

April 2, 2014

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

2014 APR 11 P 2:23

Citizen Petition

The undersigned submits this petition pursuant to Petitioner's perfect right to contract, secured by Article 6, Section 12, of the Constitution of the State of South Dakota; and, Article 1, section 10, of the Constitution for the United States of America, 1789 CE, as amended and ratified by passage of the Bill of Rights in 1791 (hereinafter referred to as "the Constitution").

In June, 2010, and thereafter, Petitioner created *Private Membership Associations* including, but not limited to, 2035 PMA, QLaser Solutions PMA, QLasers PMA, Energy for Life PMA and other PMAs (*Private Membership Association* is referred to herein as "PMA or PMAs").

The above-referenced PMAs were created by a private contract authored by Petitioner, offered to and accepted by like minded-people, settled and are administered by Petitioner; they are non-statutory *associations* of people unanimously acting in their real, private, character and capacity; not as commercial/legal/legislative or ens legis "persons" of any kind whatsoever; the PMAs are not "*legal entities*" created by or under the authority of any department or administrative agency of any state or the federal government.

Within the above-referenced PMAs, Petitioner (and all PMA members) assert and stand upon all of their state and federal constitutionally secured rights including, but not limited to, the rights to freely assemble and associate, to freedom of speech and the press under the First Amendment to the Constitution; and, the right to privacy under the Fourth Amendment to the Constitution.

Within the above-referenced PMAs, Petitioner and all PMA members have: withdrawn their consent to any and all protections offered to them by any and all departments and administrative agencies of any state and the federal governments including, but not limited to, the FDA; do not now consent to any protection offered to them by any such departments or agencies; and, specifically wave any and all protections offered to them by any such departments or agencies.

In comity with 21 CFR 5.10 Petitioner requests that the Commissioner of Food and Drugs (and thereby the entire FDA) **recognize** the PMAs created by Petitioner and refrain from taking any further administrative or judicial action of any kind whatsoever attempting to control or interfere in any way with any of the above-referenced PMAs unless and until it is proven, with conclusive documentary evidence or competent sworn/affirmed testimony proffered by a credible witness having first-hand knowledge, that Petitioner, or any PMA that Petitioner created, has created a real and clearly identifiable "*clear and present danger that they will bring about substantive evils that Congress has a right to prevent.*" Schenck v United States, 249 U.S. 47 (1919).

A. Action Requested

Petitioner requests that the Commissioner of Food and Drugs **recognize the fact** that because 2035 PMA, QLasers Solutions PMA, QLasers PMA, Energy for Life PMA, and any other PMA created by Petitioner, are *private membership associations* that deal only with PMA members (not with the **public**) that the lawful acts of the PMAs are *generally* immune from or beyond the scope and purview of the regulatory authority delegated by the **Public Law**, as amended, which created the FDA; the Regulations implementing any public law, as amended, that the FDA enforces; and the FDA's internal Rules created for protecting the public.

The only exception to the general immunity claimed above that Petitioner can find is that in the event that any PMA or any PMA member commits an act, makes an omission, publishes or utters a statement which creates a real and identifiable "*clear and present danger that they will bring about substantive evils that Congress has a right to prevent*" that then, and only then, may a state or the United States act (in the most limited and non-evasive way necessary so as not to impair, impede, obstruct, defeat or otherwise have any chilling effect on the perfect rights being exercised by the PMA members) in order to stop the substantive evil.

Petitioner requests that the Commissioner of Food and Drugs **declares** that the PMAs referred to herein are **not in the public domain, do not affect the public**, and are not *generally subject to the public law*, as amended, creating the FDA, the public law(s), as amended, that the FDA enforces, or the rules of the FDA that are created for the protection of the public.

Petitioner further requests that the Commissioner of Food and Drugs *enters an order or directive* to all FDA personnel involved in the below-referenced searches, requiring them to forthwith return to Petitioner everything relevant to any PMA created by Petitioner that was seized, removed and taken from Petitioner's office on September 10, 11, and 12, 2013.

Petitioner finally requests that the Commissioner of Food and Drugs *enters an order or directive* to all FDA personnel, ordering all FDA personnel to leave Petitioner and all PMAs created by Petitioner alone.

B. Statement of Grounds

On the 10th day of September, 2013 the UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH DAKOTA, WESTERN DIVISION, issued a WARRANT FOR ADMINISTRATIVE INSPECTION on 2035, INC.; and a second, identically titled warrant, on BUSINESS WIZARDS, INC., a.k.a. QLASER SOLUTIONS PRIVATE MEMBERSHIP ASSOCIATION, pursuant to applications made by FDA agents, employees, officers or officials JESSICA L. JOHNSON, Inspector, and COURTNEY R.A. TIEGS, Consumer Safety Officer.

The warrants authorized:

"Benjamin W. Anderson and any other duly authorized United States Food and Drug ("FDA") Investigator, duly designated FDA employee, Deputy United States Marshall, and/or local law enforcement officer; ... you are authorized to enter the above-described

premises at reasonable times during ordinary business hours to access, copy, and verify records to which the FDA is entitled under the Act for all of the firm's devices. Such records include, but are not limited to: (1) Design Controls, Purchasing Controls, Corrective and Preventive Action Records, Device Labeling, Distribution Records, Device Master Records, Device History Records, Complaint Files, and Servicing Records as described in 21 C.F.R. §§ 820.30, 820.50, 820.100, 820.120, 820.160, 820.181, 820.184, 820.198, and 820.200 and (2) Additional Listing Information, as described in 21 C.F.R. § 807.26.” (Emphasis supplied.)

On September 10, 11, and 12, 2013 FDA investigators ANDERSON and MATHIAS and two armed U.S. Marshals appeared on the private property of Petitioner, located at 2035 First Avenue, Rapid City, South Dakota, The United States of America, and entered the private office of Petitioner, 2035 INC., and several PMAs created by Petitioner and served and executed the warrant on 2035, INC., even though the FDA had been served Notice, by a letter dated June 15, 2010, delivered by postage prepaid, certified U.S. Mail, informing the FDA that 2035, INC., had ceased manufacturing lasers (See Exhibit 1).

Further Notice was served by a letter dated June 25, 2010, delivered to the FDA by postage prepaid, certified U.S. Mail that 2035 PMA was making lasers only for the members of its private membership association and would not sell lasers to the public (Exhibit 2).

Without any authority whatsoever, the above referenced investigators and Marshalls searched for, found, seized and removed records on 2035 PMA and other PMAs created by Petitioner.

Additionally, and simultaneously with the above stated, in Suite A, at 3939 Canyon Lake Drive, in Rapid City, South Dakota, The United States of America, FDA investigators JOHNSON and TIEGS and two other armed U.S. Marshals appeared served and executed the warrant on BUSINESS WIZARDS, INC., a.k.a. QLASER SOLUTIONS PRIVATE MEMBERSHIP ASSOCIATION despite the fact that BUSINESS WIZARDS, INC. had been officially closed (see the documents on file with the South Dakota Department of Corporations) for over three (3) years and the fact that QLaser Solutions PMA had never conducted any business of any kind whatsoever, pursuant to any act, document or instrument filed in the Pennington County, South Dakota, Courthouse; with the state of South Dakota; or, anywhere as, “a.k.a.”, “d/b/a”, or otherwise, as BUSINESS WIZARDS, INC.

Without any authority whatsoever, the above referenced investigators searched for, found, seized and removed records on above-referenced PMAs.

The above-referenced searches and seizures, on the above-referenced PMAs, were executed in violation of Petitioner’s right to be secure in his person, houses, papers, and effects, against unreasonable searches and seizures under Amendment IV to the Constitution.

Petitioner has reason to believe and does believe that the above-referenced or other FDA personnel will continue to violate rights secured to Petitioner by the state and federal constitutions by conducting further unwarranted searches and seizures on Petitioner and the above-referenced PMAs.

Petitioner knows of no law or other information which is unfavorable to Petitioner's position.

C. Environmental Impact

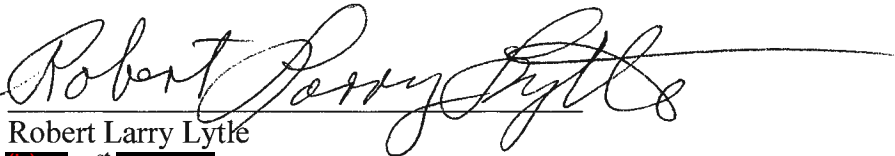
The granting of this petition by defining and clearly stating the relationship of the public law, as amended, creating the FDA; the public laws, as amended, enforced by the FDA; and the rules of the FDA in force in order to protect the public, to the above-referenced PMAs; and, the FDA's recognition of the above-referenced PMAs, will have no effect whatsoever on the environment and, therefore, will have no environmental impact.

D. Economic Impact

The granting of this petition will have no economic impact on the United States, on the FDA, or on any other entity or person.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the Petitioner which are unfavorable to the petition.

A handwritten signature in cursive script, reading "Robert Larry Lytle", written in black ink.

Robert Larry Lytle

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