

Kezhaya Law PLC

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Food and Drug Administration
ATTN: Office of the Commissioner
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: RFRA demand letter for mifepristone and misoprostol

Dear Commissioner,

I serve as general counsel for The Satanic Temple, Inc. (“**TST**”), an IRS-recognized atheistic religious corporation. I write in regard to the prescription requirement in the risk evaluation and mitigation strategy (“**REMS**”) for mifepristone and misoprostol. NDA 020687 at § 5.3; NDA 4228046. TST seeks a religious exemption for its membership to these requirements.

TST’s membership uses these products in a sacramental setting. The Satanic Abortion Ritual is a sacrament which surrounds and includes the abortive act.¹ It is designed to combat feelings of guilt, doubt, and shame and to empower the member to assert or reassert power and control over their own mind and body. The REMS prescription requirement substantially interferes with the Satanic Abortion Ritual because the Government impedes the members’ access to the medication involved in the ritual.

Based on the foregoing, it is my client’s position that the prescription requirement infringes upon its memberships’ religious liberty, in violation of the Religious Freedom Restoration Act. See 42 USC § 2000bb *et seq.* My client therefore demands a religious exemption from the REMS program for mifepristone and misoprostol. However, consistent with my client’s doctrine of conforming to the best scientific understanding of the world, my client desires to adhere to medical oversight of the drugs. TST has every desire to ensure the health and safety of its membership, the issue is with governmental control over whether TST’s membership can obtain access to these drugs.

Thus, my client proposes the following framework:

1. The member who desires to engage in the Satanic Ritual Abortion goes to a doctor for a medical examination to determine whether there are “contraindications” as defined by the American College of Obstetricians and Gynecologists or the American Academy of Family Physicians.
2. The doctor executes a form which affirms there are no “contraindications.”
3. The member returns to TST with the form.

¹ For more information, please visit TST’s website: <https://announcement.thesatanictemple.com/rrr-campaign41280784>

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4. TST dispenses the medication with instructions for use.
5. The member engages in the ritual.
6. Between 7 days and 14 days after engaging in the ritual, the member returns to the doctor for follow-up evaluation.

As I understand it, the above removes the requirement of a prescription and replaces it with a doctor's affirmation that, so far as the doctor can tell, taking the drugs should not pose any medical risk to the member. Because there is no prescription, the member would obtain the drugs from TST, directly, rather than require the use of a pharmacy. This removes the doctor and the pharmacist from the process while simultaneously ensuring medical oversight for the safety of the patient.

Please respond within 60 days of receipt of this letter with written confirmation that TST and its membership may obtain mifepristone and misoprostol without meeting REMS requirements. Or, within 60 days of receipt of this letter, please advise as to any additional information you may need to evaluate this request.

If I receive neither confirmation nor a request for further information by then, I am instructed to assume that no confirmation is forthcoming and to raise a claim with the appropriate U.S. District Court to seek prospective injunctive relief. Please let me know if I can answer any questions for provide anything further to assist your office in evaluating this request.

Sincerely,

A handwritten signature in blue ink, appearing to be 'MK' with a long, sweeping underline that extends to the right.

Matthew A. Kezhaya

Enc.