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UNITED STATES DISTRICT COURT
ALBUQUERQUE, NEW MEXICO

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

NOV 13 2002

O CENTRO ESPIRITA BENEFICIENTE)
 UNIAO DO VEGETAL, et al.,)
)
 Plaintiffs,)
)
 v.)
)
 JOHN ASHCROFT, et al.,)
)
 Defendants.)
 _____)

R. Horton March
CLERK

) No. CV 00-1647 JP/RLP

PRELIMINARY INJUNCTION

This matter came before the Court for hearing on the motion of Plaintiffs for preliminary injunction. After considering all the evidence admitted in support of and in opposition to Plaintiffs' motion, and having considered the arguments and briefs of counsel, the Court entered its Memorandum Opinion and Order of August 12, 2002. The Court's Memorandum Opinion and Order is incorporated herein by reference.

As set forth in the August 12 Memorandum Opinion and Order, the Court concludes that plaintiffs have met the standards necessary for preliminary injunctive relief:

First: The plaintiffs have demonstrated a substantial likelihood of success on the merits of their claim under the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb.

Second: The plaintiffs will suffer irreparable harm as a result of the impact of the defendants' conduct on the plaintiffs' ability to practice their religion unless the defendants are preliminarily enjoined from further interfering with the plaintiffs' practice of their religion.

Third: The threatened injury to the plaintiffs outweighs any injury to the defendants resulting from this injunction.

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Fourth: The public interest in the vindication of religious freedoms favors the entry of a preliminary injunction.

The Court therefore preliminarily enjoins Defendants as follows, and under the terms and conditions set forth below, from prohibiting or penalizing the sacramental use of *hoasca* by participants in bona fide religious ceremonies of the O Centro Espirita Beneficiente Uniao Do Vegetal (UDV).

1. The Defendants, their agencies, agents, employees, and those persons under their control are preliminarily enjoined from directly or indirectly treating Plaintiffs' importation, possession, and distribution of *hoasca* for use in bona fide religious ceremonies of the UDV as unlawful under the Controlled Substances Act ("CSA"). During the pendency of this injunction, the Defendants, their agencies, agents, employees, and those persons under their control shall not intercept or cause to be intercepted shipments of *hoasca* imported by the UDV for religious use, prosecute or threaten to prosecute the UDV, its members, or bona fide participants in UDV ceremonies for religious use of *hoasca*, or otherwise interfere with the religious use of *hoasca* by the UDV, its members, or bona fide participants in UDV ceremonies, subject to the terms and conditions set forth below.
2. Plaintiffs shall conduct themselves in accordance with the conduct that is described in the laws and regulations governing the importation and distribution of Schedule I Controlled Substances as set forth at 21 U.S.C. §§ 801-971 and 21 C.F.R. §§ 1300-1316, except as indicated below. Where this Order enjoins or modifies the application of a particular regulatory provision, the corresponding statutory provision shall be enjoined or modified accordingly. The Court preliminarily enjoins the Defendants from imposing on plaintiffs regulatory or other requirements, which by their terms apply to the importation, distribution, possession or religious use of *hoasca*, not set forth in this Order, without

further order of the Court. This prohibition shall not be construed to bar the United States Customs Service from discharging its normal duties with respect to the general oversight of international commerce.

3. By requiring the Plaintiffs to abide by the conduct set forth in the identified regulations, the Court makes no decision regarding whether the application of any such requirements does or does not violate the RFRA; nor does the Court decide whether any future enforcement of these requirements by DEA against the Plaintiffs will or will not violate RFRA. Similarly, by enjoining Defendants from requiring Plaintiffs to adhere to certain conduct set forth in the identified regulations, the Court makes no decision regarding whether the application of any such requirements would or would not violate the RFRA.
4. Defendants are enjoined from requiring the Plaintiffs to conform their conduct to the following regulations: 21 C.F.R. §§ 1301.34(a), 1301.34(b)(3), 1301.34(b)(5), 1301.34(b)(6), 1301.34(d), 1301.34(e), 1301.34(f), 1301.35(b), Part 1303, 1304.33, and 1312.13(a).
5. In applying for registration to import and distribute a controlled substance, Plaintiffs may strike out the word “business” on the relevant application form and specify that they are importing and distributing *hoasca* for religious purposes only. This modification of the form may not be deemed inconsistent with the requirements of 21 C.F.R. §§ 1301.13(i) or 1301.14(b). The Central Office of the UDV shall apply for registration as an importer, with distribution being a coincidental activity. The Central Office shall also apply on behalf of each individual congregation for registration as a distributor.
6. Where the relevant application form asks for information pertaining to “any officer, partner, stockholder or proprietor” of the UDV, these terms shall be deemed to apply to the

officers of the UDV as specified in the records of the New Mexico Corporation Commission at the time of application for registration.

7. If requested by DEA pursuant to 21 C.F.R. §§ 1301.14(d), 1301.15, or 1312.13(d), Plaintiffs shall provide the identities and social security numbers of those persons within the UDV who routinely handle *hoasca* outside of ceremonies. Plaintiffs shall not be required to provide the identities or social security numbers of any other UDV members.
8. Inasmuch as persons of authority within the UDV are not UDV “employees,” the requirements of 21 C.F.R. §§ 1301.90-93 shall not apply. Instead, Plaintiffs are required to adhere to the conduct set forth in those sections, replacing the word “employee” with “person of authority within the UDV,” defined as UDV members who are authorized to handle *hoasca* outside of ceremonies.
9. Inasmuch as persons of authority within the UDV are not UDV “employees,” 21 C.F.R. § 1301.72(d) shall not apply. Instead, Plaintiffs are required to adhere to the following conduct: If someone, other than a person of authority within the UDV, is present in the room in which the *hoasca* is stored or a vehicle in which the *hoasca* is being conveyed (other than delivery by common carrier), that person shall be accompanied at all times by a person of authority within the UDV.
10. The requirements in 21 C.F.R. § 1312.12(a)(5) will be construed to mean that the Central Office of the UDV in Santa Fe, as importer, will measure its stock of *hoasca*, which will not include the *hoasca* in the possession of other registered locations.
11. The information required under 21 C.F.R. § 1312.12(a)(8) may be stated in liters or other measure of volume rather than kilograms.
12. The physical inventories referenced in 21 C.F.R. § 1316.03(c) shall be conducted by DEA,

except that the actual handling of the containers of *hoasca* will be by the responsible UDV representatives under the direction and oversight of DEA personnel.

13. If DEA asks to inspect an item or items pursuant to 21 C.F.R. § 1316.03(f), and Plaintiffs believe that DEA's inspection of such item or items would violate their right to freedom of association or the freedom of association of others associated with the UDV, Plaintiffs may withhold such items from inspection pending a determination by this Court of whether they may be lawfully inspected.
14. The requirement of 21 C.F.R. § 1316.05 that inspections be carried out at reasonable times and in a reasonable manner applies to inspections authorized under 21 C.F.R. § 1316.03 and shall be construed to prohibit inspections during bona fide religious ceremonies of the UDV.
15. In lieu of the requirements in 21 C.F.R. § 1307.21(b), Plaintiffs and Defendants shall arrive at a mutually acceptable means of disposal of any *hoasca* that must be disposed of, which means shall not include forfeiture to Defendants.
16. Defendants are enjoined from requiring Plaintiffs to specify the amount of dimethyltryptamine (DMT) to be imported in their application for an import permit, as provided for under 21 C.F.R. § 1312.12(a). Plaintiffs shall instead specify the volume of *hoasca* to be imported, and indicate that the concentration of DMT in the imported *hoasca* is the concentration contained in the sample provided to DEA.
17. Plaintiffs shall assign a unique identifying number to each batch of *hoasca* that is received through international shipment. Immediately upon receipt of such shipment, Plaintiffs shall extract an unadulterated small sample (not significantly more or less than 60 ml) from each batch shipped, and shall label each sample with the number of the batch from which it was

taken. Plaintiffs shall also arrange to have a small sample of each batch of shipped *hoasca* preserved in Brazil, labeled with the number that corresponds to the batch of *hoasca* from which the sample was taken. These samples shall be made available to DEA on request, and shall in any case be preserved for a period of three (3) years. Any untested samples made available to DEA shall be returned to the Plaintiffs after three years.

18. Each container of *hoasca* in Plaintiffs' possession and control will be labeled with the number of the batch from which its contents were taken. 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 numbers of any and all originating batches and the precise volume that was taken from each such batch.
19. Defendants are enjoined from denying Plaintiffs' applications for registration to import and distribute *hoasca* or for an import permit on the grounds that Plaintiffs' religious use of *hoasca* is prohibited by the CSA and/or international treaties, conventions, or protocols (21 C.F.R. § 1301.34(b)); is inconsistent with state and/or local law (21 C.F.R. § 1301.34(b)(2)); or is inconsistent with public health and safety (21 C.F.R. § 1301.34(b)(7)).
20. Defendants are enjoined from denying Plaintiffs' applications for registration to import and distribute *hoasca* or for an import permit on any of the following grounds: (a) the government must restrict importation to a number of establishments which can produce an adequate and uninterrupted supply of *hoasca* under adequately competitive conditions (21 C.F.R. § 1301.34(b)(1)); (b) importation of *hoasca* by Plaintiffs would not promote technical advances in the art of manufacturing *hoasca* and developing new substances (21 C.F.R. § 1301.34(b)(3)); (c) Plaintiffs lack sufficient past experience in the manufacturing

of controlled substances (21 C.F.R. § 1301.34(b)(5)).

21. Defendants are enjoined from enforcing 21 C.F.R. § 1301.34(b)(6) to restrict the amounts of *hoasca* imported by Plaintiffs.
22. Defendants are enjoined from charging Plaintiffs an application fee in connection with their applications for registration to import and distribute *hoasca*, and from enforcing 21 C.F.R. § 1301.21(b) against Plaintiffs. To the extent that Plaintiffs' nonpayment of an application fee is inconsistent with any of the requirements of 21 C.F.R. §§ 1301.13(e) or 1301.14(a), those requirements shall not be enforced.
23. Defendants are enjoined from enforcing the specific storage requirements of 21 C.F.R. § 1301.72(a) and are enjoined from enforcing 21 C.F.R. § 1301.71(a) insofar as that subsection would require Plaintiffs to employ materials and construction which provide a structural equivalent to the physical security controls set forth in 21 C.F.R. §§ 1301.72, 1301.73 and 1301.75.
24. The initial on-site inspection by the Drug Enforcement Administration (21 C.F.R. § 1301.31) of each UDV location applying for registration will take place within two (2) weeks of receipt of the application for registration of that location. The *hoasca* will be stored in a pad-locked refrigerator in a locked room at each UDV location where it is stored. The highest Church authority at each location will retain custody of the keys to the locks for the refrigerator and to the room where the *hoasca* is stored. If DEA after its on-site inspections takes the position that Plaintiffs' security measures are not in substantial compliance with the DEA's regulatory standards for the physical security controls and operating procedures necessary to prevent diversion of the *hoasca*, and if DEA and Plaintiffs are unable to agree on a mutually acceptable means and time frame for resolving

the issue, Defendants shall, within one (1) week of the on-site inspection, apply to the Court for resolution of the issue by filing a statement setting forth the basis for DEA's position.

25. The Drug Enforcement Administration will expedite Plaintiffs' applications for registration to import and distribute *hoasca* and Plaintiffs' application for an import permit. The DEA shall issue Plaintiffs a registration to import *hoasca*, a registration to distribute *hoasca*, and an import permit within thirty (30) days of receipt of Plaintiffs' applications for such items, or will show cause before this Court why such items have not yet been issued.

Immediately upon registration, the UDV may resume its religious services using the *hoasca* presently in its possession, subject to compliance with the conduct set forth in this Order.

The provisions of 21 C.F.R. § 1301.13(a) notwithstanding, Plaintiffs are entitled to import and distribute *hoasca* immediately upon issuance of the applicable registrations, even if the Certificate of Registration has not yet been issued.

26. Plaintiffs shall keep records relating to their dispensation of *hoasca* as set forth at 21 C.F.R. § 1304.24(a), with the following qualifications: subsection (a)(2) shall not apply, and Plaintiffs shall instead be required to list the appropriate batch number (as discussed above in paragraphs 17-18); subsection (a)(5) shall not apply, and Plaintiffs shall instead be required to indicate the number of bona fide participants in the religious ceremony/event who received *hoasca*; under subsection (a)(6), Plaintiffs shall specify the total amount of *hoasca* consumed during the ceremony/event.

27. If Defendants confiscate any shipment of *hoasca* under 21 C.F.R. § 1312.15(a) because the amount imported exceeds the amount specified on the import permit, they shall preserve all of the confiscated *hoasca* and return it to Plaintiffs promptly upon a satisfactory, non-

diversion explanation by Plaintiffs as to the additional amount. If any of the confiscated *hoasca* is delivered to any other departments, bureaus, or agencies of the United States or any State pursuant to 21 C.F.R. § 1307.22, said departments, bureaus, or agencies will similarly preserve the *hoasca* pending Plaintiffs' explanation.

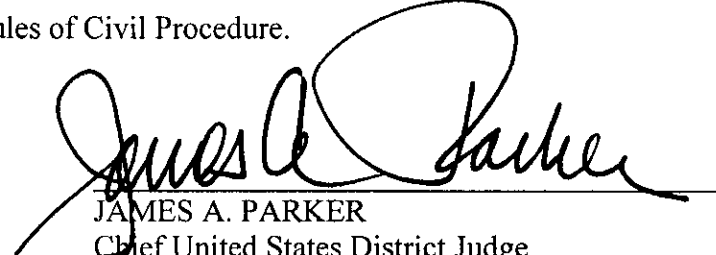
28. Plaintiffs will comply with the requirements of 21 C.F.R. Part 1305, except that Plaintiffs shall complete the relevant order forms as follows: The Central Office of the UDV will fill out the order forms when sending any *hoasca* to any UDV congregation. At the time the *hoasca* is sent to the congregation, the UDV will mail one copy of the form to the site receiving the *hoasca* and one copy to the DEA, and will retain its own copy. The site receiving the *hoasca* will annotate the form to specify the volume of *hoasca* received. If the volume received differs from the volume shipped (as indicated on the form), Plaintiffs shall notify DEA immediately of the discrepancy.
29. The provisions of 21 C.F.R. §§ 1301.36 and 1312.16(a) notwithstanding, Defendants are enjoined from suspending or revoking Plaintiffs' registration to import and/or distribute *hoasca* and/or Plaintiffs' import permit on any grounds other than the following: (a) material falsification of an application; (b) conviction of the registrant of a felony relating to a controlled substance; or (c) evidence of diversion of *hoasca* for which Plaintiffs are responsible. If Defendants believe that evidence exists that *hoasca* has negatively affected the health of UDV members, Defendants may apply to the Court for an expedited determination of whether such evidence warrants suspension or revocation of Plaintiffs' registration. If Defendants believe that a shipment of *hoasca* contain particularly dangerous levels of DMT, Defendants may apply to the Court for an expedited determination of whether the evidence warrants suspension or revocation of Plaintiffs'

registration. If the United States, subsequent to the date of this Order, enters into a treaty or other international agreement that Defendants believe clearly prohibits the importation and/or distribution of *hoasca*, Defendants may apply to the Court for an expedited determination of whether the treaty or international agreement warrants suspension or revocation of Plaintiffs' registration.

30. The Defendants, their agencies, agents, employees, and persons under their control, are enjoined 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 *hoasca* in a manner that is inconsistent with this Court's August 12, 2002, Memorandum and Opinion.
31. To enable Defendants to distinguish between authorized and unauthorized uses of *hoasca*, Plaintiffs will provide Defendants with general information about the times and locations of their ceremonies immediately upon entrance of this Order. Plaintiffs will notify Defendants in writing in advance of any significant changes to this information.
32. Plaintiffs shall maintain a thorough, accurate, updated list of prescription drugs, subject to reasonable inspection and approval by Defendants on a periodic basis, that may adversely interact with MAO inhibitors. Plaintiffs shall provide this list to all current and prospective members, shall inform them of the possibility of adverse interactions between these drugs and *hoasca*, and shall encourage them to notify a health care professional if they believe they may have experienced such an adverse interaction. These communications shall take place prior to any ingestion of *hoasca*, and shall be accomplished in one or both of the following ways: (a) direct mailing to the individual

- member/potential member; (b) hand delivery to the individual member/potential member.
33. Plaintiffs shall inform all current and prospective members in writing that if they have a history of psychosis or psychotic episodes they may be particularly susceptible to an adverse reaction in using *hoasca*, and shall encourage such persons to seek the advice of a health care professional if they fall within this category. These communications shall take place prior to any ingestion of *hoasca*, and shall be accomplished in one or both of the following ways: (a) direct mailing to the individual member/potential member; (b) hand delivery to the individual member/potential member.
34. Defendants, their agencies, agents, and employees may not be held legally or otherwise responsible for any injury or other adverse effect incurred by any person or property as a direct or indirect result of Plaintiffs' importation, possession, distribution, and use of *hoasca*.
35. Plaintiffs will designate one person to coordinate importation, storage, and distribution of the *hoasca*, and to serve as a liaison with DEA. DEA will designate one person, or a small number of persons, to serve as a liaison with Plaintiffs.
36. Nothing in this Order precludes any party from applying to the Court for any relief available under the Federal Rules of Civil Procedure.

Date: _____



JAMES A. PARKER
Chief United States District Judge