 (2012). Although “[l]itigants generally may seek review of agency action in district court under any applicable jurisdictional grant,” that presumption is displaced when Congress has established a “special statutory review scheme.” *Jarkesy v. SEC*, 803 F.3d 9, 15 (D.C. Cir. 2015) (citing *Bowles v. Russell*, 551 U.S. 205, 212 (2007)). “It is well settled that if Congress ... specifically designates a forum for judicial review of administrative action, that forum is exclusive.” *Drummond Coal Co. v. Watt*, 735 F.2d 469, 475 (11th Cir. 1984); see also *Jarkesy*, 803 F.3d at 15.

Congress expressly granted jurisdiction over DEA’s administration and application of the CSA exclusively to the courts of appeals. See 21 U.S.C. § 877. Specifically, Congress, in empowering the Attorney General to enforce the CSA, provided that:

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision.

21 U.S.C. § 877. Courts have repeatedly affirmed that § 877 channels review over DEA’s administration and application of the CSA exclusively into the courts of appeals. See, e.g., *Sharma v. DEA*, 511 F. App’x 898, 903 (11th Cir. 2013); *John Doe, Inc. v. DEA*, 484 F.3d 561, 568 (D.C. Cir. 2007); *Oregon v. Ashcroft*, 368 F.3d 1118, 1120 & n.1 (9th Cir. 2004), *aff’d sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006); *Hemp Indus. Ass’n v. DEA*, No. 20-cv-2921-JEB, 2021 WL 1734920, at *1 (D.D.C. May 3, 2021). For example, the Eleventh Circuit has determined that § 877 vests exclusive jurisdiction in the courts of appeals over challenges—including constitutional ones—to DEA’s termination of a physician’s registration. See *Sharma*, 511 F. App’x at 903 (considering claims under “the

First, Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments”). The D.C. Circuit likewise has held that § 877 vests “exclusive jurisdiction in the courts of appeals over ‘all final determinations, findings, and conclusions’ of the DEA applying the CSA.” *John Doe*, 484 F.3d at 568 (considering APA and Due Process claims).

Where Congress has established a “special statutory review scheme”—as it did in § 877—courts assume that “Congress intended [for] that procedure to be the *exclusive means* of obtaining judicial review in those cases in which it applies.” *Jarkesy*, 803 F.3d at 15 (emphasis added). Plaintiffs may not evade the exclusive-review scheme Congress established in § 877 by bringing their claims in district court. See *Green v. Brantley*, 981 F.2d 514, 521 (11th Cir. 1993) (“Where Congress has provided in the courts of appeals an exclusive forum for the correction of procedural and substantive administrative errors, a plaintiff may not bypass that forum by suing for damages in district court.”). An exclusive jurisdiction provision extends to “all issues inhering in the controversy.” *City of Tacoma*, 357 U.S. at 335-36 (interpreting similarly worded exclusive-review statute and explaining that challenges to agency action covered by exclusive-review provision “must be made in the Court of Appeals or not at all”). In this Circuit, courts have considered whether the merits of a plaintiff’s claims are “intertwined” with a review of the merits of an agency’s actions covered by an exclusive-review provision. *Green*, 981 F.2d at 521; *Doe v. FAA*, 432 F.3d 1259, 1263 (11th Cir. 2005) (holding that constitutional claims “[f]e]ll within the ambit” of an exclusive-review provision because such claims “necessarily require a review of the procedures and actions taken by the FAA with regard to the mechanics’ certificates”). This is why “as a matter of practice almost all cases” challenging DEA’s interpretation of the CSA are “filed directly in the court of appeals.” *John Doe*, 484 F.3d

at 568.

As explained below, Plaintiffs' claims are wholly intertwined with DEA's Final Determination. Because all of Plaintiffs' claims fall comfortably within the scope of § 877, review "resides exclusively in the court of appeals," *George Kabeller, Inc. v. Busey*, 999 F.2d 1417, 1421-22 (11th Cir. 1993), and Plaintiffs' claims should be dismissed for lack of jurisdiction.

A. Under § 877, jurisdiction over Plaintiffs' claims lies exclusively in the court of appeals.

Plaintiffs' complaint makes clear that they challenge DEA's Final Determination. See Compl. ¶¶ 10-16, 19, 35-36, 43, 122-129, 136-141, 147; see also 21 U.S.C. § 877; Final Determination, ECF No. 59-2 at 9 (informing Soul Quest that decision to deny petition seeking permission to use ayahuasca for religious purposes constituted final determination under § 877). And as the D.C. Circuit has previously ruled, such a "denial ... falls squarely within" § 877. *John Doe*, 484 F.3d at 568.

Plaintiffs challenge both the process that led to the Final Determination and the Final Determination itself. Though Plaintiffs' claims include constitutional, statutory, and procedural objections, all of these challenges are covered by § 877. As such, they must be brought exclusively "in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located." 21 U.S.C. § 877. Because this Court lacks jurisdiction over Plaintiffs' claims, the claims must be dismissed.

1. *Challenge to DEA's denial of Plaintiffs' exemption request*

Plaintiffs enumerate a long list of disagreements with the Final Determination (which Plaintiffs call "DEA's Order"), referring to the decision in more than two dozen paragraphs. See Compl. ¶¶ 10-16, 19, 35-36, 43, 122-129, 136-141, 147. Plaintiffs allege:

- “The DEA’s Order prohibits Plaintiffs free exercise of religion with ayahuasca.”
- “The DEA’s Order prohibits Plaintiffs from importing, possessing, manufacturing, and distributing ayahuasca.”
- “The DEA’s Order creates government-imposed coercive pressure on Plaintiffs to change or violate their religious beliefs.”
- “The DEA’s Order chills, burdens, inhibits, and destroys Plaintiffs’ religious exercise.”
- “The DEA’s Order ... is not the least restrictive means of furthering Defendants’ stated interests.”

Compl. ¶¶ 12-16. Whether brought under the APA, RFRA, or the Free Exercise Clause, each claim challenges the Final Determination, which DEA issued pursuant to its authority under Subchapter I of the CSA and in accordance with RFRA and controlling caselaw. Plaintiffs’ APA claim, for example, alleges that DEA, in issuing its Final Determination, “unlawfully adjudicated Plaintiffs’ religious sincerity,” Compl. ¶ 133, “unlawfully issued an order prohibiting Plaintiffs’ free exercise of religion,” *id.* ¶ 136, and ultimately that “the DEA’s Order ... violate[s] Plaintiffs’ rights secured to them by” the APA, *id.* ¶ 141. Plaintiffs’ RFRA claim focuses solely on the assertion that the Final Determination “prohibits Plaintiffs free exercise of religion with ayahuasca.” *Id.* ¶ 122; *see id.* ¶¶ 123-129 (each paragraph starts with “The DEA’s Order”). Plaintiffs’ Free Exercise claim takes issue with “the actions of Defendant in adjudicating Plaintiffs[’] religious sincerity,” that adjudication being part of the investigation on which the Final Determination is founded. *Id.* ¶ 147. Finally, the relief Plaintiffs seek is directed at the Final Determination. See Compl. Prayer for Relief (d) (asking Court to “void” the Final Determination).

Such challenges to DEA “final determinations” must be brought in a court of appeals. See 21 U.S.C. § 877. Plaintiffs wish to overturn DEA’s determination denying Plaintiffs’ Exemption Request. Plaintiffs seek this relief, in part, because they contend that the Final Determination “furthers no compelling governmental interest.” Compl. ¶ 126. But

DEA determined otherwise after a full investigation, see ECF No. 59-2. The relief Plaintiffs request is contrary to DEA's determination that they are not entitled to a RFRA-based exception to manufacture, distribute, or possess ayahuasca. And, because they are not entitled to engage in such activities, Plaintiffs now seek an injunction preventing Defendants "from taking any action prohibiting plaintiffs from importing, possessing, manufacturing, and distributing" ayahuasca. Compl. Prayer for Relief (c). But as the Eleventh Circuit concluded, plaintiffs in this position "should have contested" the denial of "DEA registration by appealing to [that] court, pursuant to the scheme provided by the CSA." *Sharma*, 511 F. App'x at 903; see also *John Doe*, 484 F.3d at 570 ("The DEA's denial of Doe's permit is properly reviewable in [the D.C. Circuit] pursuant to 21 U.S.C. § 877."). Because Plaintiffs' claims belong in the court of appeals, this Court must dismiss these claims for lack of jurisdiction.

2. *Plaintiffs' challenge to the Guidance*

Plaintiffs' challenge to the Guidance also falls within the ambit of § 877. Plaintiffs wish to overturn DEA's general process for considering petitions by religious individuals to manufacture and distribute controlled substances, as articulated in the Guidance. See, e.g., Compl. ¶¶ 132-134, 148-152. The CSA affords DEA exclusive federal authority over the control and handling of controlled substances, and to exercise its judgment and expertise in the exercise of that plenary authority, including, for example, drug scheduling decisions, 21 U.S.C. § 811, registration decisions, *id.* § 823, revocation decisions, *id.* § 824, and rulemakings, *id.* § 871(b). Where, as here, "Congress creates procedures designed to permit agency expertise to be brought to bear on particular problems, those procedures are to be exclusive." *Jarkesy*, 803 F.3d at 16 (quoting *Free Enter. Fund v.*

Pub. Co. Accounting Oversight Bd., 561 U.S. 477, 489 (2010)). Plaintiffs’ challenge to the Guidance and methodology that DEA used in reaching its determination is “intertwined” with their challenge to the Final Determination itself, *Green*, 981 F.2d at 521, and falls “within the ambit” of § 877, *Doe v. FAA*, 432 F.3d at 1263.

Plaintiffs fundamentally disagree with the Guidance, contending that DEA lacks statutory authority to assess religious sincerity when determining whether an individual may be exempt from the CSA’s prohibitions. See *id.* ¶ 134 (“There is no law authorizing Defendants to investigate, evaluate or adjudicate the sincerity of religious beliefs.”); ¶ 115 (allegation that Guidance does not “reference ... enabling legislation based by Congress pursuant to RFRA”). They lodge a range of procedural objections to DEA’s decisional process for religious exemptions including complaints about “when [DEA’s] process starts and finishes,” *id.* ¶ 36, and that “DEA never published any rulemaking or other formal guidelines.” *Id.* ¶ 35. Plaintiffs seek a declaration that Defendants violated RFRA, the APA, and the First Amendment. See Compl. Prayer for Relief (b).³

These claims challenge DEA’s decisional process for considering petitions for religious exemptions from the CSA, including whether and what factors DEA may consider in adjudicating such a petition, and cannot be separated from Plaintiffs’ challenge to the Final Determination. As the Eleventh Circuit held, such a claim would

³ To the extent that Plaintiffs’ challenges to the Guidance are facial, they are barred by the statute of limitations. See 28 U.S.C. § 2401(a); *Wind River Min. Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991); *Alabama v. PCI Gaming Auth.*, 801 F.3d 1278, 1292 (11th Cir. 2015) (likewise recognizing exceptions only for an as-applied challenge). Under § 2401(a), if a plaintiff “wishes to bring a policy-based facial challenge,” or a challenge to a “procedural violation in the adoption of a regulation,” he must bring suit within six years. *Wind River*, 946 F.2d at 715. Because Plaintiffs’ facial challenges do not depend on the particular application of the Guidance to Plaintiffs, they have been barred since 2015.

“necessarily require a review of the procedures and actions taken” by DEA with regard to the very decision which “falls within the ambit of the administrative scheme.” *Doe v. FAA*, 432 F.3d at 1263 (considering claims that the “FAA infringed upon [plaintiffs’] due process rights by failing to observe statutory and administrative processes”).

Courts have held that similar challenges are subject to § 877 even where plaintiffs argued they were “not challenging a final action but the applicability of the regulation entirely.” See *Woods v. DEA*, 283 F. Supp. 3d 649, 663 (W.D. Tenn. 2017). “Congress has provided an exclusive pathway for federal-court challenges to final DEA decisions” such as the Final Determination, where “the substance of a lawsuit challenges an assertion of agency authority” implicated by a final DEA decision “committed to the exclusive review” of the courts of appeals under § 877. *Hemp Indus.*, 2021 WL 1734920, at *11. Regardless of whether Plaintiffs frame their claims as a challenge to DEA’s authority to consider a petition for a religious exemption in the first instance, Compl. ¶¶ 133-37; see *Hemp Indus.*, 2021 WL 1734920, at *1, objections to DEA’s process, Compl. ¶¶ 138-141; see *Doe v. FAA*, 432 F.3d at 1263, or substantive disagreement with DEA’s conclusion, Compl. ¶ 119-129; see *John Doe*, 484 F.3d at 571, such claims must be brought in the court of appeals under § 877. This court thus lacks jurisdiction over Plaintiffs’ claims.

Sound policy supports these rules. See *City of Rochester v. Bond*, 603 F.2d 927, 936 (D.C. Cir. 1979). Allowing a plaintiff to bring in district court, either on an alternative theory or by artful pleading what is, unavoidably in substance, a challenge to DEA determinations would “encourage[] forum shopping,” and lead to “duplicative” review and accompanying delays. *John Doe*, 484 F.3d at 570; see also *John Doe, Inc. v. Gonzalez*,

No. 06-CV-966-CKK, 2006 WL 1805685, at *21 (D.D.C. June 29, 2006) (noting similar reasons for exclusive court of appeals review, even when there is no “final determination”), *aff’d*, *John Doe*, 484 F.3d 561. This is no less true for a pre-enforcement challenge seeking to enjoin DEA “from taking any action prohibiting Plaintiffs from importing, possessing, manufacturing, and distributing ayahuasca.” Compl. Prayer for Relief (c); see *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994).⁴

In enacting § 877, Congress evinced a clear intent for the courts of appeals to resolve challenges related to the CSA. But that is a consequence of Congress’s choice that determinations about the CSA be made first by the agency with relevant expertise, whose “final determinations, findings, and conclusions ... shall be final and conclusive,” subject to review—after they are made—by the courts of appeals. Plaintiffs cannot evade that intent through artful pleading or otherwise. *Cf. Califano v. Sanders*, 430 U.S. 99, 108 (1977) (“Congress’ determination so to limit judicial review to the original decision denying benefits is a policy choice obviously designed to forestall repetitive or belated litigation of stale eligibility claims. Our duty, of course, is to respect that choice.”). As the Supreme Court has held, “the declaratory judgment procedure will not be used to preempt and

⁴ Indeed, essentially any challenge to a final registration decision could be reframed as a challenge to DEA’s authority to act in the first place, or as seeking a declaration that the activity affected by the final decision is lawful or an injunction against enforcing the CSA. *Doe* is illustrative: the plaintiff sought to import a controlled substance it contended was in Schedule III; DEA denied an import registration application on the grounds that the substance was in Schedule I. 484 F.3d at 564. The plaintiff raised APA and Due Process claims, arguing that DEA wrongly concluded that the substance was in Schedule I, and that DEA’s denial was therefore erroneous. *Id.* at 571. The D.C. Circuit held that such a claim could proceed only in a court of appeals. *Id.* at 568-70. *Doe* could not simply have reframed its claim as one seeking declaratory relief that the substance was in Schedule III, and then litigated in district court. Framing its complaint as a claim that DEA was not authorized to enforce the CSA should the plaintiff choose to import the substance anyway would be equally unavailing. *Cf. Hemp Indus.*, 2021 WL 1734920, at *8-9. So too, here.

prejudge issues that are committed for initial decision to an administrative body or special tribunal any more than it will be used as a substitute for statutory methods of review.” *Pub. Serv. Comm’n of Utah v. Wycoff Co., Inc.*, 344 U.S. 237, 246 (1952); see also *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 48 (1938). The same is true for injunctive relief. See *FCC v. ITT World Commc’ns, Inc.*, 466 U.S. 463, 468 (1984).

In sum, Plaintiffs seek to nullify both DEA’s determination that they did not demonstrate that they qualify for a religious exemption and the Guidance interpreting the CSA as it applies to a registration sought for religious reasons. As the District Court for the District of Columbia—in which the overwhelming majority of district court challenges to agency actions are brought—recently held, plaintiffs seeking “declaratory and injunctive relief that would functionally nullify” the “final determination” or “conclusion made by DEA” must “obtain review of that decision in the court of appeals” under § 877. *Hemp Indus.*, 2021 WL 1734920, at *6; see also *Otwell v. Ala. Power Co.*, 747 F.3d 1275, 1282 (11th Cir. 2014) (“The review entailed by Appellants’ claims is statutorily dedicated to the court of appeals, and the district court did not err by concluding it could not resolve the merits of Appellants’ suit.”). Plaintiffs must bring their challenges under the APA, RFRA, and the Constitution in the first instance in the court of appeals. See *FCC v. ITT World Commc’ns, Inc.*, 466 U.S. 463, 468-69 (1984) (“[I]itigants may not evade [exclusive-review] provisions by requesting the District Court to enjoin action that is the outcome of the agency’s order”). This Court lacks jurisdiction and should dismiss Plaintiffs’ claims.

B. Alternate statutory provisions do not override § 877’s exclusive review provision to confer subject matter jurisdiction over Plaintiffs’ claims.

No statutory provision cited in the complaint confers subject-matter jurisdiction on this court. Plaintiffs first cite 28 U.S.C. § 1331. See Compl. ¶ 39 (citing 28 U.S.C. §§ 1331,

1346, 1361, 2201, 2202). But “[w]hen Congress provides for exclusive review in a court of appeals,” as in § 877, “that specific grant of jurisdiction displaces the general federal question statute, 28 U.S.C. § 1331.” *Bold All. v. FERC*, No. 17-CV-1822-RJL, 2018 WL 4681004, at *4 (D.D.C. Sept. 28, 2018); see also *Mims*, 565 U.S. at 378–79 (general “principle” that “when federal law creates a private right of action ... federal-question jurisdiction under § 1331” does not “endure[]” where “Congress divests federal courts of their § 1331 adjudicatory authority”). This displacement applies with equal force where “Plaintiff’s claims arise under the [CSA].” *John Doe, Inc.*, 2006 WL 1805685, at *17-18 (surveying cases holding that “challenges to DEA’s determination under the CSA” must be brought in court of appeals under § 877). The same is true here: the specific jurisdictional grant in § 877 overrides the general grant in § 1331.

That plaintiffs bring a RFRA claim does not alter this analysis. See Compl. ¶¶ 118-130. The Third Circuit recently considered whether a RFRA claim could be brought in district court where an exclusive-review provision applied. *Adorers of the Blood of Christ (“ABC”) v. FERC*, 897 F.3d 187, 198 (3d Cir. 2018) (considering exclusive-review provision of Natural Gas Act). The court held that “a claim under RFRA” brought under § 1331 “does not abrogate or provide an exception to a specific and exclusive jurisdictional provision prescribed by Congress for judicial review of an agency’s action.” *Id.*; see also *Gen. Fin. Corp. v. FTC*, 700 F.2d 366, 368 (7th Cir. 1983) (similar). The court expressly rejected the argument that RFRA grants plaintiffs the “statutory right to assert their RFRA claim in district court,” determining that “[n]owhere does the text specifically confer jurisdiction to the federal district courts to hear RFRA claims.” *ABC*, 897 F.3d at 194. Thus, RFRA is itself not jurisdictional, but sets forth a substantive legal standard.

Therefore, the court held that the RFRA claim must be brought in the manner provided in the exclusive-review provision and affirmed the district court's dismissal for lack of jurisdiction. *Id.* at 190.

The same result follows here. As explained above, Plaintiffs' RFRA claim is a direct challenge to the Final Determination and § 877 channels review of such a challenge exclusively into the court of appeals. RFRA itself does not require a claim to be brought in district court; it provides that an individual may assert a RFRA violation "as a claim or defense in a judicial proceeding." 42 U.S.C. § 2000bb-1(c). Only where "denial of review in the district court will truly foreclose all judicial review," is district court jurisdiction proper. *Kabeller*, 999 F.2d at 1421–22. Plaintiffs here may "assert [a RFRA] violation" "as a claim" in a court of appeals under § 877. 42 U.S.C. § 2000bb-1(c). As in *Kabeller*, "review is not precluded; review resides exclusively with the court of appeals." 999 F.2d at 1421-22.⁵

II. PLAINTIFFS' APA AND CONSTITUTIONAL CLAIMS MUST BE DISMISSED UNDER RULE 12(b)(6).

As established above, all of Plaintiffs' claims are subject to § 877, and this Court therefore lacks jurisdiction over the claims. In the event the Court did have jurisdiction, however, the APA and constitutional claims would still be subject to dismissal pursuant

⁵ Plaintiffs cite several other statutes as bases for jurisdiction, but none avails them. The Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, does not provide an independent basis for jurisdiction. See *Hill Dermaceuticals, Inc. v. Anthem, Inc.*, 228 F. Supp. 3d 1292, 1299 (M.D. Fla. 2017) ("Declaratory Judgment Act does not ... confer jurisdiction on federal courts") (citation omitted). Neither the Federal Torts Claim Act, 28 U.S.C. § 1346, nor the Mandamus Act, 28 U.S.C. § 1361, applies because Plaintiffs neither bring a tort claim against the United States nor seek a writ of mandamus. See *Hakki v. Sec'y, Dep't of Veterans Affs.*, No. 19-14645, 2021 WL 3354715, at *18 (11th Cir. Aug. 3, 2021).

to Rule 12(b)(6), as set forth below.⁶

A. Plaintiffs' APA claim must be dismissed.

Plaintiffs' APA claim should be dismissed. Plaintiffs' APA claim alleges that DEA lacks the statutory authority to assess sincerity when considering a petition for religious exemption from the CSA. See Compl. ¶¶ 133-136. This claim is without merit.

The Supreme Court has explicitly rejected the argument that an agency cannot craft and consider religious “exemptions from its own Guidelines” and the statutes an agency is tasked with carrying out. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380, 2383 (2020) (affirming that HHS had the authority “to exempt or accommodate ... religious objections” to the ACA and that “it was appropriate for [HHS] to consider RFRA”). Indeed, DEA’s prior failure to adequately consider religious uses of ayahuasca led to the Court’s ruling in *O Centro*. And, as a result of *O Centro*, DEA established Guidance for petitions for religious exemption from the CSA.

Agencies are therefore empowered to undertake a RFRA inquiry, including the first step of that inquiry, which asks whether the entity’s religious views are sincerely held. And though the Supreme Court expressed skepticism that an agency may decide whether “religious beliefs are mistaken or insubstantial,” in considering requests for accommodation under RFRA, an agency may determine whether the asserted religious belief “reflects an honest conviction.” *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 725 (2014); see also *Cutter v. Wilkinson*, 544 U.S. 709, 725 n.13 (2005) (under RLUIPA,

⁶ To the extent Plaintiffs’ RFRA claim is permitted to proceed, review thereof would be on the record before DEA. In § 877, Congress additionally required that DEA’s “[f]indings of fact ... if supported by substantial evidence, shall be conclusive.” 21 U.S.C. § 877.

“prison officials may appropriately question whether a prisoner’s religiosity, asserted as the basis for a requested accommodation, is authentic”).⁷ Likewise, the Court in *O Centro* held that RFRA applies only to a “particular claimant whose *sincere* exercise of religion is being substantially burdened.” 546 U.S. at 430-31 (emphasis added).⁸

By issuing the Guidance, DEA properly responded to *O Centro*’s direction that it consider religious hardship under RFRA, including RFRA’s threshold inquiry regarding religious sincerity, in applying the CSA. See 21 U.S.C. § 821; 871(b) (authorizing the Attorney General to “promulgate any rules, regulations, and procedures which he may deem necessary to ... functions under this subchapter”). Sections 821 and 871 provide DEA with ample authority to promulgate the Guidance.

In turn, RFRA—a law that imposes an independent obligation on DEA—contemplates that DEA will consider religious sincerity when evaluating a request for a religious exemption from the CSA. See *Little Sisters of the Poor*, 140 S. Ct. at 2383 (appropriate for agency to consider RFRA). That DEA exercised that authority and concluded that Plaintiffs are not entitled to such an exemption does not enable Plaintiffs to now claim that DEA lacked authority to make that determination in the first instance. Plaintiffs thus have failed to plausibly allege that DEA exceeded its authority in

⁷ Under the Free Exercise case law that RFRA was intended to restore, courts were required to confirm the sincerity of the claimed religious objection. See, e.g., *United States v. Seeger*, 380 U.S. 163, 185 (1965) (“[W]hile the ‘truth’ of a belief is not open to question, there remains the significant question whether it is ‘truly held.’ This is the threshold question of sincerity which must be resolved in every case.”).

⁸ In *O Centro*, the Supreme Court did *not* address whether the plaintiff’s use of ayahuasca constituted a sincere religious practice. 546 U.S. at 423 (noting sincerity was not contested for the purposes of the plaintiffs’ motion for a preliminary injunction). But the Court made clear that the whole of the RFRA inquiry—including sincerity determinations—is plaintiff-specific; accordingly, a court must ask whether *this* plaintiff sincerely holds the religious beliefs that it claims are burdened. *Id.* at 430-31.

considering religious sincerity in adjudicating Plaintiffs' petition under RFRA.

Plaintiffs also appear to claim that DEA had an obligation to "provide a hearing in accordance with APA procedures" to adjudicate Plaintiffs' Exemption Request. See Compl. ¶ 138. To the extent Plaintiffs assert this independent claim, it, too, lacks merit.

Under the APA, the Final Determination constitutes an "order" issued by "adjudication." 5 U.S.C. § 551(6), (7). "Formal" adjudication under the APA—*i.e.*, an adjudication involving a hearing conducted on the record—is only triggered when three conditions are met: (1) the adjudication is "required by statute," (2) to be conducted "on the record," and (3) with an "opportunity for an agency hearing." 5 U.S.C. § 554(a). See, *e.g.*, *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 236-38 (1973); *Wong Yang Sung v. McGrath*, 339 U.S. 33 (1950) (oral hearings are compulsory only when the statute governing the agency's actions make an oral hearing mandatory); see also *Clark Cnty. v. FAA*, 522 F.3d 437, 441 (D.C. Cir. 2008) (explaining that APA distinguishes between "formal" adjudication requiring "on-the-record hearings" and "informal" adjudication requiring less stringent procedures). Plaintiffs, however, identify no provision explicitly requiring a hearing on the record, whether as to the adjudication undertaken in the Final Determination or any other adjudication under the CSA. Accordingly, they have not plausibly alleged a claim that the Final Determination contravened 5 U.S.C. § 554(a).

Plaintiffs suggest that 5 U.S.C. § 558(c) imposed on DEA an independent obligation to conduct a hearing on the record before issuing the Final Determination. But § 558(c) does not independently require formal adjudication. See *Taylor v. Dist. Eng'r, U. S. Army Corps of Engineers, Jacksonville, Fla.*, 567 F.2d 1332, 1337 (5th Cir. 1978) ("[W]e do not read § 558 as requiring a § 556 hearing[.]"); *Marathon Oil Co. v. EPA*, 564

F.2d 1253, 1260-1261 n.25 (9th Cir. 1977) (“Section 558(c) does not independently provide that full adjudicatory hearings must be held.”). Because Plaintiffs identify no provision explicitly requiring DEA to hold a hearing on the record before issuing the Final Determination, to the extent Count Two incorporates this claim, it must be dismissed.

B. Plaintiffs’ Free Exercise claim must be dismissed.

Plaintiffs also fail to allege a Free Exercise claim. Plaintiffs contend that DEA violated the First Amendment by “adjudicating Plaintiffs’ religious sincerity and prohibiting Plaintiffs religious exercise with ayahuasca.” Compl. ¶ 147. As an initial matter, Plaintiffs’ allegedly religious exercise appears to have continued through the investigation and since DEA issued its determination, as Soul Quest has continued to advertise and host ayahuasca retreats throughout this period. Compl. Ex. 2, ECF 59-2; see also Soul Quest Ayahuasca Church of Mother Earth, Programs, <https://perma.cc/KU6M-SAVH> (last visited Aug. 24, 2021).

To the extent that Plaintiffs allege that DEA’s application of the CSA violates the First Amendment, their claim fails because the CSA is a neutral and generally applicable law, and “the right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes” what one’s religion requires. *Emp. Div., Dep’t of Hum. Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990). “[T]he threshold questions in analyzing a law challenged under the Free Exercise Clause are (1) is the law neutral, and (2) is the law of general applicability?” *First Assembly of God of Naples v. Collier Cnty.*, 20 F.3d 419, 423 (11th Cir. 1994). A law is neutral unless its “object ... is to infringe upon or restrict practices because of their religious motivation.” *Church of the Lukumi Babalu Aye, Inc. v. Hialeah*,

508 U.S. 520, 533 (1993). A law is generally applicable if the government does not “in a selective manner impose burdens only on conduct motivated by religious belief.” *Id.* at 543. A neutral and generally applicable law “is presumed constitutional and the burden is on the plaintiff to prove that it is not rationally related to a legitimate government interest.” *Keeton v. Anderson-Wiley*, 664 F.3d 865, 880 (11th Cir. 2011).

Plaintiffs do not dispute the CSA’s neutrality or general applicability. See Compl. ¶¶ 143-153. Nor could they: Congress enacted the CSA to prevent “the diversion of drugs from legitimate channels to illegitimate channels.” *United States v. Blanton*, 730 F.2d 1425, 1427 (11th Cir. 1984). The CSA’s purpose is to ensure public health and safety, see 21 U.S.C. § 801, not to “suppress[] ... religion or religious conduct,” *Lukumi*, 508 U.S. at 533. The CSA is rationally related to legitimate public interests by ensuring an adequate supply of drugs with a “useful and legitimate medical purpose” while preventing the “illegal importation, manufacture, distribution, and possession and improper use of controlled substances,” 21 U.S.C. § 801; see *O Centro*, 546 U.S. at 436-37.

Rather, Plaintiffs allege that the Guidance is not neutral and generally applicable because it creates a “mechanism for individualized exemptions to the [CSA].” Compl. ¶ 149. Plaintiffs appear to be invoking the Supreme Court’s recent decision in *Fulton v. City of Philadelphia*, 141 S. Ct. 1868 (2021). But *Fulton* does not apply here. In issuing the Guidance, DEA has not “refuse[d] to extend” a system of exemptions to cases of “religious hardship.” *Fulton*, 141 S. Ct. at 1878. Instead, the Guidance is the very means through which DEA is making an exemption process available to religious entities. That the Guidance “invites the government to consider the particular reasons for a person’s conduct, including religious sincerity” is not a flaw, as Plaintiffs allege. Compl. ¶ 149.

Rather, that individualized determination is precisely what RFRA demands. See *O Centro*, 546 U.S. at 430–31 (RFRA requires consideration of the alleged burden imposed by governmental action “‘to the person’—the particular claimant whose sincere exercise of religion is being substantially burdened.”). Indeed, while Plaintiffs allege that others have been “uniformly” permitted to use ayahuasca in their religious practices, Compl. ¶ 9, Plaintiffs “cannot simply point to other groups who have won accommodations for the sacramental use of ... [ayahuasca] and say ‘we’ll have what they’re having,’” particularly when there are “material differences between those particular groups and their sacramental practices, on the one hand, and the [plaintiffs’ allegedly] religious exercise, on the other.” *United States v. Christie*, 825 F.3d 1048, 1061 (9th Cir. 2016).

In any event, even if the *Fulton* rubric applied to Plaintiffs’ challenge to DEA’s Guidance, and even if Plaintiffs could establish that the CSA burdens religious beliefs that they sincerely hold, which the record establishes that they cannot, see Final Determination, ECF No. 59-2 at 1-4, the result simply would be that the standard applicable to RFRA claims would apply. Accordingly, at best, Plaintiffs’ third count would be duplicative of their first. And dismissal of the Free Exercise claim would be warranted on that basis as well. See, e.g., *Diaz v. Medline Indus., Inc.*, No. 20-24952-CIV, 2021 WL 2075422, at *1 (S.D. Fla. Feb. 24, 2021) (“[A] court should dismiss claims that are duplicative of other claims,” such as those “that stem from identical allegations, that are decided under identical legal standards, and for which identical relief is available.”).

CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs’ Complaint.

Dated: August 26, 2021

Respectfully submitted,

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Certificate of Compliance with Local Rule 3.01(g)

By email on August 20 and 23, 2021, undersigned counsel conferred in good faith regarding the relief requested by this motion. Counsel for plaintiffs advised that plaintiffs oppose the relief sought in this motion.

/s/ Michael J. Gaffney
MICHAEL J. GAFFNEY