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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON

THE CHURCH OF THE HOLY LIGHT OF THE QUEEN, a/k/a The Santo Daime Church, *et al.*, Plaintiffs, v. ERIC H. HOLDER, JR., *et al.*,[1] Defendants.	CIV. NO. 08-3095-PA **MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO AMEND JUDGMENT PURSUANT TO FED. R. CIV. P. 59(e)**

[1] Pursuant to Fed. R. Civ. P. 25(d), the newly confirmed Attorney General, Eric H. Holder, Jr., is substituted for former Attorney General, Michael B. Mukasey.

INTRODUCTION

The Court's Judgment dated March 19, 2009 (Doc. #161), as amended by the Court's Amended Judgment dated March 27, 2009 (Doc. #164), enjoins the Drug Enforcement Administration ("DEA") from "prohibiting or penalizing the sacramental use of Daime tea by Plaintiffs during Plaintiffs' religious ceremonies." *Id.* at 1. In addition to enjoining Defendants from banning Plaintiffs' religious use of Daime tea, the Amended Judgment significantly curtails the DEA's regulatory authority without first establishing that these regulatory requirements were inapplicable or that enforcement of these regulatory requirements would violate Plaintiffs' rights under the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §§ 2000bb *et seq.*

For example, the Court's Amended Judgment permanently enjoins the DEA from "requiring Plaintiffs to conform their conduct to any regulations except as set forth [in the Court's Amended Judgment,]" *see* Am. J. at ¶ 3, or "imposing on Plaintiffs regulatory or other requirements, which by their terms apply to the importation, distribution, possession, or religious use of Daime tea," *see id.* at ¶ 2. These and other provisions of the permanent injunction divest the DEA of essential enforcement authority, nullifying regulatory requirements that have not been found to substantially impair Plaintiffs' exercise of religion and that are unnecessary to implement this Court's RFRA decision. If not corrected, the DEA's ability to enforce the CSA through the closed regulatory system detailed in 21 U.S.C. §§ 801-971 and 21 C.F.R. §§ 1301-1316 would be seriously inhibited. *See* Declaration of Denise Curry (attached hereto as Appendix A).

The injunction of vital regulatory requirements within the terms of the Amended Judgment is particularly troubling because the relief granted to Plaintiffs exceeds the scope of

relief sought by Plaintiffs in their complaint. Defendants asserted a compelling interest in full enforcement of the regulatory regime. Plaintiffs did not assert a RFRA claim against the CSA regulatory requirements, present any evidence concerning any burden on their religious practice that may be imposed upon them by any regulatory requirement, and (most significantly) the Court did not engage in any RFRA analysis concerning the regulatory requirements that have now been enjoined. Therefore, Defendants respectfully move that the Court's Amended Judgment be modified in order to correct this legal error.

BACKGROUND

At an early stage of litigation in the present case, Defendants asserted that if an exemption were granted for Plaintiffs to consume Daime tea for ceremonial purposes, the government has a compelling interest in compliance with the CSA's closed regulatory scheme that governs all permissible uses of controlled substances. As the government stated in its Trial Brief:

> The government has a compelling interest in enforcing the closed regulatory system under which controlled substances are manufactured, imported into the United States, and/or distributed within this country. As the government will demonstrate at trial, only in accordance with the closed regulatory system established by the CSA and implemented through DEA regulations can the government ensure accountability, prevent diversion, and protect public health and safety. In their complaint, Plaintiffs allege only that the ban on importation, distribution, and use of ayahuasca under the CSA violates RFRA, *see* Compl. ¶ 1; any future claims brought by Plaintiffs concerning any of the CSA's implementing regulations are outside the scope of the complaint here. Therefore, Plaintiffs cannot sufficiently demonstrate that any particular regulation operates as a de facto ban on their religious use, thereby entitling them to relief.
>
> The government also has a compelling interest in ensuring that controlled substances, including controlled substances which are manufactured, imported, and/or distributed for purported religious uses, are not repackaged or re-labeled in such as a manner as to frustrate the application of the closed regulatory system to maintain accountability and deter and prevent diversion into illicit channels. The government will demonstrate at trial that Plaintiffs' practices significantly hamper the government's efforts to pursue this compelling interest.

See Defs.' Trial Br. at 15-16 (Doc. #28). Plaintiffs' complaint did not discuss the CSA regulations or suggest that any regulations would burden their religious rights. *See generally* Compl. (Doc. #1). Moreover, Plaintiffs failed to show through discovery or evidence at trial how any of the CSA regulations operate as a substantial burden on their religious practice. Defs.' Trial Br. at 1.[2]

The government sought to clarify this issue during discovery. Interrogatory No. 12 read as follows:

> DEFENDANTS' INTERROGATORY NO. 12: State whether you contend that any statutory provision of the Controlled Substances Act, 21 U.S.C. §§ 801-971, or any regulation promulgated pursuant to the Controlled Substances Act, 21 C.F.R. §§ 1300-1316, that does not in and of itself explicitly ban Plaintiffs' use of ayahuasca nonetheless violates any statutory or constitutional rights of Plaintiffs, including but not limited to those rights conferred by the Religious Freedom Restoration Act. Your answer should include the identification of each and every statutory provision and/or regulation that you contend violates any statutory or constitutional right of Plaintiffs and a detailed description of the burden imposed by each and every individual statutory or regulatory provision.
>
> PLAINTIFFS' OBJECTION: This is a contention interrogatory called for legal opinion and it is vague.
>
> PLAINTIFFS' RESPONSE: Plaintiffs incorporate by reference Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, which answers this inquiry. Plaintiffs have not alleged in the Complaint that the CSA violates their rights.

See Letter from Eric J. Beane to Judge Owen M. Panner (Dec. 5, 2008), at 3 (Doc. #62). After unsuccessful efforts to resolve this discovery dispute with Plaintiffs, the government asked the Court to require Plaintiffs to clarify the scope of their complaint:

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[2] Even in their late-filed "Plaintiffs' Reply to Defendants' Trial Brief" (Doc. #130), Plaintiffs failed to allege that any or all of the CSA regulations burdened their religious exercise, or respond to the government's argument that any claim brought by Plaintiffs alleging that the CSA regulations violate RFRA is outside the scope of their complaint in this case.

> Plaintiffs repeatedly have asserted that their consumption of ayahuasca is "non-drug" use that is not prohibited by the CSA, and they have argued that the CSA regulations would not apply to them if they were to obtain relief. In Defendants' view, the central issue in this case is not whether Plaintiffs' engage in "drug use" or "non-drug use," but instead whether RFRA would or would not prohibit the potential application of the CSA and/or its regulations to Plaintiffs.
>
> If Plaintiffs want relief from any regulations, then they must allege (and prove) that the regulation imposes a substantial burden that is not justified by the government's compelling interests . . . . Plaintiffs' refusal to address this issue guarantees that the upcoming trial will not resolve all of the disputes in this case and that additional litigation will be necessary if the Court denies Defendants' jurisdictional motion and rules in favor of Plaintiffs on the merits. Defendants respectfully urge the Court to ensure that significant issues are not being deferred until after the trial. It would be inappropriate for Plaintiffs to seek post-trial relief from regulations that were neither specifically challenged in the Complaint nor specifically addressed during discovery and at trial.

See id. at 3-4. However, at the pretrial conference on December 22, 2008 (Doc. #87), the Court declined to require Plaintiffs to clarify whether they were challenging the application of any CSA regulation to their religious use of Daime. *See* Doc. #87 minute order "sustain[ing] plaintiffs' objections to defendants' interrogator[y . . .] 12."

Notwithstanding Plaintiffs' failure to allege that the CSA regulatory requirements violate any of their statutory or legal rights, the Court's Amended Judgment enjoins the DEA from "requiring Plaintiffs to conform their conduct to any regulations" other than those drafted by the Court in the Amended Judgment. Am. J. at ¶ 3. Respectfully, however, it is through enforcement of these regulatory requirements that the government administers the closed system of legitimate controlled substance importation, manufacture, distribution, and dispensing within the United States. The purpose of the closed system is to deter and prevent trafficking in legitimately imported and manufactured controlled substances, as well as chemicals used in illicit manufacture, and to ensure that controlled substances and regulated chemicals are used only for lawful purposes. DEA's Diversion Control Program administers the CSA and the regulations

promulgated pursuant to the CSA in a manner that seeks to ensure that controlled substances that have legitimate and legal uses are available within the closed system of the CSA.

Under the closed system, registrants are subject to record-keeping, reporting, and inspection requirements. Through the procedures established by the regulations, DEA can verify and track the amounts of controlled substances which are imported and/or manufactured in this country from the importer or manufacturer to the distributor through ultimate use or disposal. Given this Court's ruling that RFRA authorizes Plaintiffs to consume Daime tea for religious purposes, the regulatory requirements which are most important to DEA are those which enable DEA to track imported Daime tea from the U.S. border to its ultimate use or disposal. These regulations are those which permit DEA to: (a) ascertain when, where, and in what quantities and strengths Plaintiffs import Daime tea into this country; (b) identify where and by whom the Daime tea is stored and how much Daime tea is stored in each location; (c) conduct audits and inspections to confirm the existence of appropriate security safeguards in each storage location; (d) track when, where, and in what amounts and strengths the CHLQ's churches distributes Daime tea to its centers and points; (e) receive reports and conduct inspections and audits to confirm when and in what amounts Daime tea is consumed by CHLQ members in each location; and (f) receive reports and conduct inspections and audits to confirm that all Daime tea imported into this country by Plaintiffs has been consumed in a religious ceremony, was destroyed, or remains in inventory. The full list of DEA's regulations are set forth in Parts 1300 through 1316 of Title 21 of the Code of Federal Regulations.

STANDARD OF REVIEW

Under Rule 59(e) of the Federal Rules of Civil Procedure, a court may "alter or amend" a

judgment upon motion made within ten days after entry of judgment. *See* Fed. R. Civ. P. 59(e). Courts typically consider several factors in ruling on a motion to alter or amend a judgment, including whether amendment is "necessary to correct manifest errors of law . . . upon which the judgment is based" or "necessary to prevent manifest injustice." *See Turner v. Burlington N. Santa Fe R.R. Co.*, 338 F.3d 1058, 1063 (9th Cir. 2003) (citing *McDowell v. Calderon*, 197 F.3d 1253, 1254 n.1 (9th Cir. 1999)) (quotations and original emphasis omitted). A district court enjoys "considerable discretion" in addressing a motion under Rule 59(e). *See Turner*, 338 F.3d at 1063.

ARGUMENT

Here, amendment of the Amended Judgment is necessary to correct a legal error and to prevent manifest injustice produced by the Amended Judgment's acute compromise of DEA's ability to meet its ongoing obligation to ensure that controlled substances are not diverted to unauthorized uses. This permanent injunction appears to be based on a manifest error of law that the CSA regulatory requirements may be enjoined absent an inquiry into whether they substantially burden Plaintiffs' sincere religious exercise, whether that substantial burden is justified by a compelling interest, and whether the burden is the least restrictive means to protect that compelling interest, as required by RFRA. *See Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 436 (2006) (holding that "RFRA operates by mandating consideration, under the compelling interest test, of exceptions to rules of general applicability" and finding "no cause to believe that the compelling interest test would not be applied in an appropriately balanced way to specific claims for exemptions as they arose") (internal quotations and citations omitted).

I. The Court Erred by Enjoining the CSA Regulatory Requirements Without Engaging in RFRA Analysis.

A. The CSA Regulatory Requirements Apply to All Permissible Uses of Controlled Substances.

That the CSA regulatory requirements apply to all uses of controlled substances, including religious uses, is clear from the plain language of the regulatory requirements themselves. First, the CSA regulatory requirements clearly apply to all "importers" and "distributors" of controlled substances. The regulations define "importer" as follows: "The term importer includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule." 21 C.F.R. § 1300.01(b)(16). A "distributor" is defined as a person who distributes a controlled substance, and "distribute" means "to deliver (other than by administering or dispensing) a controlled substance or a listed chemical." 21 U.S.C. § 802(11) (incorporated by 21 C.F.R. § 1301.02). "Deliver" means "the actual, constructive, or attempted transfer of a controlled substance or a listed chemical," while the activities excluded from the definition of "distribute" – "administering" and "dispensing" – apply only to researchers and practitioners. *See* 21 U.S.C. § 802(2), (8), & (10). Plaintiffs cannot dispute that they meet these definitions. If the DEA wanted to limit the definition of "importer" and "distributor" to persons who import and distribute for a particular purpose, the DEA would have done so.

In a provision titled "Persons required to register," the regulations clearly state that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or

pursuant to §§ 1301.22–1301.26." 21 C.F.R. § 1301.11. Plaintiffs cannot cite to any applicable exemption. By choosing broad, all-inclusive language such as "all persons" and an extensive list of possible activities, rather than simply identifying the general groups (*e.g.*, physicians, researchers, industrial manufacturers) authorized to undertake specific activities, the DEA ensured that the regulatory definition was flexible enough to encompass an evolving set of parties who could be authorized under the law to import and distribute controlled substances.

Finally, the explicit regulatory exemption for the Native American Church ("NAC") strongly suggests that the DEA intended the CSA regulatory requirements to apply to religious use of drugs. *See* 21 C.F.R. § 1307.31. Otherwise, a regulatory exemption for the NAC would have been unnecessary. Moreover, whether the regulatory requirements apply to the NAC in all, some, or no circumstances has no bearing on whether regulatory requirements promulgated pursuant to the CSA apply to Plaintiffs.

In the *O Centro* case, Judge Parker directly addressed the question of whether the CSA regulatory requirements apply to sacramental use of controlled substances and held, unambiguously, that they do. After the Supreme Court upheld Judge Parker's preliminary injunction barring the government from banning sacramental use of hoasca, the *O Centro* plaintiffs filed an amended complaint arguing, *inter alia*, that "[t]he CSA's regulatory scheme does not apply to Plaintiffs[' religious use of hoasca.]" *See* Amended Complaint at 20, *O Centro Espirita Beneficiente Uniao do Vegetal v. Clement*, No. 00-1647 (D.N.M. Sept. 21, 2007). Judge Parker dismissed this argument entirely:

> The CSA requires registration of "every person who manufactures, distributes, dispenses, imports, or exports any controlled substance," unless that person has an exemption. 21 C.F.R. § 1301.11; *see also* 21 U.S.C. § 822(a). The statutory and regulatory definitions of "importer" and "distributor" are not limited to persons

> who import and distribute controlled substances only for a particular purpose. There is no basis for reading these unambiguous and all-encompassing definitions to exclude those importing or distributing substances for religious purposes, as Plaintiffs advocate. The CSA regulations make one reference to religious use—the exemption of the Native American Church (NAC) from certain restrictions on the ceremonial use of peyote. *See* 21 C.F.R. § 1307.31. This exemption demonstrates that the CSA regulations do apply to religious drug use absent a specific allowance for that use.
>
> Plaintiffs also argue that because "the courts have ordered the government to allow Plaintiffs to lawfully import and distribute hoasca," the Drug Enforcement Administration ("DEA") lacks the power to apply any CSA regulations to Plaintiffs. (Pls.' Response at 57.) Plaintiffs' argument assumes that if there is no compelling interest in banning hoasca, then *a fortiori*, there is no compelling interest in any regulation of hoasca's use. This argument misinterprets the law of this case. The Supreme Court affirmed this Court's finding that the government had not established a compelling interest in banning Plaintiffs' use of hoasca. *Gonzales v. O Centro Espirita Beneficiente Uniao Do Vegetal*, 546 U.S. 418 (2006). The decision cannot be read to exempt Plaintiffs from any and all regulation under the CSA, because the balancing of interests required by RFRA may be different for regulation of hoasca than for a ban on hoasca. Plaintiffs' response to the motion to dismiss seems to concede the point. Plaintiffs "recognize[] that the government may have a compelling interest in requiring certain conduct in relation to UDV's importation of hoasca" and that they are willing to consider these compelling needs. (Pls.' Response at 47.)
>
> The Court concludes that there is no legal basis for Plaintiffs' contention that the CSA regulations do not apply to UDV's importation and use of hoasca. An exemption for religion in general cannot be fairly implied from the statute and regulations . . . .

See O Centro, No. 00-1647, slip op. at 3 (D.N.M. Aug. 4, 2008) (*O Centro* Doc. #197) (attached hereto as Appendix B). To the extent the Court's Amended Judgment relied on the assumption that the CSA regulatory requirements do not apply to Plaintiffs' religious use of Daime tea, that conclusion constitutes a manifest error of law for which modification under Rule 59(e) is proper.

B. The Court Erred by Enjoining Regulatory Requirements Without Finding That RFRA Had Been Violated.

The Court's Amended Judgment effects a blanket injunction against application of the CSA regulatory requirements to Plaintiffs, replacing the comprehensive closed regulatory system

with a list of terms and conditions to which Plaintiffs are instructed to conform their conduct. Am. J. at ¶¶ 1-2, 24. This broad injunction prohibits the government "from applying or enforcing any of the laws, regulations, and treaties that govern the legal importation and distribution of Schedule I substances for the purpose of prohibiting, preventing, unduly delaying, or otherwise interfering with Plaintiffs' religious use of Daime tea in a manner that is inconsistent with this Court's Findings of Fact and Conclusion of Law." *Id.* at ¶ 24. From the Court's Findings of Fact and Conclusions of Law, this Amended Judgment appears to be based on the conclusion "[g]uided by [. . . *O Centro*], 546 U.S. 418 (2006) . . . that the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb to 2000bb-4, requires that plaintiffs be allowed to import and drink Daime tea for their religious ceremonies, subject to reasonable restrictions." *See* Findings of Fact and Conclusions of Law (Doc. #160) at 1-2. However, despite finding that "the government may be said to have a compelling interest in regulating any drug listed on Schedule I of the Controlled Substances Act[,]" *see id.* at 19-20 (emphasis added), this Court's Amended Judgment enjoins enforcement of all of the CSA regulatory requirements without having conducted the more specific inquiry that the Court recognizes that RFRA requires. *See id.* at 20.

A broad injunction against application of the majority of the CSA regulatory requirements to Plaintiffs is inconsistent with the Supreme Court's decision in *O Centro*. The Supreme Court did not set the *O Centro* plaintiffs beyond the reach of any and all drug laws and regulations. It merely said that the government had not established, for the purpose of opposing a preliminary injunction, a compelling interest in banning the *O Centro* plaintiffs' use of hoasca. *See* 546 U.S. at 439. As such, the Supreme Court decision in *O Centro* cannot be read to entitle Plaintiffs here to be free from any or all of the CSA regulatory requirements that every other person authorized

to possess Schedule I controlled substances must meet. Rather, as Judge Parker recognized in his August 4, 2008 Order, the Supreme Court's decision in *O Centro* held that "the balancing of interests required by RFRA may be different for regulation of [ayahuasca] than for a ban on [ayahuasca]," and "cannot be read to exempt Plaintiffs from any and all regulation under the CSA." *See* App. B at 3.

Judge Parker's holding is firmly rooted in the Supreme Court's decision in *O Centro*, which characterized RFRA as adopting a "strict scrutiny test" which "at least requires a case-by-case determination of the question, sensitive to the facts of the particular claim." 546 U.S. at 430-31 (internal quotations and citations omitted). Furthermore, as the Supreme Court in *O Centro* explained, "RFRA makes clear that it is the obligation of the courts to consider whether exemptions are required under the [strict scrutiny] test set forth by Congress." *Id.* at 434. This involves inquiring into whether "the compelling interest test is satisfied through application of the challenged law to the person . . . and scrutiniz[ing] the asserted harm of granting specific exceptions . . . ." *Id.* at 430-31 (quotations omitted). The specific exemptions provided for in the Court's Amended Judgment were granted in the absence of any scrutiny of each of the "challenged laws" – that is, each enjoined regulation.

However, by failing to apply "the more focused inquiry required by RFRA and the compelling interest test," *see id.* at 432, the Amended Judgment here does not satisfy the obligation reaffirmed by the Supreme Court in *O Centro* and, therefore, is based on a manifest error of law warranting amendment.

Thus, in enjoining the CSA regulatory requirements, Defendants respectfully submit that the Amended Judgment was based upon legal error. First, in addition to the fact that Plaintiffs'

complaint neither alleged that the CSA regulatory requirements violated RFRA nor prayed for relief from those regulatory requirements, Plaintiffs presented no evidence or argument, in briefing or discovery, or at trial, that the regulatory requirements imposed any burden, let alone a substantial one, on their religious practice. And, moreover, Plaintiffs did not – nor could they – assert that the CSA regulatory requirements do not apply to their religious use. Indeed, the regulatory requirements at issue apply to all persons who handle Schedule I controlled substances for approved purposes, and there is no evidence to suggest that Plaintiffs – like others subject to the regulatory requirements – cannot comply with them with minimal effort. Finally, the Amended Judgment enjoins many CSA regulatory requirements without undertaking the case-specific RFRA inquiry as to any of the regulatory requirements, despite the Supreme Court's decision in *O Centro* reaffirming the obligation to do so.

II. Amendment of the Amended Judgment Is Necessary to Prevent Manifest Injustice.

The Amended Judgment strips Defendants of substantial regulatory authority, regardless of whether the enforcement of those enjoined regulatory requirements would constitute a ban on Plaintiffs' sacramental use of Daime tea. Amendment of the Amended Judgment is therefore necessary to prevent manifest injustice. *See Turner*, 338 F.3d at 1063. These regulatory requirements were promulgated to ensure that legitimately-held controlled substances would not be diverted to illicit uses, and there has been no showing that these regulatory requirements have been or could be applied in ways that would burden Plaintiffs' religious exercise. Yet the Amended Judgment enjoins the Defendants from enforcing these regulatory requirements, many of which are discussed in the Declaration of Denise Curry. App. A.

For example, Paragraph 15 of the Amended Judgment requires Plaintiffs to extract and

preserve two samples from each shipment of Daime tea: one sample would be taken before the shipment leaves Brazil and a second sample would be taken upon the shipment's receipt in the United States. The purpose of this Paragraph is to permit DEA to compare the product that enters the United States with the product that leaves Brazil to ensure that, during the course of international shipment, the imported substance has not be altered but is, in fact, Daime tea. However, implementation of this two-step process would be less effective than simply permitting DEA to spot-sample shipments of Daime tea upon their arrival in the United States. DEA has found that, like many liquids, the composition of the Daime tea is likely to undergo changes during shipment and, therefore, comparison of the two samples would not enable DEA to detect adulteration or international alteration. *See* Curry Decl. at ¶ 15. Withdrawing a sample of Daime tea at the point of importation rather than at the point of origin would place no added burden on the Plaintiffs, but would enable DEA to ensure that the imported substance is, in fact, Daime tea.

Another essential aspect of the closed regulatory scheme is the record-keeping system DEA administers to track the contents of every container holding controlled substances from its manufacture or point of entry through its ultimate use or disposal. While Paragraph 15 requires Plaintiffs to assign a unique identifier to each imported container, it does not require labeling of subsequent containers into which substances are decanted after importation for storage or distribution. As controlled substances are often imported in bulk containers, registrants often find it necessary to remove the substances from the bulk containers and repackage them into multiple smaller containers. *See id*. at ¶ 17. The smaller containers are then distributed to ultimate users. Such "repackaging" increases the difficulty of tracking controlled substances. In other circumstances, DEA regulatory requirements address this concern by defining

repackaging as a form of manufacture, thus triggering specific regulatory requirements as to the labeling of the new containers and the records that manufacturers must maintain. *See id*. Here, the Amended Judgment covers the first step of tracking (uniquely labeling the larger containers), yet does not require any labeling or tracking of repackaged Daime tea, thus eviscerating the purpose of the labeling and tracking. To permit effective tracking of the movement of the Daime tea and to maintain an accurate accounting, it is necessary for Plaintiffs who repackage Daime tea to comply with the regulatory requirements of labeling and recordkeeping. *See id*. Such compliance would impose no burden on the Plaintiffs' exercise of religion, yet would allow DEA to efficiently and effectively track the Daime tea to protect against diversion.

In addition to containing unnecessarily broad restrictions on the government's regulatory enforcement authority, the Amended Judgment prohibits the DEA from enforcing specific regulatory requirements that play an essential role in maintaining the CSA's closed regulatory system. *See id.* at ¶¶ 7-8. For example, paragraph 21 of the Amended Judgment prescribes the records Plaintiffs shall keep, but does not require Plaintiffs to maintain records "with respect to distribution of Daime tea between registered locations," specifically, via DEA-222 forms. As Ms. Curry explains in her declaration, "[t]his documentation enables DEA to accurately follow the movement of controlled substances from import to their ultimate dispensation or destruction." *See id.* at ¶ 24. Without the capacity to follow the movement of controlled substances, DEA's awareness of and ability to prevent diversion is severely compromised. *See id*.

Finally, paragraph 19 of the Amended Judgment authorizes DEA to conduct pre-registration inspections of each location where Plaintiffs intend to store Daime tea, and

paragraphs 10 through 12 seem to contemplate that DEA may also conduct inspections and audits at registered locations. The Amended Judgment does not, however, explicitly authorize DEA to perform inspections or audits of registered locations as described in 21 C.F.R. §§ 1316.01-1316.13. Without the authorization to conduct these inspections and audits, the limited record keeping requirements imposed on Plaintiffs by the Amended Judgment could not be enforced. These inspections and audits are essential regulatory tools to prevent diversion and maintain accountability. *See id*. at ¶ 19. Through inspections and audits, DEA Diversion Investigators review the records maintained by registrants and conduct physical inventories to confirm that the registrant can account for all controlled substances, a necessary step in ensuring proper use of the substance without in any way burdening Plaintiffs' religious practice. *See id*.

Each of these examples, as well as others described in the attached declaration, unnecessarily constrains DEA's regulatory authority so as to severely impede DEA's ability to protect the government's compelling interests, even when the means to do so does not burden Plaintiffs' religious exercise. As such, the Amended Judgment should be amended to prevent the resulting manifest injustice.

CONCLUSION

For the foregoing reasons, the government's motion to amend the Amended Judgment pursuant to Fed. R. Civ. P. 59(e) should be granted, and the Amended Judgment should be amended to explicitly state that Defendants maintain the authority to enforce CSA regulatory requirements, *see* 21 U.S.C. §§ 801-971 and 21 C.F.R. §§ 1300-1316, except to the extent that enforcement of a specific regulation would constitute a ban on Plaintiffs' sacramental use of

Daime tea. Alternatively, Defendants request the opportunity to submit a proposal that addresses DEA's most significant interests concerning the regulatory scheme.

Dated: April 2, 2009

Respectfully submitted,

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