

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

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O CENTRO ESPIRITA BENEFICIENTE)
UNIAO DO VEGETAL, <i>et al.</i> ,)
)
Plaintiffs,)
)
v.) No. CV 00-1647 JP/RLP
)
ERIC H. HOLDER, JR., <i>et al.</i> ,)
)
Defendants.)
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INTRODUCTION

This action arises under the Religious Freedom Restoration Act (“RFRA”), 42 U.S.C. § 2000bb, the Free Exercise Clause of the First Amendment, the Establishment Clause of the First Amendment, constitutional principles of equal protection, and the Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801 *et seq.*, and its implementing regulations, 21 C.F.R. Parts 1300 - 1316. A number of issues remain in dispute. These issues involve the legality of applying the CSA and its implementing regulations to Plaintiff O Centro Espirita Beneficente Uniao do Vegetal (“UDV”) and its members. The parties explained their positions on the remaining disputed issues in briefs they filed in support of and in opposition to Defendants’ Motion to Dismiss Plaintiffs’ First Amended Complaint [Dkt. # 166-1, 166-2, 178, 182]; in briefs they filed in support of and in opposition to Plaintiffs’ Motion for Leave to File Second Amended Complaint [Dkt. # 172, 173, 174]; and in their presentations during the April 9, 2008 hearing before the Honorable Judge James A. Parker, United States District Judge for the District of New Mexico.

Plaintiff O Centro Espirita Beneficente Uniao do Vegetal and its members import *hoasca*

for use in UDV religious ceremonies. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006). *Hoasca* contains dimethyltryptamine (“DMT”), a Schedule I controlled substance under the CSA, 21 U.S.C. §§ 801 *et seq.* The CSA and its regulations are administered by the United States Department of Justice, Drug Enforcement Administration (“DEA”).

To summarize, Plaintiffs contend that (1) the United States District Court for the District of New Mexico has jurisdiction over Plaintiffs’ claims challenging the regulations; (2) Plaintiffs’ claims challenging the regulations are ripe; (3) Plaintiffs have standing to assert their claims challenging the regulations; (4) the CSA’s regulations are facially inapplicable to the importation, distribution, possession, and use of their sacrament; (5) application of the CSA’s regulations to Plaintiffs would violate Plaintiffs’ rights under RFRA; (6) application of the CSA’s regulations to Plaintiffs would create a standardless licensing scheme in violation of Plaintiffs’ rights under the First Amendment and RFRA; (7) application of the CSA’s regulations to Plaintiffs would entangle the government in religious activity in violation of the First Amendment; (8) because the CSA and its regulatory scheme are neither neutral nor generally applicable, application of the CSA and its regulatory scheme to Plaintiffs would substantially burden their religious practices in violation of Plaintiffs’ First Amendment rights; and, (9) applying the CSA and its regulatory scheme to Plaintiffs, while exempting the Native American Church from the CSA and its regulatory scheme, would violate Plaintiffs’ rights under the First Amendment, constitutional principles of equal protection, and RFRA.

In summary, Defendants contend that (1) no federal court has decided, finally and on the merits, that application of the CSA to Plaintiffs’ *hoasca* use violates RFRA; (2) the regulations promulgated pursuant to the CSA apply to Plaintiffs’ religious use of *hoasca*; (3) the Court lacks

jurisdiction to consider Plaintiffs' claim that the CSA regulations violate RFRA because (a) Plaintiffs have never applied to the DEA for a waiver from any regulation and the court of appeals has exclusive jurisdiction to review the denial of such a waiver, (b) Plaintiffs' pre-enforcement challenge to the regulations is unripe for review, and (c) Plaintiffs lack standing to challenge a regulation that has not been applied to them; (4) as Judge Parker already has found, Plaintiffs' First Amendment claims – that the CSA regulations constitute a standardless licensing scheme, would entangle the government in religious activity, and are not neutral nor generally applicable – lack merit; (5) and, as Judge Parker already has found, Plaintiffs' claims that the Equal Protection and Establishment clauses are violated – by exempting the Native American Church from the CSA regulations but not exempting Plaintiffs – lack merit.

By entering into this Agreement, the parties do not intend to compromise their positions on the disputed issues or to make any concessions with respect to any of the disputed issues. Nothing in this Agreement shall be construed as an admission or concession as to any of the disputed issues in this action. Desiring to amicably resolve the remaining issues about which the parties can agree, and having considered the record before the United States District Court for the District of New Mexico in *O Centro Espirita Beneficiente Uniao do Vegetal v. Ashcroft*, 282 F. Supp. 2d 1236 (D.N.M. 2002); the decisions of the United States Court of Appeals for the Tenth Circuit in *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 342 F.3d 1170 (10th Cir. 2003) and *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 389 F.3d 973 (10th Cir. 2004) (en banc); and the decision of the Supreme Court of the United States in *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006); as well as the experience to date operating under the terms of the Preliminary Injunction [Dkt. #100] entered by Judge Parker on November 13, 2002, Plaintiffs O Centro Espirita Beneficente Uniao Do

Vegetal, *et al.*, and Defendants Eric H. Holder, Jr., Attorney General of the United States; Michele Leonhart, Acting Administrator of the United States Department of Justice, Drug Enforcement Administration (“DEA”); U.S. Customs and Border Protection (“CBP”), *et al.*, through their undersigned counsel, hereby agree as follows:

GENERAL PROVISIONS

1. This Agreement shall not be construed to bar the United States government, or any of its agents or agencies, departments, components, or other subparts, from exercising any of its law enforcement authority to ensure that Plaintiffs’ activities fully comply with U.S. law, except to the extent provided in this Agreement. Subject to the terms and conditions set forth in this Agreement, Defendants, their agencies, agents, employees, and those persons under their control will not apply or enforce the CSA or its implementing regulations governing the legal importation and distribution of DMT, a Schedule I substance, in a way that would violate Plaintiffs’ rights under RFRA or the First or Fifth Amendment to the United States Constitution. Nothing in this Agreement shall restrict or limit CBP’s lawful authority to inspect, sample, detain, or take any other action with regard to Plaintiffs’ *hoasca*, once CBP determines that such activities should be undertaken, for a reason other than the fact that a properly registered shipment of *hoasca* contains DMT, a Schedule I controlled substance.

2. DEA will waive as to Plaintiffs all fees otherwise required under its regulations implementing the CSA. The UDV asserts that, since January 2005, it has been listing its sacramental *hoasca* as a “liquid tea” (Code # 31KMY20 for FDA-US Customs “Prior Notice” Import purposes), and has not paid import fees or customs duties on any of the sixty-one shipments imported during that time period, up to and including the date of this Agreement. Plaintiffs acknowledge that they have not sought a formal ruling on whether *hoasca* is exempt

from current import fees or customs duties pursuant to the procedures set out in 19 C.F.R. Part 177. Plaintiffs reserve the right to object to the imposition of any future import fees or customs duties on any available legal grounds including but not limited to RFRA or provisions of the United States Constitution.

3. Plaintiffs will account for the *hoasca* which they import into this country until its ultimate use or disposal and cooperate with DEA's verification efforts, as described below.

DEA REGISTRATION

4. The Central Office of the UDV will maintain a DEA registration to import the Schedule I controlled substance dimethyltryptamine ("DMT") as described in 21 C.F.R. §§ 1312.11 - 1312.19, with distribution as a coincident activity allowed as described in § 1301.13(e). Each UDV congregation which directly imports *hoasca* shall apply for registration as an importer with distribution as a coincident activity allowed as described in § 1301.13(e). To facilitate accountability and maintain recordkeeping, each UDV congregation which repackages *hoasca* shall also apply for registration as manufacturer, with dispensation in religious ceremonies and distribution to other registered UDV congregations as coincident activities, as described in paragraphs 10 and 33 through 39, below.

a. Except as set forth below, Plaintiffs will submit DEA applications for registration and renewal of registration using the form described in 21 C.F.R. § 1301.13. If DEA makes a reasonable request for additional information that DEA needs to process Plaintiffs' DEA applications, Plaintiffs will provide such information.

b. Each DEA application for registration will list the physical location where the *hoasca* will be stored. Plaintiffs acknowledge that, as registrants, they must apply to modify their registration before the physical location changes. See 21 C.F.R. § 1301.51.

c. Notwithstanding the inclusion of the word “business” in 21 C.F.R.

§§ 1301.13(i) or 1301.14(b), in applying for registration, Plaintiffs may strike out the word “business” on the relevant DEA application form and specify that they are importing and distributing *hoasca* only for religious purposes.

d. Each UDV congregation will maintain its current registration status and may continue its current activities while its DEA application for registration as an importer and/or manufacturer is pending.

5. Plaintiffs will make a DEA application as described in 21 C.F.R. § 1312.12(a) for a permit to import controlled substances, using DEA Form 357, for each consignment of *hoasca* to be imported. DEA will not require Plaintiffs to specify in the DEA-357 the amount of the controlled substance DMT contained in each consignment, as described in 21 C.F.R.

§ 1312.12(a). Plaintiffs shall instead specify the volume of *hoasca* to be imported.

a. Each location registered as an importer will measure its stock of *hoasca*, which will not include the *hoasca* in the possession of other registered locations.

b. The information described in 21 C.F.R. § 1312.12(a)(8) may be stated in liters or other measures of volume, rather than kilograms or other measures of weight.

6. Whenever the DEA application form asks for information pertaining to any “officer, partner, stockholder or proprietor” of the importer, Plaintiffs shall supply the names of officers of the UDV Central Office or congregation, as specified in the records of the state in which the congregation is incorporated at the time of the application for registration.

7. Except as otherwise authorized by law, DEA shall not publish and will not voluntarily disclose the address of any registered location where UDV stores *hoasca*. DEA shall not publish any notice in the *Federal Register* concerning any application by the UDV or a UDV

congregation for registration as importer, manufacturer, or distributor of a Schedule I substance. DEA shall ensure that no UDV registered location appears in the National Technical Information Service (“NTIS”) database.

8. DEA will expedite Plaintiffs’ DEA applications for registration, renewal of registration, and import permits, and will issue import permits.

a. DEA will conduct the initial on-site inspection of each new location for which Plaintiffs seek DEA registration within 30 days of receipt of a complete DEA application, unless justified by exceptional circumstances.

b. DEA will issue registrations for which Plaintiffs have applied within 60 calendar days after receipt of a complete DEA application for registration unless justified by exceptional circumstances.

c. DEA will issue import permits within 30 days of receipt of a complete DEA application unless justified by exceptional circumstances.

9. DEA will not deny Plaintiffs’ DEA applications for registration, renewal of registration, or import permits on the ground that Plaintiffs’ sacramental use of *hoasca* constitutes a basis for denial under 21 C.F.R. §§ 1301.34(b) and (b)(1)-(7). DEA agrees not to enforce the provisions of 21 C.F.R. §§ 1301.34(a), (b)(6), (d)-(f), 1301.35(b), Part 1303, and §§ 1304.33, 1312.13(a), and 1313.13(a) against Plaintiffs for the sacramental use of *hoasca*.

10. If Plaintiffs decide to manufacture *hoasca* from plants grown in the United States, Plaintiffs will apply to DEA for registration as a bulk manufacturer. Plaintiffs will determine the amount of *hoasca* to be imported or manufactured solely for their religious use. Plaintiffs acknowledge that, if in the future, a DEA application to import or manufacture a substance containing DMT is filed with DEA by a third party, DEA may initiate quota proceedings under

21 C.F.R. Part 1303 to determine the total amount which should be authorized to be imported and/or manufactured to meet all anticipated legitimate needs. In any quota proceeding, DEA will not seek to limit the quantity of *hoasca* necessary for Plaintiffs' religious use.

IMPORTATION OF HOASCA

11. Plaintiffs shall provide two weeks' advance notice to the DEA Point of Contact (defined in paragraph 46 below) of the identity of the courier and the date, time, place of entry, airline information, and connecting flights of a particular international shipment. Plaintiffs shall promptly advise the DEA Point of Contact of any changes in the itinerary. The DEA Point of Contact will undertake to coordinate the shipment with its local offices to facilitate the shipment's delivery to the importing Central Office or congregation. DEA will reasonably coordinate with the Department of Homeland Security in an effort to facilitate processing and clearance of shipments through the U.S. port of entry.

a. To facilitate DEA's efforts to coordinate shipments, Plaintiffs have advised DEA that they initially intend to import *hoasca* through ports of entry in Miami, Atlanta, Los Angeles, and Dallas. Plaintiffs' Point of Contact, as defined in paragraph 45 below, will inform DEA's Point of Contact of any changes in the ports of entry.

b. To facilitate the movement of shipments, Plaintiffs will ensure that their authorized couriers carry with them copies of the appropriate DEA import registration certificate (Form 223), together with a copy of the import permit (Form 35) authorizing the particular shipment.

12. Notwithstanding 21 C.F.R. § 1312.15, if a consignment of *hoasca* is detained by CBP officials because the amount consigned is significantly greater than the amount authorized by the import permit, DEA will work with Plaintiffs to remedy the discrepancy through the

issuance of an amended import permit to facilitate the prompt clearance by CBP of the shipment upon Plaintiffs' provision to DEA of a satisfactory non-diversionary explanation as to the discrepancy. Such shipments will be detained by CBP pending a satisfactory, non-diversionary explanation by Plaintiffs as to the discrepancy. Plaintiffs have explained that the consigned volume of *hoasca* may be as much as 5% greater than or less than the volume specified in the permit due to (1) the thermal contraction of *hoasca*, which is packaged at high temperatures but arrives at Ports of Entry at ambient temperatures over which Plaintiffs have no control and (2) variable rates of precipitation of inactive dissolved solids at the bottom of containers of *hoasca*.

13. All goods, conveyances, and persons are subject to search upon entry into the United States from a foreign country upon the demand of any CBP official. *See* 19 U.S.C. §§ 482, 1433, 1459, 1461, 1582; 8 U.S.C. § 1357; 19 C.F.R. Part 162; 8 C.F.R. Part 235.

INSPECTIONS AND RECORD-KEEPING

14. Each UDV registered location shall establish and maintain on a current basis a complete and accurate written record of its importation, receipt, distribution, and disposal of *hoasca* in accordance with 21 C.F.R. § 1304.21 *et seq.* Each UDV registered location shall take a physical inventory of all *hoasca* at least once a year. All transfers of *hoasca* from an importer registration location to another registered location shall be documented on a DEA Form 222, Official Order Form, as described in 21 C.F.R. § 1305. All required records shall be in readily retrievable form and available for inspection upon request by DEA for a minimum of two years. See 21 C.F.R. §§ 1304.04, 1304.11, 1304.21-1304.22, 1305.

15. Plaintiffs shall maintain records of their dispensation of *hoasca*, listing the date dispensed; the number of participants in the religious ceremony or event who received *hoasca*; the total amount of *hoasca* consumed during the ceremony or event; and the dispenser's initials.

Plaintiffs' records will also identify the batch(es) and container(s) from which the consumed *hoasca* was taken. See 21 C.F.R. § 1304.24(a).

16. DEA may inspect any location which Plaintiffs seek to register as an import, manufacture, or distribution location. See 21 C.F.R. § 1301.31. Plaintiffs will cooperate with any such inspection. During on-site inspections and audits at registered locations, DEA Diversion Investigators will offer educational materials and tutoring as to the conduct described in 21 C.F.R. Part 1304.

17. DEA has the authority to enter registered premises and conduct administrative inspections and audits at reasonable times and in a reasonable manner. See 21 C.F.R. § 1316.03. DEA shall not conduct administrative inspections during UDV-authorized religious ceremonies. The DEA acknowledges that the registered locations where UDV stores *hoasca* are not businesses with regular business hours, and, accordingly, that it might be necessary to make arrangements before the inspection to ensure that an authorized person, as defined in paragraph 28, is available at the time the DEA seeks to conduct an inspection. If representatives of the DEA arrive at a registered location unannounced and an authorized person is not present, the DEA representatives will promptly attempt to notify an authorized person of their intent to inspect the location, and the authorized person will make every reasonable effort to ensure that DEA representatives are able to inspect the location promptly. DEA representatives may only enter a registered location to conduct an administrative inspection pursuant to 21 C.F.R. § 1316.03 when an authorized person is present at the location.

18. Plaintiffs will provide the DEA Point of Contact, as defined in paragraph 46 below, with general information about the times and locations of their ceremonies. Plaintiffs will notify DEA in writing of any significant changes to this information.

19. During administrative inspections, DEA may inspect, copy, and verify the correctness of any records which Plaintiffs are required to maintain, including inventory records.

20. During administrative inspections, DEA may take a physical inventory of all *hoasca* on the premises. Plaintiffs' authorized individuals, as defined in paragraph 28, at each location will assist in the physical inventory by handling the containers of *hoasca* so that their labels can be read by DEA personnel without the need for DEA personnel to physically touch the containers.

21. If DEA seeks to inspect an item or items as described in 21 C.F.R. § 1316.03(f) and Plaintiffs believe that DEA's inspection of the item or items would violate their right to freedom of association or the freedom of association of others associated with the UDV, Plaintiffs may package the item or items in a container in the presence of DEA personnel; DEA personnel will affix a seal to the container. DEA may then submit an application for an administrative inspection warrant to a United States District Judge or Magistrate Judge as described in 21 C.F.R. § 1316.09. Plaintiffs agree that the seal will remain unbroken and that the container will not be opened until a determination is made by a court of competent jurisdiction whether the item(s) can lawfully be inspected by DEA.

22. Plaintiffs shall assign a unique identifier to each batch and container of *hoasca* that is received through international shipment. The DEA import permit number shall also appear on each container. Each container being imported into the United States shall bear a sufficiently prominent label with clear and sufficiently large symbols to enable DEA personnel to read from arm's-length distance the DEA permit number, point of origin (city, state/province, and country), batch identifier, end location, quantity, and date shipped.

23. To facilitate maintenance of a chain of custody, the unique identifier shall follow the

imported *hoasca* and shall be used in Plaintiffs' records until its ultimate use or disposal and shall also appear on any container into which imported *hoasca* from a particular batch or consignment may be decanted or repackaged.

24. Each imported batch and container shall remain vacuum sealed and unopened from its arrival at a U.S. port of entry until its receipt at the registered import location. Plaintiffs shall ensure that the vacuum seal is tamper-resistant and tamper-evident. DEA will reasonably coordinate with the Department of Homeland Security to facilitate movement of shipments through the U.S. port of entry.

25. DEA may spot sample any consignment of imported *hoasca* once it has arrived at the registered location for the purpose of confirming that the consignment in fact contains *hoasca* and no controlled substance other than dimethyltryptamine.

a. DEA will notify Plaintiffs' Point of Contact, as defined in paragraph 45 below, of DEA's intent to obtain a sample, which shall be taken when a sealed container, secured with a tamper-resistant and tamper-evident seal, is received by the registered importer at the registered location.

b. When requested by DEA to do so, a UDV authorized individual, as defined in paragraph 28 below, will extract an unadulterated sample of up to 50 milliliters of *hoasca* under the observation of DEA personnel. The authorized individual will place the sample in a container, to be provided by DEA, which will be shipped directly to a DEA forensics laboratory for testing.

c. DEA will not return the sample to Plaintiffs. Storage and/or disposal of samples will be solely within the discretion of DEA.

STORAGE AND SECURITY

26. Plaintiffs acknowledge their obligation to provide effective controls and procedures to guard against theft and diversion.

27. Plaintiffs may designate any individual(s) of their choice to handle *hoasca* when conducting religious ceremonies and performing religious functions.

28. Plaintiffs agree to limit access to stored *hoasca* outside the context of religious ceremonies to two specifically authorized individuals at each registered location at any given time. The authorized individuals will be the only persons who will have access to and/or custody of the keys or combinations to the locks of the UDV refrigerator and/or storage room dedicated to the storage of *hoasca*, or handle *hoasca* outside the context of religious ceremonies.

a. Plaintiffs shall designate in writing the two authorized individuals at each registered location.

b. Plaintiffs shall provide written notification of the names (including aliases and maiden names, where applicable), dates of birth, and social security numbers of each authorized individual to the DEA Point of Contact, as defined in paragraph 46 below, and to the local DEA Diversion Program Manager.

c. DEA may conduct appropriate inquiries to ascertain whether an authorized individual has been convicted of a felony relating to controlled substances. If DEA discovers that an authorized individual has been convicted of such a felony, DEA will promptly so advise the UDV Point of Contact, as defined in paragraph 45 below. The parties' Points of Contact will discuss whether, based on all the facts and circumstances of the particular case, in light of Plaintiffs' religious concerns and DEA's security concerns, the authorized individual should have access to or custody of the locked refrigerator and/or room in which *hoasca* is stored or

handle *hoasca* outside the context of religious ceremonies. This Agreement does not address the forum in which a disagreement over this issue should be resolved or whether RFRA considerations may be implicated.

d. Whenever anyone, other than an authorized individual, or an authorized official or agent of the U.S. government, is present in the room in which *hoasca* is stored at a registered location, that person shall be accompanied at all times by an authorized individual. Plaintiffs will not designate anyone other than an authorized person to transport *hoasca*.

29. DEA will conduct a preregistration inspection of any location at which DEA registration is sought. In evaluating the overall security system and the needs of each registrant, DEA will consider the factors enumerated under 21 C.F.R. § 1301.71(b) to properly safeguard the *hoasca* under the control of each registrant. The parties agree that the DEA Diversion Program Manager and Plaintiffs' representative at each location will engage in discussions to attempt to arrive at a mutually agreeable security plan based on the security needs of each specific location and commensurate with the quantity stored.

30. As to Plaintiffs, DEA agrees to enforce only the modified versions of the specific physical security measures described in 21 C.F.R. § 1301.72(a) through (c) as set forth in this Agreement.

31. At all registered locations, *hoasca* will be stored in a room which is protected by a solid core door and a deadbolt lock. Plaintiffs aver that *hoasca* which has been repackaged and is no longer in a vacuum-sealed container must be refrigerated. At all registered locations, any refrigerated *hoasca* will be stored in a locked refrigerator which is used solely for the purpose of storing *hoasca*. In the event there is any diversion, theft, or significant loss of *hoasca* from a registered location, Plaintiffs and Defendants will discuss what, if any, additional security

measures are reasonably necessary to prevent future theft. Plaintiffs will maintain at Plaintiffs' expense at the current UDV Central import and storage location a 24-hour alarm system through which a report of any unauthorized access to the location will be immediately transmitted to a protection company with a duty to respond or to the appropriate local law enforcement agency. Defendants acknowledge that UDV is not required to install and maintain such alarm systems at its other registered locations.

32. When importing or domestically distributing *hoasca*, each registrant is responsible for selecting couriers or contract carriers that provide adequate security to guard against in-transit loss, as described in 21 C.F.R. § 1301.74(e).

33. Plaintiffs will immediately advise the DEA Point of Contact and the local Diversion Program Manager of any diversion, theft, or significant loss of *hoasca*. Written notification must be made within one business day of discovery of the diversion, theft, or loss. A completed DEA Form 106, Report of Theft or Loss of Controlled Substances, shall accompany the notification.

MANUFACTURE AND DISTRIBUTION

34. Plaintiffs aver that it is sometimes necessary to decant stored *hoasca*, clear off mold and other impurities, and boil the *hoasca* in order to render the *hoasca* suitable for use. Plaintiffs agree to measure the volume of *hoasca* before and after boiling and to maintain a written record of all such processing of *hoasca* memorializing any incidental change of volume.

35. Plaintiffs routinely distribute *hoasca* from registered import locations to other congregations in the original containers in which it was imported, which constitutes distribution incidental to importation. As to such distribution incidental to importation by Plaintiffs, DEA agrees not to enforce the DEA regulations applicable to distributors, except as provided by this Agreement.

36. Plaintiffs will conduct themselves in conformity with 21 C.F.R. Part 1305, except that Plaintiffs will complete the relevant order forms as follows:

a. At the time the *hoasca* is sent to the congregation, the import location (the Supplier) shall complete his portion of the order form in accordance with 21 C.F.R. Part 1305, fill the order for the congregation which ordered the *hoasca* (the Purchaser), and retain copy one (the Supplier's copy) of the DEA order form for their records. The import location shall simultaneously mail copy 2 of the DEA Form 222 to the local DEA office. A copy of the DEA 222 order form shall also be supplied to the Point of Contact at DEA Headquarters at the time the form is executed.

b. The congregation receiving the *hoasca* will annotate on copy 3 of the form, the amount (Number of Packages and total volume) received, and the Date of Receipt. If the volume received differs from the amount indicated on the form as having been shipped, Plaintiffs shall immediately inform the DEA point of contact and the local Diversion Program Manager of the discrepancy. All executed DEA 222 order forms will be kept at the registered location for a minimum of two years.

37. Plaintiffs aver that they may sometimes find it necessary to combine batches and boil them into a union of different batches, which would then be packaged as a new batch before on-site religious use or distribution to other congregations. Plaintiffs also aver that some loss of volume may occur during the boiling of the *hoasca* due to evaporation. UDV agrees to keep a written record of the volume of each batch before combining them and to keep a record of the total volume after boiling.

38. All manufacturing activities, including processing, packaging, and labeling, shall be conducted at the registered location by an authorized person. All *hoasca* being processed,

packaged, or labeled, shall be securely locked at the end of the activity as provided in paragraph 31 above.

39. If *hoasca* originating from one batch is mixed with *hoasca* originating from a different batch, the resulting mix shall be stored in containers labeled with the unique identifiers of any and all originating batches and the precise volume taken from each.

40. Plaintiffs shall maintain inventories of all repackaged *hoasca* for a minimum of two years. See 21 C.F.R. § 1304.11.

DISPOSAL

41. Plaintiffs aver that it is sometimes necessary to dispose of *hoasca* in a manner which will render it unavailable for future use. When Plaintiffs determine that it is necessary to make final disposition of *hoasca*, the registrant shall advise the Special Agent in Charge (“SAC”) of the area by submitting a DEA Form 41 listing the amount of tea to be disposed of, identifying the batch and container in which it was imported, stating the date, time, and place at which Plaintiffs propose to dispose of the *hoasca*, and identifying the individuals who will take part in the *hoasca* disposal. Plaintiffs shall give the SAC a minimum of fourteen days’ advance notice of their intent to dispose of *hoasca*.

42. The SAC and/or designee shall have the discretionary authority to observe the disposal of *hoasca*.

43. By observing the disposal of *hoasca*, DEA does not approve or endorse the disposal method selected by Plaintiffs. Plaintiffs accept sole responsibility for compliance with all applicable federal, state, and local laws implicated by disposal of *hoasca*.

DENIAL, SUSPENSION, OR REVOCATION OF REGISTRATIONS AND DISPUTE
RESOLUTION

44. Except as specifically stated above, the parties do not agree (1) whether the regulations governing denial, suspension, or revocation of registrations apply to Plaintiffs or (2) the proper forum in which future disputes between the parties are to be resolved. Defendants contend that the Administrator of DEA may suspend or revoke a registration by serving upon Plaintiffs an order to show cause pursuant to 21 C.F.R. § 1307.37 and, if requested by the registrant, holding a hearing pursuant to 21 C.F.R. § 1301.41 before an Administrative Law Judge. Defendants also contend that the United States Courts of Appeals have exclusive jurisdiction to review any final agency decision by the DEA. Plaintiffs contend that the Administrator of the DEA cannot lawfully revoke or suspend Plaintiffs' registrations except through an appropriate judicial proceeding as contemplated in the Religious Freedom Restoration Act or any applicable constitutional provisions, and that all future disputes between the parties with respect to Plaintiffs' importation, possession, distribution, and use of *hoasca* should be resolved in the United States District Court for the District of New Mexico. Nothing in this Agreement shall be construed as a waiver by Plaintiffs of any of their rights, including, without limitation, their rights under RFRA, the First Amendment, and principles of equal protection. Nothing in this Agreement shall be construed as a concession by any party with respect to (1) the appropriate procedure for revoking or suspending Plaintiffs' registrations; (2) the appropriate procedure for denying any registration Plaintiffs seek; or (3) the forum in which future disputes between the parties will be resolved. Nothing in this Agreement shall be construed as a waiver by any party with respect to any claim relating to (1) the appropriate procedure for revoking or suspending Plaintiffs' registrations; (2) the appropriate procedure for

denying any registration Plaintiffs seek; or (3) the forum in which future disputes between the parties will be resolved.

POINTS OF CONTACT

45. Plaintiffs shall designate a primary Point of Contact to coordinate importation, storage, and distribution of *hoasca* and act as liaison with DEA. Jeffrey Bronfman or his designee will serve as Plaintiffs' initial primary Point of Contact.

46. Defendants shall designate a primary Point of Contact on importation, storage, and distribution issues and act as liaison with Plaintiffs. James Arnold, the Chief of the Regulatory Unit in the Office of Diversion Control in DEA Headquarters, or his designee, will serve as Defendants' initial primary Point of Contact.

ATTORNEYS' FEES

47. Plaintiffs agree to accept and Defendants agree to pay the amount of [REDACTED] [REDACTED] in full and final settlement and satisfaction of any and all claims by Plaintiffs and their undersigned counsel and all persons currently or formerly associated with undersigned counsel as partner, associate, contractor, co-counsel, or otherwise, pursuant to any statute or any other basis, for attorneys' fees, expenses, and costs for work performed on the above-referenced matter. Included within this Agreement are any claims for fees-on-fees, enhancement of fees, costs, or expenses. Defendants agree to submit this payment for processing within 10 days of the execution of this Agreement.

48. Payment will be made to Freedman Boyd Hollander Goldberg Ives & Duncan, P.A., who will be responsible for allocating the total payment among all Plaintiffs, their counsel, expert witnesses, or any other individuals that may have a claim for all or part of this sum. Counsel for the Plaintiffs declares that she is authorized to collect the total payment on behalf of

Plaintiffs.

49. Neither this Settlement Agreement nor the payment of attorneys' fees, costs, and expenses hereunder is an admission by Defendants of the truth of any allegation or the validity of any claim asserted in this action, or of Defendants' liability therein. The provision of attorneys' fees, expenses, and costs in this Settlement Agreement is by the agreement of the parties and is not intended to serve as precedent, nor may it be cited as such, in this or any case.

50. Compliance with all applicable federal, state, and local tax requirements shall be the sole responsibility of Plaintiffs and their attorneys.

RESOLUTION OF DISPUTES ARISING OUT OF THIS AGREEMENT

51. This Agreement does not address the proper forum in which any future disputes will be resolved.

RELEASE, DISCHARGE, AND DISMISSAL OF PLAINTIFFS' CLAIMS

52. Upon the execution of this Settlement Agreement, and receipt of the agreed upon payment described in paragraph 47, Plaintiffs hereby release and forever discharge Defendants and their successors, the United States of America, and any department, agency, or establishment of the United States, and any officers, employees, agents, successors, or assigns of such department, agency, or establishment, from any and all past, present, or future claims for attorneys' fees, costs, or litigation expenses in connection with this litigation.

53. Upon the execution of this Settlement Agreement, Plaintiffs hereby release and forever discharge Defendants, and their successors, the United States of America, and any department, agency, or establishment of the United States, and any officers, employees, agents, successors, or assigns of such department, agency, or establishment, from any and all claims and causes of action that Plaintiffs assert or could have asserted in this litigation.

54. This Settlement Agreement contains the entire agreement between the parties hereto, and Plaintiffs acknowledge that no promise or representation not contained in this Agreement has been made to them and further acknowledge that this Settlement Agreement contains the entire understanding between the parties, and contains all terms and conditions pertaining to the compromise and settlement of the disputes referenced herein.

55. Within ten days of the receipt of the payment described in paragraph 47, Plaintiffs shall dismiss this case with prejudice pursuant to Fed. R. Civ. P. 41(a) by filing a Stipulation of Dismissal with Prejudice.

56. The undersigned represent that they are fully authorized to enter into this Agreement.

For Plaintiffs:



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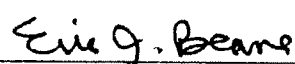
Dated: 7/16/10



JEFFREY BRONFMAN
On behalf of the Plaintiffs
and as President of UDV-USA

Dated: 7/19/2010

For Defendants:



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Dated: 7-14-10