UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

CIVIL ACTION FILE NUMBER _____

Fleminger, Inc.

PLAINTIFF,

V.

U.S. DEPT. OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION, Kathleen Sebelius In Her Official Capacity As Secretary Of U.S. Health And HUMAN Services, Margaret Hamburg, M.D. In Her Official Capacity As Commissioner Of The U.S. Food And Drug Administration

DEFENDANTS.

310CV855 VLB

COMPLAINT

JUNE 1, 2010

Now comes Fleminger, Inc., by its attorney Anthony J. Musto, and makes the following for its Complaint.

INTRODUCTION

1. Plaintiff brings this action under the Administrative Procedure Act, 5 U.S.C. § 701, et. seq. for a review of the denial by Defendant Food and Drug Administration ("FDA") of Plaintiff's petition for qualified health claims ("QHC") regarding the claims made in "Tea for Health" products, and to enjoin Defendants from violating Plaintiff's rights of free speech under the First Amendment to the United States Constitution.

PARTIES, JURISDICTION & VENUE

2. Plaintiff is an entity duly formed under the laws of the State of Connecticut.

3. Defendant United States Department of Health and Human Services ("HHS") is a department of the United States.

4. Defendant Food and Drug Administration ("FDA") is an agency of HHS and an agency of the United States.

5. Defendant Kathleen Sebelius is the Secretary of HHS and is sued only in her official capacity.

6. Defendant Margaret Hamburg, M.D. is the Commissioner of FDA and is sued only in her official capacity.

7. Venue is proper in this District under 28 U.S.C. Sec. 1391(e) as Plaintiff resides in this district.

8. Jurisdiction is founded upon the existence of a federal question and proper in this Court pursuant to 28 U.S.C. §1331 as arising under the laws of the United States and the Administrative Procedure Act codified as 5 U.S.C. § 701 et. sec. as a review of an administrative decision.

FACTUAL BACKGROUND

9. Plaintiff is a manufacturer, and retailer, of Green Tea, and it markets its tea primarily through a website called teaforhealth.com.

10. Plaintiff markets its green tea in a way that cites green tea's health benefits.

11. On January 27, 2004, Plaintiff filed a petition with the FDA regarding health claims and green tea, supplemented on May 21, 2004 by another petition regarding qualified health claims for green tea and the reduced risk of certain cancers.

12. By letter dated June 30, 2005, the FDA informed Plaintiff that there was limited credible evidence regarding the consumption of green tea and the reduced risk of prostate cancer and breast cancer.

13. In the June 30, 2005 letter the FDA provided Plaintiff with two disclaimers that the FDA required when making qualified health claims pertaining to both breast and prostate cancer, to wit:

a. "Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer."

b. "One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based

on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."

14. The FDA has stated in an August 19, 2008 letter that the two disclaimers it crafted for Plaintiff's use provide the "precise language" that allows Plaintiff's qualified health claims to be "truthful and not misleading."

15. The FDA's website characterizes these statements as "Nonbinding recommendations."

16. Plaintiff filed a petition for administrative reconsideration dated August 5, 2005 which was denied on August 19, 2008.

17. The FDA sent Plaintiff a letter dated February 22, 2010 titled "Warning Letter" that threatened "the seizure of [Plaintiff's] illegal products and injunctions against manufacturers and distributors of those products."

18. In the FDA's Warning Letter, the FDA required Plaintiff to use only the exact language of the disclaimers that FDA had approved without modification.

19. None of the claims made by Plaintiff are deceptive, dishonest, false, misleading, or otherwise harmful to the public at large.

FIRST COUNT: Defendants Violated The Rights Of Plaintiff As Guaranteed Under The First Amendment To The United States Constitution.

Paragraphs 1-19 are incorporated herein by reference.

20. By prohibiting Plaintiff from making any alterations to the disclaimers and making other truthful statements, Defendants are forcing Plaintiff to choose between speaking exactly as Defendants wish, remaining silent, or risking adverse action for its own commercial speech in violation of the First Amendment.

21. Plaintiff has suffered and will continue to suffer irreparable injury to its constitutionally protected commercial speech rights so long as it is prevented from using truthful, non-misleading disclaimers by Defendants.

22. FDA's requirements for Plaintiff's speech are not the least restrictive means of preventing any alleged deception of consumers who choose to purchase his green tea.

23. By compelling Plaintiff to use government speech or none at all, Defendants have violated Plaintiff's First Amendment rights.

24. Defendants' prohibition on Plaintiff's speech is overly broad in violation of the First Amendment.

25. Defendant's prohibition on Plaintiff's speech constitutes a prior restraint in violation of the First Amendment.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff requests that this Court:

1. Review and overturn the denial of the petition,

2. Enjoin Defendants from taking any action against Plaintiff, and

3. Order such other relief as the Court sees fit.

THE PLAINTIFF

BY: _____

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