UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC.
5600 NW 102nd Avenue, Suite A
Sunrise, Florida 33351

Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION,
JOSHUA M. SHARFSTEIN, M.D., Acting Commissioner for Food and Drugs,
MARGARET HAMBURG, M.D.,
Commissioner Designate for Food and Drugs
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

and

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CHARLES E. JOHNSON, acting Secretary of the Department of Health and Human Services,
KATHLEEN SEBELIUS, Secretary Designate for the Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Defendants.

Case: 1:09-cv-00771
Assigned To : Leon, Richard J.
Assign. Date : 4/28/2009
Description: TRO/PI

MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR INJUNCTIVE RELIEF

Plaintiff Smoking Everywhere, Inc. ("SE") is an importer and distributor of electronic cigarettes—an electronic product that allows adult consumers to inhale a nicotine vapor that is derived from tobacco products without any of the flame, tar, combustion, carbon monoxide, cancerous by-products, ash, stub, or smell of a traditional cigarettes. One hundred percent of SE's revenue is derived from the importation of electronic cigarettes, and it has binding contracts with its suppliers and its independent distributors for the purchase and sale of electronic cigarettes.

Defendant United States Food and Drug Administration ("FDA") has recently declared electronic cigarettes and their component parts, including their naturally derived liquid nicotine mixture, to be a new drug and/or new drug-device combination. The FDA implemented this new policy despite the fact that Congress and the Supreme Court of the United States have both clearly declared that the FDA is without jurisdiction to regulate tobacco products, and it further implemented this new, substantive policy without engaging in the statutorily required notice-and-comment procedure. In furtherance of this new policy, Defendants have ordered all shipments of electronic cigarettes and component parts to be refused entry into the United States. SE's shipments of electronic cigarettes have been refused entry into the United States. Defendants' actions are *ultra vires* to its enabling act, the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and are further in violation of the notice and comment requirements of the Administrative Procedures Act ("APA"), 5 U.S.C. § 553.

Because SE will be irreparably harmed if Defendants continue enforcement of these unlawful new policies, SE respectfully moves this Court, pursuant to Federal Rule of Civil Procedure 65, for a temporary restraining order and preliminary and permanent injunction ordering that:

(1) Defendants do not have statutory authority to regulate electronic cigarettes, as they are a tobacco product and thus outside the jurisdiction of the FDA;

(2) Defendants are without statutory authority to define electronic cigarettes and/or electronic cigarette component parts as a new drug and/or drug-device combination as defined by the FDCA;

(3) Defendants' import ban against electronic cigarettes is unlawful and must be lifted, including the immediate release of all electronic cigarettes that have been detained by Defendants or by any other governmental agency at the request of the Defendants;

(4) In the alternative, issue an Order stating that Defendants implemented a

new, substantive policy relating to electronic cigarettes without engaging in the required notice and comment procedures under the APA and declaring Defendants' attempted regulation of electronic cigarettes unlawful and void.

A memorandum in support and a proposed order are attached and incorporated herein by reference.

Respectfully submitted,

THOMPSON HINE LLP

Dated: April 28, 2009

By: _____

Kip Schwartz (D.C. Bar # 444650)
1920 N Street, N.W., Suite 800
Washington, D.C. 20036
(202) 331-8800 Telephone
(202) 331-8330 Facsimile

Counsel for Plaintiff Smoking Everywhere, Inc.

Of Counsel:

Walt Linscott signed with permission by Eric Heyer

Walt Linscott
THOMPSON HINE LLP
1201 West Peachtree Street, N.W.
Suite 2200
Atlanta, GA 30309
Phone: (404) 541-2900
Facsimile: (404) 541-2905

Brian Lamb signed with permission by Eric Heyer

Brian Lamb
THOMPSON HINE LLP
3900 Key Center
127 Public Square
Cleveland, OH 44144-1291
Phone: (216) 566-5500
Facsimile: (216) 566-5800

Matthew Ridings signed with permission by Eric Heyer

Matthew Ridings
THOMPSON HINE LLP
3900 Key Center
127 Public Square
Cleveland, OH 44144-1291
Phone: (216) 566-5500
Facsimile: (216) 566-5800

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC.
5600 NW 102nd Avenue, Suite A
Sunrise, Florida 33351

Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION,
JOSHUA M. SHARFSTEIN, M.D., Acting Commissioner for Food and Drugs,
MARGARET HAMBURG, M.D.,
Commissioner Designate for Food and Drugs
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

and

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CHARLES E. JOHNSON, acting Secretary of the Department of Health and Human Services,
KATHLEEN SEBELIUS, Secretary Designate for the Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Defendants.

Case No. _____

Judge 09 0771

MEMORANDUM IN SUPPORT OF PLAINTIFF SMOKING EVERYWHERE, INC.'S MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

INTRODUCTION

Tobacco is a product that has for centuries been used in this country as a means to derive the effects of nicotine. In smoked or smokeless form, tobacco's primary use is to deliver levels of nicotine to the human body for the non-therapeutic effect on the user. Even in the face of overwhelming evidence of the severely negative health effects on the user and, in the case of smoked tobacco, to the innocent bystander, the laws of this nation have been structured and interpreted to permit the use of tobacco to derive the effects of nicotine. At issue in this case is

Electronic cigarettes—electronic products that allow adult consumers to inhale naturally derived nicotine vapors without the thousands of chemicals and dozens of known carcinogens of traditional cigarettes. Electronic cigarettes are made from tobacco and are the functional equivalent of traditional cigarettes and should be regulated in the same manner as traditional cigarettes.

Throughout most of the last century, the Food and Drug Administration ("FDA") consistently maintained, both to Congress and the American people, that it was without jurisdiction to regulate cigarettes and other tobacco products. The delivery of nicotine through the use of tobacco was not viewed as a use subject to the grant of authority under the Federal Food, Drug, and Cosmetic Act ("FDCA").

In 1995, the FDA abruptly reversed course, making the claim that it could assert jurisdiction over tobacco products, despite the fact that tobacco was customarily marketed to people as a means to enjoy the effects of nicotine. The Supreme Court ultimately rejected the FDA's newly asserted jurisdictional claims over the use of tobacco, finding that tobacco products were in essence marketed for the enjoyment of nicotine without therapeutic benefit. Notwithstanding the dramatically negative health effects known to exist with the use of tobacco products to the user and innocent bystander, the Court determined that existing statutes and regulations promulgated by agencies other than the FDA were sufficient to regulate the use of tobacco in a non-therapeutic manner or, as articulated by the Supreme Court, "as customarily marketed." Marketed within the framework applicable to cigarettes, cigars and smokeless tobacco, the use of nicotine for non-therapeutic purposes is outside of the FDA's current jurisdiction. The FDA continues to push for the ability to regulate tobacco products and the debate continues in Congress.

With the door to regulation of traditional tobacco products having been firmly shut by the Supreme Court, the FDA has now asserted the same unsuccessful arguments it used for traditional tobacco products in order to attempt to regulate electronic cigarettes. Perhaps mindful that its jurisdiction does not properly extend to electronic cigarettes, the FDA chose not to regulate electronic cigarettes by engaging in the required rule making process; instead, without providing an opportunity for public notice and comment, the FDA unilaterally blocked all imports of electronic cigarettes and detained all shipments of electronic cigarettes at their ports of entry. By failing to engage in the required rule making process, the FDA's attempt to regulate electronic cigarettes violated the clear language of the Administrative Procedures Act ("APA") that requires opportunity for notice and comment during substantive rule making. But even beyond its failure to follow legally required procedure, its attempt to regulate electronic cigarettes, which are not "drugs" or "drug device combinations" under the FDCA, is *ultra vires* of the FDA's enabling statute and must be considered void as a matter of law.

The FDA's conduct has far-reaching and immediate consequences for Smoking Everywhere, Inc. ("SE"), similarly situated businesses, SE's independent distributors, their employees, and consumers. Without injunctive relief that requires the FDA to rescind the import ban and follow the existing construct of the FDCA in the context of non-therapeutic uses of nicotine, SE, which derives 100 percent of its revenue from the importation and distribution of electronic cigarettes, may be forced to cease operations, thereby affecting its contracts with its suppliers, distributors, and its employees. Accordingly, because the FDA's conduct was *ultra vires* of the FDCA, violated the APA, and because SE will suffer irreparable harm without the issuance of an injunction, this Court should issue a temporary restraining order and preliminary and permanent injunctions requiring that the FDA lift the import ban on electronic cigarettes and

order the release of all electronic cigarettes that have been improperly detained by the FDA pursuant to its unlawful import ban.

STATEMENT OF FACTS

The Electronic Cigarette Device

SE is a Florida corporation that has pioneered the importation, marketing, and distribution of electronic cigarettes ("E-cigarettes"). E-cigarettes were first invented in approximately 2004 as an alternative to traditional smoked tobacco products. The E-cigarette is designed to replicate the adult experience of smoking and enjoying nicotine without combustion or the use of cancerous by-products. The E-cigarette essentially functions by vaporizing a naturally derived liquid nicotine mixture, thereby allowing the adult consumer to inhale the natural nicotine vapor in a manner similar to that of inhaling actual tobacco smoke. Unlike with tobacco smoke, however, the E-cigarette does not use fire or contain shredded tobacco leaves, tar, carbon monoxide, known carcinogens or result in the ash, stub, or smell found in traditional cigarettes. There is no second-hand smoke and no cigarette butt refuse strewn about where the product is used.

E-cigarettes consist of three basic parts: the cartridge (also called the mouthpiece), the heating element (also called the atomizer), and the battery and electronics. The cartridge is a hollow, disposable plastic tube that contains a batting that is soaked in liquid mixture primarily composed of propylene glycol and nicotine.[1] The cartridge acts as the mouthpiece, or "butt," of the E-cigarette and is placed over the heating element, or atomizer, as a cover. The heating element then screws into a rechargeable battery pack that also contains electronics that monitor the function of the E-cigarette. The battery and electronics on an E-cigarette are designed to

[1] Depending on the recipe, the cartridge may contain other trace ingredients, such as flavoring, menthol, preservatives, etc. Not all cartridges contain nicotine; instead, some cartridges contain only flavoring.

replicate the portion of a traditional cigarette that contains tobacco. When assembled, the E-cigarette resembles (though is slightly larger than) a traditional cigarette. In addition, the end of the battery pack contains an LED lamp that glows when the user inhales, again in a manner designed to resemble the function, look and feel of a traditional cigarette.

The E-cigarette functions by a user inhaling on the end of the cartridge, like a traditional cigarette. When a user inhales, the electronics in the E-cigarette detect air flow and signal the battery to activate the heating element. When the heating element is activated, it vaporizes the liquid nicotine mixture, creating a nicotine vapor that the user inhales. In the case of SE's E-cigarette, the nicotine mixture is 100 percent derived from natural tobacco plants. The vapor may contain a flavoring designed to mimic the flavor and feel of actual tobacco, but without the combustion, flame, tar, carbon monoxide, known carcinogens, second-hand smoke, or other smoking by-products. When the user exhales the vapor, it disappears into the air within seconds and is odorless.

Since SE's inception, it has quickly established itself as a market leader in the importation, distribution, and sale of electronic cigarettes. SE markets its product as an alternative form of smoking for adult consumers. It does not market the product as a smoking cessation device. Instead, the E-cigarette is properly understood as an "extension" of traditional smoking, simply allowing the user to simulate the smoking experience in places where traditional smoking is illegal or not practical; in fact, the product is merely an electronic analogue for traditional cigarettes, designed to mimic the function, look, and feel of a traditional cigarette. SE's marketing campaign has been tremendously successful, with the company deriving 100 percent of its revenue from sale of imported E-cigarettes, through its supply contracts with overseas manufacturers. In slightly more than twelve months of operation, SE has

sold more than 600,000 units through its nationwide network of over 120 independent distributors, operating from physical storefronts throughout the country.

The FDA's Conduct

During late 2008 and early 2009, the FDA began to take an increased interest in the marketing and importation of E-cigarettes. The FDA's interest in E-cigarettes resulted in an un-promulgated new policy within the FDA, which includes the apparent classification of E-cigarettes as a drug-device under Section 503(g)(1) of the FDCA. Over the past several months, the FDA has made repeated and public statements to various media outlets that it considers E-cigarettes to be drug-device combinations, notwithstanding that the FDA has no jurisdiction to regulate tobacco products. Upon SE learning of the FDA's interest in E-cigarettes, SE requested an audience or dialogue with the FDA's Office of Compliance in order to discuss SE's view of the regulatory environment, any proposed changes in rules, regulations, or policy, and to discuss proposed legislation or regulation that would target E-cigarettes and E-cigarette accessories.

The FDA did not provide a substantive response to SE's request for dialogue. Instead of responding to SE, the FDA added "Electronic Cigarettes and Electronic Cigarette Components" to Import Alert 66-41.[2] Adding E-cigarettes to the import alert directly constituted a substantive and un-promulgated policy change in which the FDA determined that E-cigarettes were drug-device combinations under the FDCA. It made this policy change without the opportunity for public notice or public comment, and without personal notice to SE.

Import Alert 66-41 operates to bar unapproved or misbranded drugs from being imported into the United States. Since the time that E-cigarettes were added to Import Alert 66-41, the

[2] An import alert advises FDA field offices of ongoing problems with a specific product offered for import and suggests appropriate action, such as detention for inspection and sampling.

FDA has denied SE's products entry into the United States on at least two separate occasions, at the ports of Los Angeles and Miami.

On or about March 13, 2009, SE received a shipment of 1000 E-cigarette kits and accompanying E-cigarette cartridges from one of its overseas suppliers at the Port of Los Angeles. Pursuant to Import Alert 66-41, SE's shipment of E-cigarette kits and E-cigarette cartridges was denied entry into the United States. On or about March 16, 2009, the Los Angeles District Office of the FDA issued a "Notice of Action" to SE (attached hereto as Exhibit A). The Notice of Action stated that SE's shipment of E-cigarettes was refused entry into the United States because the "product appears to be a combination drug-device product that requires pre-approval, registration and listing with FDA." The Notice of Action stated that admission was further refused because the "device was subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20(a)(4)."

The Notice of Action stated that SE was afforded an opportunity to respond to the notice of detention; however, SE received no such opportunity, either through personal service or through notice in the Federal Register. Following SE's receipt of the Notice of Action, it again contacted the FDA in an attempt to respond to the FDA's detention of its shipment and the FDA's decision to reclassify E-cigarettes as a drug-device combination. Again, despite repeated requests for dialogue, the FDA has not provided SE with a substantive response.

On or about April 13, 2009, SE received a second shipment of E-cigarettes from its overseas supplier, this time at the Port of Miami in Miami, Florida. Upon information and belief, SE's Miami shipment of E-cigarettes was detained by the United States Customs and Border Patrol because the shipment of E-cigarettes required entry approval from an other governmental agency, or "OGA," namely, the FDA, due to E-cigarettes' inclusion on Import Alert 66-41.

LAW & ARGUMENT

In the District of Columbia Circuit, a four part test governs requests for injunctive relief.[3] A party seeking injunctive relief must demonstrate: "(1) they are likely to prevail on the merits; (2) they will suffer irreparable harm absent the injunction; (3) an injunction would not substantially impair the rights of the defendants or other interested parties; and (4) an injunction would be in the public interest, or at least would not be adverse to the public interest. *Estate of Coll-Monge v. Inner Peace Movement*, 524 F.3d 1341, 1349 (D.C. Cir. 2008); *Tenacre Foundation v. INS*, 892 F. Supp. 289, 292 (D.D.C. 1995), *aff'd* 78 F.3d 693 (D.C. Cir. 1996).

This test is a flexible one: "if the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Estate of Coll-Monge*, 524 F.3d at 1349 (quoting *CSX Trans., Inc. v. Williams*, 406 F.3d 667, 670 (D.C. Cir. 2005)); *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (If showing in one area is particularly strong, an injunction may issue even if the showings in other areas are weak); *Virginia Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958). The factors should be considered on a "sliding scale" such that they are "balanced against each other." *Davenport v. Int'l Bhd. of Teamsters, AFL-CIO*, 166 F.3d 356, 360-61 (D.C. Cir. 1999).

I. SE Will Suffer Irreparable Harm Absent an Injunction.

Although the District of Columbia Circuit has noted that the definition of irreparable harm is difficult to define, several guideposts have emerged to determine whether a moving party has suffered irreparable harm. "First, the injury must be both certain and great; it must be actual and not theoretical. Injunctive relief will not be granted against something merely feared as liable to occur at some indefinite time." *Washington Gas Co. v. Fed. Energy Regulatory Comm'n*, 758

[3] The same standard applies to both temporary restraining orders and to preliminary injunctions. *Experience Works, Inc. v. Chao*, 267 F.Supp. 2d 93, 96 (D.D.C.2003).

F.2d 669, 674 (D.C. Cir. 1985) (quotations omitted). Second, economic loss does not, in and of itself, constitute irreparable harm *unless* the loss threatens the very existence of the movant's business. *Id.* (citing *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 n.2 (D.C. Cir. 1977) ("The destruction of a business is, of course, an essentially economic injury. It is not, however, one of the 'mere' economic injuries which under *Virginia Petroleum Jobbers* are insufficient to warrant a stay.")); *see also Tom Doherty Assocs., Inc. v. Saban Enm't, Inc.*, 60 F.3d 27, 38 (2d. Cir. 1995) (stating that where the availability of a product is "essential to the continued life of the business . . . the damages caused by the loss of the product will be far more difficult to quantify than where sales of one of many products is the sole loss. In such cases, injunctive relief is appropriate.").

In this case, SE clearly falls within the "destruction of a business" exception outlined by the District of Columbia Circuit in *Holiday Tours* and affirmed in *Washington Gas*: one hundred percent of SE's revenue is derived from the importation of E-cigarettes. The FDA's issuance of Import Alert 66-41, along with its repeated and continued detention of SE's shipments, threatens the very viability of SE's business. Without an ability to receive shipments of its product, SE cannot generate revenue after its existing inventories in the United States are depleted. Its ability to pay its expenses as they come due will be jeopardized, and it will likely be forced to close its business, affecting not only SE and its employees, but also its contracts with its suppliers, its distributors and their employees. On these facts, SE has demonstrated irreparable harm as a matter of law.

II. SE is Likely to Succeed on the Merits of its Claims that Defendants' Conduct is *Ultra Vires* and Violated the Administrative Procedures Act.

Although the demonstration of irreparable harm is the most important factor in determining whether to issue an injunction, *Sampson v. Murray*, 415 U.S. 61, 88 (1974); *Experience Works*, 267 F.Supp. 2d at 96, and SE has demonstrated clear irreparable harm by showing that its business may close without an injunction, SE also has a high probability of success on the merits of its claims because the FDA's conduct in declaring E-cigarettes to be a new drug is *ultra vires* to the FDCA. The FDA's position is directly contrary to the Congressional intent of the statute, as Congress has explicitly excluded the non-therapeutic use of nicotine from regulation under the FDCA and, in addition, is contrary to the statutory meaning of the Act's language, including nearly one hundred years of law interpreting the FDCA. Finally, the FDA's decision to block the importation of E-cigarettes without providing an opportunity for public notice and comment is in contravention of the APA. Accordingly, SE is likely to prevail on the merits of these claims and an injunction and temporary restraining order should therefore issue.

A. Plaintiff is Likely to Succeed on its Claim that the Food, Drug, and Cosmetic Act Does Not Give the FDA the Authority to Regulate E-Cigarettes.

It is now well beyond any dispute that federal agencies are bound to follow the statutory mandate of Congress if it is clear and unambiguous. If Congress has plainly spoken, the inquiry must end and the court should give full effect to the expressed intent of Congress. *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); *see also Nutritional Health Alliance v. Food & Drug Admin.*, 318 F.3d 92, 104 (2d Cir. 2003) (holding that no deference need be given to the FDA where its proposed interpretation conflicts with Congressional intent). Further, the agency's power to promulgate rules or regulations is limited to the authority delegated by Congress. *Assn. of Am. Physicians & Surgeons, Inc. v. Food &*

Drug Admin., 226 F. Supp. 2d 204, 210 (D.D.C. 2002). Thus, an agency's attempt to regulate beyond its enabling statute is unlawful and void. *Id.* at 211. Here, the unquestionable intent of Congress is to exclude the non-therapeutic use of nicotine from the scope of the FDA's jurisdiction.

1. The E-Cigarette is the Functional Equivalent of Traditional Cigarettes and Thus Outside the Scope of the FDA's Jurisdiction.

The FDA has demonstrated an arbitrary approach with respect to the regulation of nicotine. For nearly a century FDA consistently maintained that it did not have jurisdiction to regulate tobacco products as a delivery vehicle for nicotine because Congress did not so intend in the passage of the FDCA. *Brown & Williamson*, 529 U.S. at 125; *see also Action on Smoking*, 655 F.2d at 239 (affirming FDA's disclaimer of jurisdiction over tobacco, noting that there is "no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man."). This position radically changed in 1996, when the FDA asserted jurisdiction over tobacco products, claiming that they were a drug device combination within the meaning of the FDCA.

In *Brown & Williamson*, the Supreme Court directly addressed the issue of whether Congress intended the FDA to have jurisdiction over tobacco products as part of the FDCA, holding that Congress unambiguously intended to exclude tobacco from the FDA's jurisdiction. To support its holding, the Court recounted the lengthy history and purpose of the FDA, noting the dilemma of the FDA's position: because of the known health problems associated with the use of tobacco products and because tobacco has no known countervailing health benefits, the plain terms of the FDCA would *require* the FDA to ban tobacco outright. This, the Supreme Court reasoned, was contrary to the intent of Congress because Congress, since 1965, had passed six separate pieces of legislation that addressed tobacco use and human health, none of which

attempted or purported to ban tobacco use. *Id.* at 143-44. Furthermore, the Court noted, Congress, on several occasions, had considered and specifically rejected legislation that would have given the FDA jurisdiction over tobacco products. Based on Congress' conduct, the Court found that Congress had intended tobacco products to fall outside the FDA's jurisdiction. Therefore, the Court found unlawful and blocked the implementation of the FDA's proposed tobacco regulations. *Id.* at 144.

As is made clear from the Supreme Court's findings in *Brown & Williamson*, both Congress and the Supreme Court have clarified that tobacco, as the delivery mechanism for nicotine use and when intended for use in a non-therapeutic manner, fall outside the scope of the FDCA as a matter of law. Here, E-cigarettes fall into the same exception: E-cigarettes are made from tobacco itself and are marketed, sold, and used by consumers as the functional equivalent of a traditional tobacco product that delivers nicotine for non-therapeutic purposes when the user chooses not to or cannot enjoy a traditional cigarette. There is nothing in the treatment of E-cigarettes to indicate that these products, using technology to deliver nicotine in a manner similar to the nicotine delivery of smoked tobacco and marketed for the same purposes as a traditional tobacco product, should be treated any differently than their traditional tobacco counterparts. In fact, quite the opposite is true: the E-cigarette allows a user to replicate the smoking experience by inhaling nicotine that is naturally derived from tobacco plants through a device designed to mimic the look, feel, and function of a cigarette. Thus, E-cigarettes are made from tobacco and are otherwise functionally identical to traditional tobacco products for the non-therapeutic delivery of nicotine and should be regulated in the same manner as are traditional cigarettes. The mere fact that the E-cigarette delivers nicotine to the user through a cloud of water vapor instead of a cloud of smoke, as is the case with a traditional cigarette, is simply not enough to separate

the E-cigarette from the function of traditional tobacco products. Instead, the E-cigarette should be treated in the same manner as all other tobacco products for the non-therapeutic delivery of nicotine, which Congress has intended to fall outside the regulatory power of the FDA.

It is clear that Congress was aware that tobacco products could be considered as a delivery mechanism for nicotine at the time that it drafted the statutes which allow for the sale and distribution of tobacco-based products. Despite this knowledge, Congress nevertheless chose not empower FDA to regulate nicotine in this context. As articulated by the Supreme Court in *Brown & Williamson:*

> Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, **as were nicotine's pharmacological effects**. See, *e.g.*, U.S. Dept. of Health, Education, and Welfare, U.S. Surgeon General's Advisory Committee, Smoking and Health 25—40, 69—75 (1964) (hereinafter 1964 Surgeon General's Report) (concluding that cigarette smoking causes lung cancer, coronary artery disease, and chronic bronchitis and emphysema, **and that nicotine has various pharmacological effects, including stimulation, tranquilization, and appetite suppression**); U.S. Dept. of Health and Human Services, Public Health Service, Health Consequences of Smoking for Women 7—12 (1980) (finding that mortality rates for lung cancer, chronic lung disease, and coronary heart disease are increased for both women and men smokers, and that smoking during pregnancy is associated with significant adverse health effects on the unborn fetus and newborn child); U.S. Dept. of Health and Human Services, Public Health Service, Why People Smoke Cigarettes (1983), in Smoking Prevention Education Act, Hearings on H. R. 1824 before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 32—37 (1983) (hereinafter 1983 House Hearings) (**stating that smoking is "the most widespread example of drug dependence in our country," and that cigarettes "affect the chemistry of the brain and nervous system"**); U.S. Dept. of Health and Human Services, Public Health Service, The Health Consequences of Smoking: Nicotine Addiction 6—9, 145—239 (1988) (hereinafter 1988 Surgeon General's Report) (concluding that tobacco products are addicting in much the same way as heroin and cocaine, and that nicotine is the drug that causes addiction).

Id. at 137-38 (emphasis added) (some citations omitted). Despite the well-established myriad health risks and consequences of the use of tobacco products as a delivery mechanism for non-

therapeutic nicotine use, both Congress and the Supreme Court have determined that statutes and regulations administered by agencies other than FDA are appropriate to allow the sale and marketing of traditional cigarettes. With its demonstrable lack of second-hand smoke, demonstrable lack of known carcinogens, demonstrable lack of tar, demonstrable lack of combustion products, the electronic cigarette should be afforded at least the same statutory and regulatory status of a product that produces all of these hazardous components.

2. E-Cigarettes Do Not Contain a "Drug" as Defined by the FDCA.

In addition to Congress' direction that the FDA not retain jurisdiction over tobacco products (and thus E-cigarettes), the text of the FDCA itself precludes jurisdiction over E-cigarettes. The statutory language at issue here is clear and unambiguous: under the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA may only assert jurisdiction over a product it claims to be a drug if it falls into one of three categories of "drug" as defined by the Act: (1) if the product is listed in the United States Pharmacopoeia, National Formulary, or supplement thereto; (2) the product is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" or (3) the product is "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g). Because the first manner of jurisdiction is not applicable here, in order for the FDA to assert jurisdiction over E-cigarettes, it must demonstrate that E-cigarettes are either intended for use in the diagnosis or cure of a disease or that the product is intended to affect the structure or function of the body of man. The FDA has not even attempted to so demonstrate—and indeed, it cannot make such a demonstration—thus, it cannot properly exercise jurisdiction over E-cigarettes and any and all orders or regulations directed at E-cigarettes must be declared void.

Since the enactment of the FDCA's predecessor act in 1906, the phrases "intended use" and "intended to affect" (enacted as part of the FDCA) have become terms of art in drug regulation. The 1906 Pure Foods Act focused exclusively on manufacturer claims on the product label, *see, e.g., United States v. Johnson*, 221 U.S. 488 (1911), and that understanding—that the manufacturer's intent[4] is gleaned only from objective statements made in the labeling and marketing of a particular product—was carried over through the enactment of the FDCA and through the subsequent decades of FDA regulation.

By the time the FDCA was adopted in 1938, the meaning of the "intended use" language of the Pure Foods Act had already become cemented in the Act's interpretation. Congress intended that this interpretation be adopted as part of the FDCA, as is made clear by a Senate Report that accompanied the legislation that later became the FDCA: "[t]he use to which a product is to be put will determine the category into which it will fall. . . . *The manufacturer of the article through his representations in connection with its sale can determine the use to which the article is to be put.*" S. REP. NO. 73-493, at 2-3 (1934) (emphasis added). Under this well-settled understanding of the meaning of these terms, the intended use or intended effect of a product is determined by the communications that a manufacturer makes to the consumer. *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 153 F.3d 155, 163 (1998) *aff'd* 529 U.S. 120 (2000). Thus, "off-label" uses or abuses of a product, even if common, will not subject a manufacturer to the jurisdiction of the FDA if the manufacturer's labeling, promotion, and marketing do not claim that the product has therapeutic value or will alter the functions of the body.

[4] Although most cases discuss marketing and labeling in the context of the manufacturer, the Act's terms apply equally to a distributor engaged in labeling, such as SE. To avoid confusion, SE will continue to use the customary term and refer generally to "manufacturer" labeling and marketing.

Since 1938, this well understood meaning of "intended use" and "intended to affect" has not been seriously challenged by any court or by Congress; instead, both courts and the FDA itself have repeatedly emphasized that in order for the FDA to assert jurisdiction over a product, the manufacturer must make representations about the product's therapeutic uses or its ability to alter the function of the body. *See Action on Smoking & Health v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980) (upholding the FDA's position that it did not have jurisdiction to regulate tobacco products because they are not customarily marketed for therapeutic use or to alter a function of the body); *see also NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974) ("[A] court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration."); *Assn. of Am. Physicians & Surgeons, Inc. v. Food & Drug Admin.*, 226 F. Supp. 2d 204, 217-18 (D.D.C. 2002) (noting that an agency's traditional position should be given increased weight). Indeed, the Fourth Circuit noted that this body of law is so uniformly accepted that "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the Act absent manufacturer claims as to that product's use." *Brown & Williamson*, 153 F.3d at 163. Accordingly, "[t]he crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent." *Action on Smoking*, 655 F.2d at 238-39.

In 1996, however, the FDA did an about face from its eighty-year position and asserted that it had jurisdiction over tobacco products because nicotine was a "drug" within the meaning of the FDCA and tobacco was a combination product that delivered nicotine to the body. *Brown & Williamson*, 529 U.S. at 125. As part of this new position, the FDA asserted that manufacturer product claims were no longer determinative as to "intent" under the FDCA; instead, the FDA asserted, intent would be found if the effects of the product were "so widely known and

foreseeable that they may be deemed to have been intended by the manufacturer." Likewise, the FDA asserted, intent could be found when consumers predominantly used the product in order to obtain a therapeutic benefit or for the purpose of physiological alteration, particularly if the manufacturer intentionally *designed* the product for the purpose of affecting the function of the body, even if the product was not so *marketed*. *Id.* at 127.

The Fourth Circuit squarely rejected the FDA's attempt to alter its long-standing policy, noting that "an initial problem with the government's theory is that the definitions of drug and device require not only that the article 'affect the structure or any function of the body,' *but also that these effects be intended.*" *Brown & Williamson*, 153 F.3d at 163 (emphasis added). The Supreme Court affirmed the Fourth Circuit's decision; however, in so doing, the Supreme Court did not reach the issue of whether the FDA's new interpretation of the statute was valid. Instead, the Supreme Court affirmed the Fourth Circuit on a separate ground, holding, as discussed above, that Congress "clearly precluded the FDA from asserting jurisdiction to regulate tobacco products." *Brown & Williamson*, 529 U.S. at 126. Despite that the Supreme Court left this question unresolved, lower courts have continued to apply the long-standing rule that the manufacturer's marketing plans and labeling are the primary factors to consider in determining the manufacturer's intent. *See, e.g., United States v. Livdahl*, 459 F. Supp. 2d 1255, 1260 (S.D. Fla. 2005) ("Regardless of the actual physical effect of a product, it will be deemed a drug for purposes of the Act where the labeling and promotional claims show intended uses that bring it within the drug definition."); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 567 (D.N.J. 2004). Indeed, this is a case that amounts to a purely legal question, thus not triggering any obligation of deference to the agency's interpretation. *United States v. 29 Cartons of an Article of Food*, 987 F.2d 33, 38 (1st Cir. 1993). Thus, notwithstanding the FDA's recent attempt

to assert jurisdiction over products far beyond those that Congress intended, the law remains clear and constant: absent manufacturer claims of medical or therapeutic effects, FDA jurisdiction will not lie. *See Assn. of Am. Physicians & Surgeons, Inc. v. Food & Drug Admin.*, 226 F. Supp. 2d 204, 217-18 (D.D.C. 2002) (noting that a newly adopted agency position need not be given equal weight as an agency's traditional position).

As shown above, the meaning of the twin concepts of "intended use" and "intended to affect" has a long and settled history. This meaning, which was embraced by the FDA itself for over eighty years regarding the delivery of nicotine through tobacco products, requires that a product's intended use be determined by the manufacturer's objective marketing and labeling of its products. Only if a manufacturer's marketing and labeling of the product promotes a therapeutic or body function altering use is jurisdiction allowed; indeed, this type of marketing is *essential* for jurisdiction under the FDCA. *Brown & Williamson*, 153 F.3d at 163. The meaning of these terms is well settled because it is the most consistent with Congressional intent, the wording of the statute itself, and the overarching purpose of the FDA and the FDCA.

In the case at hand, Smoking Everywhere does not intend—and does not claim in its current marketing or labeling—that E-cigarettes can be used for therapeutic purposes or for the purpose of altering a function of the body. Instead, SE's E-cigarette is designed and intended simply as an inexpensive alternative to traditional cigarette smoking without the inconveniences of fire, ash, smell, tar, carcinogens, second-hand smoke or the stub of a traditional cigarette. Indeed there are benefits over traditional cigarettes due to the lack of combustion products that create less of the risk environment of a traditional cigarette but in the end, the electronic cigarette is intended to replicate the non-therapeutic experience of smoking a traditional cigarette that does not deliver nicotine through the chemical laden tobacco leaf. Although some users and

some independent distributors may have used or advertised the E-cigarette as a smoking cessation device, this "off-label" use is insufficient to bring the E-cigarette within the scope of FDA jurisdiction because it is a use that is not intended by the manufacturer of the product—a test that has been part of the FDCA and its predecessor acts for over one hundred years. Because the intended use of the E-cigarette is to replicate the smoking experience of a tobacco product and not for any therapeutic purpose, the E-cigarette is not a drug-device combination under the FDCA and therefore is outside the scope of the FDA's jurisdiction.

B. *SE is Likely to Succeed in Showing that the FDA's Decision to Include E-cigarettes on Import Alert 66-41 Without Allowing Opportunity for Notice and Comment Violated the Administrative Procedures Act.*

When an agency adopts a new, substantive position, "[t]he agency must make findings that support its decision, and those findings must be supported by substantial evidence." *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962) *cited in Motor Vehicle Mfgs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). This fundamental requirement has been explicitly extended to the issuance of import alerts by the FDA. An import alert advises FDA field offices of ongoing problems with a specific product offered for import and suggests appropriate action, such as detention for inspection and sampling. When an agency issues an import alert that affects a substantive change in the law, it is *required* to follow the notice and comment procedures outlined in the APA, 5 U.S.C. § 553. *Bellarno Int'l Ltd. v. Food & Drug Admin.*, 678 F. Supp. 410, 416 (E.D.N.Y. 1988). A substantive rule is defined as one that "grants rights, imposes obligations, or produces other significant effects on private interests." *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992) (finding that an import alert was a substantive rule, requiring notice and comment).

The Eastern District of New York's decision in *Bellarno* is on all fours with the present case. In *Bellarno*, the plaintiffs attempted to import into the United States a shipment of Bufferin

and Excedrin pain reliever tablets. When the shipment arrived in New York, the FDA, pursuant to an import alert, blocked its entry, stating that the Bufferin and Excedrin were both "new drugs" and "misbranded" under the FDCA. *Id.* at 411. The plaintiffs brought an action against the FDA, alleging that its issuance of an import alert blocking the entry of the pain reliever products violated the APA because the FDA failed to follow the required notice and comment procedure before issuing the import alert. The court agreed, holding that the import alert was binding, non-discretionary, and affected the substantive rights of plaintiffs. *Id.* at 412-16. Accordingly, the Court found, the import alert was unlawful and void. *Id.* at 416.

Under *Bellarno*, four factors must be considered in determining whether agency action is a substantive rule, thus triggering the notice and comment requirement, or an interpretative rule, which does not require notice or comment. The factors to be considered are: (1) the binding effect of the pronouncement; (2) the degree of discretion accorded the agency in applying the pronouncement; (3) deference to the agency's characterization; and (4) the language of the pronouncement itself. *Id.* at 413. In this case, when viewing the four prongs together, the totality of the factors weigh in favor of classifying the FDA's decision to add E-cigarettes to Import Alert 66-41 as a substantive rule, thus requiring the opportunity for notice and comment under the APA.

While the language of Import Alert 66-41 differs from *Bellarno* in that it does not contain the same non-discretionary language that appeared in the *Bellarno* import alert, it is apparent from the surrounding circumstances that the Import Alert 66-41 is being treated by the FDA as mandatory. Since the time that the FDA has become interested in E-cigarettes, the agency has made repeated, public statements indicating that the agency considers E-cigarettes to be a drug-device combination under the FDCA and will be regulated as such. As is evident from the

addition of E-cigarettes to Import Alert 66-41, the FDA has officially classified E-cigarettes as a drug-device combination, and has done so without the benefit of the formal rule making process and without the opportunity for interested parties, such as SE, to present evidence or voice objections to the FDA. Instead of seeking public input and offering opportunity for notice and comment, the FDA simply added E-cigarettes to Import Alert 66-41, thus triggering their mandatory detention upon entry. Prior to the addition of E-cigarettes to the import alert, none of SE's shipments was detained by either the FDA or Customs and Border Patrol; however, since the time that E-Cigarettes were added to the import alert, several SE shipments of E-cigarettes has been denied entry into the country on the basis that E-cigarettes are both new drugs (requiring FDA approval) and misbranded; these are, not coincidentally, the same reasons that E-cigarettes were added to Import Alert 66-41.

Far from "discretionary," the addition of E-cigarettes to Import Alert 66-41 is a substantive directive that reflects an official policy of the FDA that E-cigarettes are to be considered "new drugs" under the FDCA. While the FDA may make this determination, it must do so by following the procedures established by Congress in the APA, which include providing an opportunity for public notice and comment. That was not done here. Instead, the FDA promulgated a new, binding rule, announced it to the world, and is now enforcing it without providing the statutorily required notice and comment. This is improper.

Although the import alert itself contains discretionary language and the FDA will undoubtedly assert that the alert is merely issued for guidance, the "analysis of the other criteria militate toward a finding that the pronouncement is not a general statement of policy or interpretative rule, but rather is a binding legislative rule that is subject to notice-and-comment procedures." *Bellarno*, 678 F. Supp. at 415-16. Further belying the FDA's anticipated

contention that Import Alert 66-41 is merely guidance (as opposed to a binding order) is the FDA's continued refusal to engage in a dialogue with SE about the importation of E-cigarettes. SE has sent several letters and emails to FDA employees following the initial detention of E-cigarettes, and at no time has the FDA provided a substantive response to SE or indicated any willingness whatsoever to engage in discussion or provide SE with a hearing at which it could present evidence. Instead, as is clear from its comments made to the news media, the FDA made its decision to regulate and ban the use of E-cigarettes, and it has done so by blocking their entry to the United States pursuant to Import Alert 66-41.[5] Most troubling, it has done so without following the process that Congress explicitly required federal agencies to undertake before making decisions such as this.

Because the FDA added E-cigarettes to Import Alert 66-41 without following the APA's required notice and comment procedure, SE is likely to prevail on the merits of its claim that the FDA's conduct is unlawful.

III. An Injunction Would Not Harm Defendants and Would Not Be Adverse to the Public Interest.

The balance of hardships unquestionably tips heavily in favor of SE. Any harm that Defendants might suffer if the requested injunction is granted will be administrative in nature and is outweighed by the irreparable harm that SE faces if an injunction does not issue: the likely ceasing of SE's business operations.

The requested injunctive relief merely requires that the FDA comply with the terms of the APA and withhold judgment on the status of E-cigarettes until such time as it has engaged in the formal rule making process, during which SE will be provided with the opportunity to present evidence and testimony. Unlike with other potentially dangerous products, the FDA does not

[5] To SE's knowledge, the FDA has not attempted to seize domestic E-cigarettes or block the distribution of E-cigarettes that have already been imported into the United States.

contend that SE's product is an immediate danger to the public or is completely unsafe when used as an alternative smoking device, thus there is no harm to either the FDA or the general public by requiring the FDA to engage in the APA's formal rule making process. Accordingly, because SE will be forced to cease operations if an injunction does not issue, and the FDA will face no harm if an injunction issues, the balance of hardships weighs heavily in favor of SE.

CONCLUSION

Because SE is substantially likely to succeed on the merits of its claims and because it faces certain irreparable harm with no adequate remedy at law, SE respectfully requests that this Court issue a temporary restraining order, and a preliminary and permanent injunction lifting the import ban on E-cigarettes, or, in the alternative, enjoin the FDA from enforcing its import ban on E-cigarettes until such time as the FDA has properly completed the formal rule making process required by the Administrative Procedures Act. Further, SE respectfully requests that this Court order the release of all products detained on the basis of the unlawful import ban.

Respectfully submitted,

THOMPSON HINE LLP

Dated: April 28, 2009

By: _____

Kip Schwartz (D.C. Bar # 444650)
1920 N Street, N.W., Suite 800
Washington, D.C. 20036
(202) 331-8800 Telephone
(202) 331-8330 Facsimile

Counsel for Plaintiff Smoking Everywhere, Inc.

Of Counsel:

Walt Linscott

signed with permission by Eric Heyer

Walt Linscott
THOMPSON HINE LLP
1201 West Peachtree Street, N.W.
Suite 2200
Atlanta, GA 30309
Phone: (404) 541-2900
Facsimile: (404) 541-2905

Brian Lamb

signed with permission by Eric Heyer

Brian Lamb
THOMPSON HINE LLP
3900 Key Center
127 Public Square
Cleveland, OH 44144-1291
Phone: (216) 566-5500
Facsimile: (216) 566-5800

Matthew Ridings

signed with permission by Eric Heyer

Matthew Ridings
THOMPSON HINE LLP
3900 Key Center
127 Public Square
Cleveland, OH 44144-1291
Phone: (216) 566-5500
Facsimile: (216) 566-5800

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC.
5600 NW 102nd Avenue, Suite A
Sunrise, Florida 33351

Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION,
JOSHUA M. SHARFSTEIN, M.D., Acting
Commissioner for Food and Drugs,
MARGARET HAMBURG, M.D.,
Commissioner Designate for Food and Drugs
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

and

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
CHARLES E. JOHNSON, acting Secretary of
the Department of Health and Human Services,
KATHLEEN SEBELIUS, Secretary Designate
for the Department of Health and Human
Services
200 Independence Avenue, SW
Washington, D.C. 20201

Defendants.

09 0771

Case No. _____

LOCAL RULE 65.1 CERTIFICATION OF NOTICE

I, Kip Schwartz, counsel for Plaintiff, hereby certify that notice of the Moti Temporary Restraining Order and/or Injunctive Relief has been provided by send facsimile copies of the verified complaint, motion for temporary restraining order, s memorandum, and proposed order to the Office of the General Counsel of the Dep Health and Human Services at fax number (202) 690-5452, and to Eric Blumberg, E

Litigation in the Office of the General Counsel of the Food and Drug Administration at fax number (301) 443-0933. The faxes were sent at 12:05 PM and 12:07 PM respectively on April 28, 2009.

Kip Schwartz (D.C. Bar # 444650)
kip.schwartz@thompsonhine.com
1920 N Street, N.W., Suite 800
Washington, D.C. 20036
(202) 331-8800 Telephone
(202) 331-8330 Facsimile

Counsel for Plaintiff Smoking Everywhere, Inc.

CERTIFICATE OF SERVICE

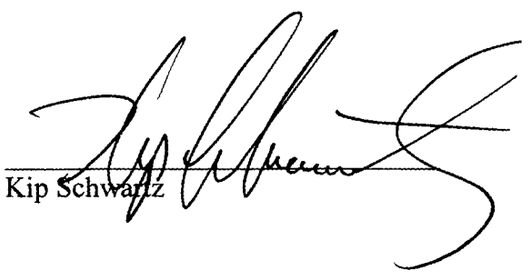
I, Kip Schwartz, hereby certify that on April 28, 2009, I caused the original of the foregoing Local Rule 65.1 Certification of Notice to be filed in hard copy with the Clerk of Court and that I served a true and correct copy of the same via registered first class United States mail on the following pursuant to Federal Rule of Civil Procedure 4(i):

United States Food and Drug Administration
Joshua M. Sharfstein, M.D., Acting Commissioner for Food and Drugs
Margaret Hamburg, M.D. Commissioner Designate for Food and Drugs
10903 New Hampshire Avenue,
Silver Spring, Maryland 20903

United States Department of Health and Human Services
Charles E. Johnson, Acting Secretary of the Department of Health and Human Services
Kathleen Sebelius, Secretary Designate for the Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Civil Process Clerk
Office of the United States Attorney for the District of Columbia
555 4th Street, N.W.
Washington, D.C. 20530

Eric H. Holder, Attorney General of the United States
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530-00001



Kip Schwartz