

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

0313 8 MAR -5 P6:37

Mr. Jerry Staton

FEB 05 2008

RE: Docket No. 2006P-0390

Dear Mr. Staton:

This letter responds to your citizen petition dated September 17, 2006, ("petition") regarding the potential health hazards associated with the Church of Scientology's ("Scientology") use of the E-meter in the practice of auditing by its practitioners.

In your petition, you request the Commissioner "to order the Church of Scientology to clearly disclose the potential health hazards inherent in the use of the E-meter and Scientology's practice of 'auditing'" and to warn all future and potential practitioners of Scientology of such health hazards before a decision to practice Scientology is made.¹ You request the following statement in labeling:

The Church of Scientology's practice of auditing has been determined to constitute a form of coercive persuasion. Persons subject to coercive persuasion without their knowledge or consent may sustain irreparable physical and psychological injury up to and including schizophrenia, self-mutilation, and suicide.

For the reasons explained below, we are denying your petition.

In *United States v. Article or Device, etc.*, 333 F. Supp. 357 (D.D.C. 1971), FDA sought condemnation of the E-meter on the basis that it was misbranded because it lacked adequate directions for use under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 352(f)(1)). The court agreed with the basis of FDA's position that the E-meter could not be distributed and promoted for use with the public for secular purposes. However, the court held that in a religious context the E-meter may be used, sold, or distributed for counseling (auditing) for use in bona fide religious counseling, which includes counseling by the Founding Church of Scientology. *Id.* at 364. In addition, in *Founding Church of Scientology v. United States*, 409 F.2d 1146, 1159-60 (D.C. Cir. 1969), *cert. denied*, 396 U.S. 963 (1969), the court interpreted the Act as not including, within the meaning of "labeling," the "literature developing the doctrines of religion" which would include such literature that relates to the use of the E-meter for religious purposes.

¹ The requirements related to the submission of a citizen petition are in 21 CFR 10.30 and we consider your request for agency action under that provision.

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Your petition does not provide a basis for a violation of any FDA laws.
We appreciate your concerns on this subject. If you have any questions, please contact
Casper E. Uldriks at (240) 276-2974.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jeffrey Shuren". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Shuren" clearly distinguishable.

Jeffrey Shuren
Assistant Commissioner for Policy

**DIVISION OF DOCKETS MANAGEMENT
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES** SEP 19 2006
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Docket No. _____

JERRY STATON,

Petitioner

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CITIZEN PETITION

The undersigned submits this petition under 21CFR7.41 of the Code of Federal Regulations pertaining to health hazard evaluation and recall classification to request the Commissioner of Food and Drugs to order the Church of Scientology to clearly disclose The potential health hazards inherent in the use of the E-meter and Scientology's practice Of "auditing" to current practitioners of Scientology and to warn all future and potential practitioners of Scientology of the potential health hazards inherent in the use of the E-meter and Scientology's practice of "auditing" before a decision to practice Scientology is made.

Dated this 17th day of September 2006

Respectfully Submitted,


Jerry Staton

2006P-0390

ACTION REQUESTED

The following caveat should be made visible in relation to anything related to or encouraging the practice of Scientology:

The Church of Scientology's practice of auditing has been determined to constitute a form of coercive persuasion. Persons subjected to coercive persuasion without their knowledge or consent may sustain irreparable physical and psychological injury up to and including schizophrenia, self-mutilation, and suicide.

STATEMENT OF GROUNDS

In the case of "Lawrence Wollersheim v. the Church of Scientology," it was determined that Scientology's practice of "auditing" constituted coercive persuasion and is what precipitated his developing severe bipolar disorder and psychogenic amnesia. It was also determined that Scientology's practice of "auditing" was what drove Lawrence Wollersheim to attempt suicide.

<http://www.factnet.org/letters/FACTNewsMay2002Wollersheim.html>

In United States v. Lee 455 U.S. 252, 257-258 (1982), the California Supreme Court found that "when a person is subjected to coercive persuasion without his knowledge or consent... [he may] develop serious and sometimes irreversible physical and psychiatric disorders, up to and including schizophrenia, self-mutilation, and suicide."

ENVIRONMENTAL IMPACT

The only potential impact that this action would have on the environment would be due to the possible crippling of the Church of Scientology's effectiveness in recruiting and retaining membership, however, the available capacity of the nations refuse system should comfortably handle any increase in demand posed by the discarding of individuals' Scientology-related materials.

ECONOMIC IMPACT

Due to a decreased membership and subsequent financial standing, properties currently occupied by the Church of Scientology will most likely have to be vacated as the corporation downsizes, and an increased burden on the nation's mental healthcare system is likely as former Scientologists seek to come to terms with their feelings of anger over having been so deceived, controlled, and manipulated.

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 it includes representative data and information known to the petitioner which is unfavorable to the petition.


Jerry Staton

