

APPENDIX B**REDLINE COMPARING CURRENT DEA RELIGIOUS EXEMPTION
GUIDANCE (ISSUED IN 2020) AGAINST PRIOR VERSION IN EFFECT
WHEN ICH FILED ITS APPLICATION IN 2019**

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised)

Summary: The Drug Enforcement Administration sets forth guidance, in conformance with Executive Order 13891, which will inform religious organizations which use controlled substances within the free exercise of their religion, of the process in which they may petition for an exemption from the Controlled Substances Act.

Activity: Request for religious exemptions from the Controlled Substances Act.

To Whom It Applies: Parties requesting religious exemptions from the Controlled Substances Act.

In recent years, the Drug Enforcement Administration (DEA) has seen an increase in requests from parties requesting religious exemptions from the Controlled Substances Act (CSA) to permit the use of controlled substances. The Religious Freedom Restoration Act (RFRA) provides that the "Government shall not substantially burden a person's exercise of religion" unless the Government can demonstrate "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." 42 U.S.C. § 2000bb-1. In *Gonzales v. O Centro Espirito Beneficente Uniao do Vegetal*, 126 S.Ct. 1211 (2006), the Supreme Court held that government action taken pursuant to the CSA is subject to RFRA. In order to obtain an exemption under RFRA, a party must, as a preliminary matter, demonstrate that its (1) sincere (2) religious exercise is (3) substantially burdened by the CSA. 42 U.S.C. § 2000bb et seq.

The guidelines that follow are an interim measure intended to provide guidance to parties who wish to petition for a religious exemption to the CSA:

1. Filing Address. All petitions for exemption from the Controlled Substances Act under RFRA shall be submitted in writing ~~to Susan A. Gibson, Deputy~~ or email to the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152-~~7~~₃, ODLP@usdoj.gov.

2. Content of Petition. A petition may include both a written statement and supporting documents. A petitioner should provide as much information as he/she deems necessary to demonstrate that application of the Controlled Substances Act to the party's activity would (1) be a substantial burden on (2) his/her sincere (3) religious exercise. Such a record should include detailed information about, among other things, (1) the nature of the religion (e.g., its history, belief system, structure, practice, membership policies, rituals, holidays, organization, leadership, etc.); (2) each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance; (3) the specific controlled substance that the party wishes to use; and (4) the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession. A petitioner is not limited to the topics outlined above, and may submit any and all information he/she believes to be relevant to DEA's determination under RFRA and the Controlled Substances Act.

3. Signature. The petition must be signed by the petitioner, who must declare under penalty of perjury that the information provided therein is true and correct. *See* 28 U.S.C. § 1746.

4. Acceptance of Petition for Filing. Petitions submitted for filing are dated upon receipt by DEA. If it is found to be complete, the petition will be accepted as filed, and the petitioner will receive notification of acceptance. Petitions that do not conform to this guidance will not generally be accepted for filing. A petition that fails to conform to this guidance will be returned to the petitioner with a statement of the reason for not accepting the petition for filing. A deficient petition may be corrected and resubmitted. Acceptance of a petition for filing does not preclude DEA from making subsequent requests for additional information.

5. Requests for Additional Information. DEA may require a petitioner to submit such additional documents or written statements of facts relevant to the petition as DEA deems necessary to determine whether the petition should be granted. It is the petitioner's responsibility to provide DEA with accurate contact information. If a petitioner does not respond to a request for additional information within 60 days from the date of DEA's request, the petition will be considered to be withdrawn.

6. Applicability of DEA Regulations. A petitioner whose petition for a religious exemption from the Controlled Substances Act is granted remains bound by all applicable laws and Controlled Substances Act regulations governing registration, labeling and packaging, quotas, recordkeeping and reporting, security and storage, and periodic inspections, among other things. *See* 21 C.F.R. §§ 1300-1316. A petitioner who seeks exemption from applicable CSA regulations (as opposed to the CSA itself)

may petition under 21 C.F.R. § 1307.03. Such petition must separately address each regulation from which the petitioner seeks exemption and provide a statement of the reasons for each exemption sought.

7. Activity Prohibited Until Final Determination. No petitioner may engage in any activity prohibited under the Controlled Substances Act or its regulations unless the petition has been granted and the petitioner has applied for and received a DEA Certificate of Registration. A registration granted to a petitioner is subject to subsequent suspension or revocation, where appropriate, consistent with CSA regulations and RFRA.

8. Final Determination. After the filed petition—along with all submissions in response to any requests for additional information—has been fully evaluated, the ~~Deputy~~ Assistant Administrator of the Diversion Control Division shall provide a written response that either grants or denies the petition. Except in the case of affirming a prior denial or when the denial is self-explanatory, the response shall be accompanied by a statement of reasons upon which the decision is based. This written response is a final determination under 21 U.S.C. § 877.

9. Application of State and Other Federal Law. Nothing in these guidelines shall be construed as authorizing or permitting any party to take any action which such party is not authorized or permitted to take under other Federal laws or under the laws of the State in which he/she desires to take such action. Likewise, compliance with these guidelines shall not be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department policies.

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