FILED
APR 28 2009
Clerk, U.S. District and Bankruptcy Courts

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

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND TEMPORARY RESTRAINING ORDER

Plaintiff Smoking Everywhere, Inc. ("SE"), for its Complaint against the United States Food and Drug Administration, Joshua M. Sharfstein, M.D., Acting Commissioner for Food and Drugs, and Margaret Hamburg, M.D., Commissioner Designate for Food and Drugs (collectively, "FDA"), and the United States Department of Health and Human Services, Charles E. Johnson, acting Secretary of the Department of Health and Human Services, and Kathleen

Sebelius, Secretary Designate for the Department of Health and Human Services (collectively, "DHHS") hereby alleges as follows:

Preliminary Statement

1. This is an action for declaratory and injunctive relief pursuant to 28 U.S.C. § 2201 and 5 U.S.C. § 702 *et seq.* to stop the FDA from improperly exceeding its delegated authority by attempting to regulate electronic cigarettes—electronic products that are derived from tobacco and allow a user to inhale a liquid nicotine vapor for the purpose of "smoking" pleasure. The FDA has further exceeded its properly delegated authority by adding, without opportunity for public notice and comment, electronic cigarettes to an FDA "import alert," which alerts FDA field offices and the United States Customs and Border Protection ("USCBP") to the attempted entry of certain products into the United States, resulting in their refused admittance. By including electronic cigarettes on the FDA's import alert, several shipments of SE's products have been wrongfully refused entry into the United States. The FDA's conduct is *ultra vires* of its authority under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and by failing to engage in mandatory public notice and opportunity for comment, the FDA's conduct further violates the notice and comment procedures codified at 5 U.S.C. § 553.

Parties

2. Plaintiff SE is a Florida corporation with its principal place of business located at 5600 NW 102nd Avenue, Suite A, Sunrise, Florida 33351. SE is an importer and distributor of Electronic cigarettes ("E-cigarettes") and E-cigarette accessories.

3. Defendant United States Food and Drug Administration is a division of Defendant Department of Health and Human Services. FDA has responsibility, *inter alia*, for ensuring that certain defined medical devices and medical products sold within the United States are safe and

effective. The headquarters and principal place of business of the FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903. The headquarters and principal place of business of Defendant DHHS is at 200 Independence Avenue, SW, Washington, D.C. 20201.

Jurisdiction and Venue

4. This Court has subject matter jurisdiction over Plaintiff's claims pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 2201, and 5 U.S.C. § 706.

5. This Court has personal jurisdiction over Defendants FDA, DHHS, and Acting Commissioner Joshua M. Sharfstein, Commissioner Designate Margaret Hamburg, Acting Secretary Charles Johnson, and Secretary Designate Kathleen Sebelius in their official capacities, as each is an agency or official of the United States Government.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because Defendant DHHS resides within the district of Washington, D.C.

Statement of Facts

SE and the Development of the E-Cigarette

7. SE is a Florida corporation that has pioneered the marketing and importation of electronic smoking devices. Since SE's founding over one year ago, SE has become an industry leader in the marketing, importation, and wholesale distribution of E-cigarettes and similar products, having imported and sold over 600,000 units since its founding.

8. An E-cigarette is an alternative to traditional smoked tobacco products and is designed to replicate the adult experience of smoking without combustion or the use of cancerous by-products. The E-cigarette functions by vaporizing a liquid nicotine mixture that, in the case of SE's product, is naturally derived from tobacco plants. Once the nicotine mixture is vaporized, the user may inhale the nicotine vapor in a manner similar to that of inhaling actual

tobacco smoke, but without the fire, flame, tar, carbon monoxide, known cancerous substances, ash, stub, or smell found in traditional cigarettes.

9. E-cigarettes are made up of three basic parts: the cartridge, the heating element or atomizer, and the battery and electronics. The cartridge is a disposable plastic container that contains a mixture of propylene glycol and liquid nicotine and serves as the mouthpiece of the E-cigarette. The heating element serves to vaporize the naturally derived nicotine mixture that is ultimately inhaled by the user. Finally, the battery and electronics power the heating element and monitor air flow. Each of the parts of an E-cigarette is designed to look like an actual cigarette, thereby further mimicking a traditional smoking experience.

10. When a user inhales on an E-cigarette, the air flow is detected by the device's electronics and activates the heating element within the E-cigarette. When the heating element is activated, the natural liquid nicotine mixture is vaporized, and the user inhales the nicotine vapor. The vapor contains a flavoring designed to simulate the flavor and feel of tobacco, but no flame, combustion, or smoke occurs with the use of an E-cigarette.

11. SE does not market the E-cigarette for any therapeutic purpose, as a smoking cessation aid, or as a product that is designed to affect the function of the body of man. Instead, E-cigarettes are marketed, labeled, and sold solely to provide adult consumers with alternative "smoking" pleasure, without the inconveniences of traditional tobacco smoking.

12. SE imports one hundred percent of its supply of E-cigarettes from overseas manufacturers, and, upon information and belief, there is no domestic manufacturer of E-cigarettes or their component parts. One hundred percent of SE's revenue is derived from the importation and distribution of E-cigarettes, and if SE could not obtain a reliable supply of E-cigarettes – its only product line – its viability as a business would be gravely threatened.

13. As part of its distribution network, SE has binding contracts with overseas suppliers and manufacturers of E-cigarettes. Additionally, SE has entered into contracts with over one hundred independent distributors of E-cigarettes. These distributors sell E-cigarettes at physical storefronts throughout the United States.

The FDA Action

14. Throughout most of the FDA's history, the FDA has explicitly and repeatedly disclaimed the authority and jurisdiction to regulate tobacco products as nicotine delivery mechanisms. During this same time period, Congress, on several occasions, debated whether to extend the FDA's jurisdiction to include tobacco products. Each time, however, Congress determined that the FDA should not have jurisdiction over tobacco products.

15. In or around 1995, the FDA reversed course on its long-standing policy, asserting that it had jurisdiction to regulate cigarettes and tobacco products as a nicotine delivery device, further proposing and adopting binding regulations relating to the marketing and sale of cigarettes and tobacco products.

16. Each of the major tobacco companies brought suit against the FDA, alleging that the FDA regulations were *ultra vires* and that the FDA had no authority to regulate tobacco products as nicotine delivery devices.

17. In 2000, the Supreme Court of the United States, in *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), held that Congress did not intend that the FDCA grant the FDA jurisdiction to regulate cigarettes or tobacco products as nicotine delivery devices.

18. Upon information and belief, unable to regulate traditional cigarettes or tobacco products, the FDA, during late 2008 and early 2009, began to take an increased interest in the

importation, distribution, and sale of E-cigarettes. This increased interest has led to the FDA's adoption of a new policy, which includes the apparent classification of E-cigarettes as a drug-device combination under Section 503(g)(1) of the FDCA. In 2009, the FDA has made repeated and public statements claiming that it now considers E-cigarettes to be drug-device combinations within its purview. It has made these statements notwithstanding that the FDA is explicitly not authorized to regulate tobacco products as drug-device combinations.

19. Since the time that SE became aware of the FDA's new, un-promulgated policy relating to E-cigarettes, SE has repeatedly sought to engage the FDA in a dialogue relating to the classification and marketing of E-cigarettes. The FDA has not provided substantive response to SE's requests for a dialogue on the classification of E-cigarettes.

20. Upon information and belief, in or around early 2009, the FDA added E-cigarettes to Import Alert 66-41, which, *inter alia*, directed the USCBP to reject the entry of "Electronic Cigarettes and Electronic Cigarette Components" into the United States. An import alert advises FDA field offices of potential issues relating to particular products, and Import Alert 66-41 stated that that E-cigarettes were unapproved drugs and/or misbranded drugs promoted in the United States. This constitutes a substantive, binding regulation.

21. Upon information and belief, the FDA added E-cigarettes to Import Alert 66-41 without publishing its proposed action in the Federal Register and without personally serving notice of the rule making proceedings upon SE.

22. At no time before the FDA added E-cigarettes to Import Alert 66-41 was SE given the opportunity to participate in the FDA's rule making process by submitting its written views or being allowed to make oral arguments before the FDA. Further, at no time since E-

cigarettes were added to Import Alert 66-41 has SE been given the opportunity to formally present its views to the FDA or any other governmental agency.

23. Following the FDA's decision to add E-cigarettes to Import Alert 66-41, SE's overseas shipments of product have been denied entry into the United States on multiple occasions. With no ability to import E-cigarettes, SE's inventory will soon be depleted, leaving SE with no products to distribute or sell, effectively shutting down SE's business.

24. In or about late 2008 and early 2009, SE received several "Notices of FDA Action" from the Los Angeles district office of the FDA, including one that was dated March 16, 2009. The March 16, 2009 Notice of Action stated that SE's shipment of E-cigarettes was refused admission into the United States on or about March 13, 2009. A true and accurate copy of the March 16, 2009 Los Angeles Notice of Action is attached hereto as Exhibit A.

25. The Notice of Action stated that the FDA refused admission of the E-cigarette products because the "product appears to be a combination drug-device product that requires pre-approval, registration and listing with FDA."

26. The FDA Notice of Action further stated that 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 FDA refused entry of the E-cigarettes on these, and other, bases.

27. Upon information and belief, the FDA did not publish in the Federal Register its proposed decision to classify E-cigarettes as a new drug-device combination and it did not give SE personal notice of the proposed action.

28. Upon information and belief, on or about April 13, 2009, SE received a shipment of E-cigarettes and E-cigarette accessories at the Port of Miami, in Miami, Florida. Upon information and belief, SE's shipment of E-cigarettes was denied entry into the United States by

the USCPB upon the FDA's request. Upon information and belief, SE's shipment of E-cigarettes was denied entrance at the Port of Miami because of the FDA's inclusion of E-cigarettes on Import Alert 66-41.

29. Upon information and belief, the FDA will continue to order that all overseas shipments of E-cigarettes be denied entry into the United States until such time that E-cigarettes have been approved by the FDA as a new drug within the meaning of section 201 of the FDCA.

30. The FDA's addition of E-cigarettes to Import Alert 66-41 is a final decision by the FDA that E-cigarettes are a drug-device combination product. Furthermore, the FDA, in repeated and public statements, has declared that it considers E-cigarettes to be within the agency's jurisdiction because E-cigarettes are a drug-device combination product.

31. The new policy and classification of E-cigarettes threatens the continued viability of SE, which receives one hundred percent of its revenue from the distribution and sale of imported E-cigarettes. The FDA's un-promulgated policy threatens to disrupt not only SE's business, but its contracts with its suppliers and distributors, and also threatens the ongoing viability of SE's authorized distributors.

32. Other than review in this Court, no avenue for redress exists for SE to undo the harm that has been done to date and to prevent the harm that will be done in the future. Unless FDA's assertion of jurisdiction is reviewed, the Agency will continue to assert unauthorized power over SE and, indeed the entire E-cigarette industry, by condemning its products as "drugs" or "drug delivery devices."

33. The FDA's attempt to regulate E-cigarettes tacitly infringes Congress's clear intent to withhold FDA jurisdiction over tobacco products as nicotine delivery devices from FDA and is a clear violation of the jurisdictional limits on the FDA's authority as stated by the Supreme

Court. Because there is no legislative basis for FDA's action, immediate review by this Court is necessary.

34. SE seeks a temporary restraining order, preliminary injunction, and permanent injunction: (a) prohibiting Defendants from continuing to enforce the FDA's new policy and classification of E-cigarettes; and (b) lifting the import ban on E-cigarettes, which was issued without notice and comment. SE also requests the issuance of a declaratory judgment that the FDA's conduct in regulating or attempting to regulate E-cigarettes is invalid and unlawful.

COUNT I

(The FDA Assertion of Jurisdiction Over E-Cigarettes is Ultra Vires*)*

35. SE incorporates paragraphs 1-34 above by reference as if fully set forth herein.

36. The FDA has no authority under the FDCA or any other relevant statute or regulation with respect to E-cigarettes because Congress and the United States Supreme Court have explicitly determined the delivery and use of nicotine through hazardous tobacco products to be outside the jurisdiction of the FDCA.

37. The FDA has no authority under the FDCA or any other relevant statute or regulation with respect to E-cigarettes because E-cigarettes are not "drugs," "drug delivery systems," or "drug device combinations" under 21 U.S.C. § 321(g).

38. The FDA's action in asserting jurisdiction over E-cigarettes is therefore "in excess of statutory jurisdiction, authority, or limitations of statutory right," and is further contrary to the public interest. The FDA's assertion of authority is unlawful, and any regulations or policies stemming from its unlawful conduct must be set aside in accordance with Section 706(2) of the Administrative Procedures Act ("APA"). 5 U.S.C. § 706(2).

39. Additionally, any FDA enforcement resulting from its declaration of jurisdiction over E-cigarettes should be preliminarily enjoined pending judicial review of such actions pursuant to Section 705 of the APA.

40. As a direct and proximate result of FDA's unlawful acts, SE has been seriously injured and faces irreparable harm as alleged in this Complaint.

COUNT II

(Failure to Comply with the Administrative Procedures Act)

41. SE incorporates paragraphs 1-40 above by reference as if fully set forth herein.

42. As a federal agency, the FDA is required to follow and apply all laws, rules, and regulations in a uniform manner and in such a way as to provide for due process for citizens of the United States.

43. FDA is charged by Congress with enforcing the FDCA and several other public health laws. Congress has permitted the FDCA to be implemented and applied through the lawfully promulgated regulations of the Code of Federal Regulations. Any final rule or regulation issued by an administrative agency that affects a substantive change in the law must be adopted pursuant to the required notice and comment procedures of the APA. 5 U.S.C. § 553 *et seq.*

44. Import Alert 66-41, which, *inter alia*, directed the USCBP to reject the entry of "Electronic Cigarettes and Electronic Cigarette Components," is a binding, substantive rule that imposes obligations on other parties and significantly affects the interests of SE and others in the electronic cigarette industry.

45. The FDA did not provide opportunity for notice and comment pursuant to the APA before classifying E-cigarettes as a new drug or drug-device combination. The FDA

neither published notice of the new rule in the Federal Register nor served personal notice on the parties affected by the un-promulgated rule.

46. The FDA's failure to comply with the observance of the procedures required by law is a violation of Section 706 of the APA and thus renders its actions unlawful.

47. In addition, the FDA has not established a rational nexus between the addition of E-cigarettes to Import Alert 66-41 and the Congressional mandate empowering the FDA to ensure that medical devices and medical products sold within the United States are safe and effective.

48. The FDA has had a custom and practice of not interfering with the importation of E-cigarettes and other tobacco products that are outside of the FDA's jurisdiction. With its addition of E-cigarettes to Import Alert 66-41, the FDA has departed from precedent without cause, good reason, and notice.

49. The FDA's addition of E-cigarettes to Import Alert 66-41 is an "arbitrary" and "capricious" agency action because it departs from precedent without benefit of notice, public hearing, and good cause.

50. The FDA's addition of E-cigarettes to Import Alert 66-41 is an "arbitrary" and "capricious" agency action because it seeks to treat the use of nicotine for non-therapeutic uses differently than uses found in traditional tobacco products.

51. This conduct by FDA is ongoing and immediate. As a result of the ongoing conduct of FDA, SE has been harmed and is being harmed in that: (a) SE receives 100 percent of its revenue from imported E-cigarettes, and E-cigarettes are not manufactured in the United States, at least not in sources currently available to SE; (b) SE will lose the ability to fulfill its outstanding obligations and contracts with its suppliers and distributors; (c) Import Alert 66-41

threatens the ongoing viability of both SE itself and its authorized distributors; and (d) the inability to import E-cigarettes will lead to SE having to terminate its distributors and/or dismiss employees whose work relates to the retail sale and distribution of these products.

52. As a direct and proximate result of FDA's unlawful acts, SE has been seriously injured and faces irreparable harm as alleged in this Complaint.

53. Consequently, the FDA's issuance of Import Alert 66-41 must be enjoined pursuant to 5 U.S.C. § 706(2)(A) and (D).

COUNT III
(Declaratory Judgment)

54. SE incorporates paragraphs 1-53 above by reference as if fully set forth herein.

55. Defendants' actions are in violation of federal statute and regulations.

56. SE is experiencing harm from Defendants' failure to follow the law.

57. This conduct by FDA is ongoing and immediate. As a result of the ongoing conduct of FDA, SE has been harmed and is being harmed in that: (a) SE receives 100 percent of its revenue from imported E-cigarettes, and E-cigarettes are not manufactured in the United States, at least not in sources currently available to SE; (b) SE will lose the ability to fulfill its outstanding obligations and contracts with its suppliers and distributors; (c) Import Alert 66-41 threatens the ongoing viability of both SE itself and its authorized distributors; and (d) the inability to import E-cigarettes will lead to SE having to terminate its distributors and/or dismiss employees whose work relates to the retail and distribution of these products.

58. SE requests the Court: (1) to declare that the actions of the FDA as set forth in this Complaint are contrary to the language of the law, are contrary to binding Supreme Court of the United States precedent, are arbitrary and capricious in its application, and are *ultra vires*; (2) to enter judgment in favor of SE; and (3) to enjoin and prohibit FDA from enforcing Import

Alert 66-41 with respect to E-cigarettes or from enforcing any import ban on E-cigarettes relating to their classification under the FDCA and from taking any other action to regulate E-cigarettes.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Enter a temporary restraining order and a preliminary injunction, pending a decision on the merits, that enjoins Defendants from enforcing any import ban on E-cigarettes relating to their classification under the FDCA, or from enforcing Import Alert 66-41 with respect to electronic cigarettes and electronic cigarette component parts;

B. Upon hearing the merits, enter a declaratory judgment that Defendants are without statutory authority to regulate E-cigarettes under the FDCA and that addition of E-cigarettes to Import Alert 66-41 is invalid, unlawful, and *ultra vires* of Defendants' authority, and further enter a permanent injunction prohibiting Defendants from regulating E-cigarettes or E-cigarette component parts, or, in the alternative, enter a permanent injunction that prohibits Defendants from regulating E-cigarettes unless and until such time that Defendants undergo the required procedures pursuant to the APA;

C. Order the release of any E-cigarettes currently detained or seized by the United States Government pursuant to the FDA's unlawful declaration that it has jurisdiction over E-cigarettes;

D. Award SE its costs and expenses, including reasonable attorneys' fees; and

E. Award such further and additional relief as is just and proper.

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

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EXHIBIT A

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: DO7-1112223-7

Notice Number: 4
March 16, 2009

Importer:
Smoking Everywhere Llc
4500 N Hiatus Rd
Ste 215
Fort Lauderdale, FL 33351

Port of Entry: 2720, Los Angeles International Airport, Los Angeles, CA
Carrier: CATHAY PACIFIC AIRWAYS;
Date Received: October 16, 2008
Arrival Date: September 29, 2008

Filer of Record: TNT Express WORLDWIDE, Los Angeles, CA 90045
Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
	001/001	ATOMIZER DEVICE	36 BX	Line Split
*	001/001A	Electronic Cigarette E-Cigararette Kit	1000 PCS	Refuse 03-13-2009
*	001/001B	Electronic Cigarette Cartridges	600 BX	Refuse 03-13-2009

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
001/001A	Electronic Cigarette E-Cigararette Kit

Refused : 1,000 PCS

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA.

FD&CA Section 801(a)(3); 502(o) Misbranding
It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.

001/001B Electronic Cigarette Cartridges

Refused : 3,000 PCS

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(4).

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA.

FD&CA Section 801(a)(3); 502(o) Misbranding
It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device.

For the District Director of Customs:

Chih-Shang J. Shen, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700
San Pedro, CA 90731

(310) 971-2353
(310) 971-2363 (FAX)
JIM.SHEN@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this

notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

CBP LAX
11099 S. La Cienega Blvd.
Los Angeles, CA 90045-6115

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: AT

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: DO7-1112224-5

Notice Number: 4
March 16, 2009

Importer:
Smoking Everywhere Llc
4500 N Hiatus Rd
Ste 215
Fort Lauderdale, FL 33351

Port of Entry: 2720, Los Angeles International Airport, Los Angeles, CA
Carrier: CATHAY PACIFIC AIRWAYS;
Date Received: October 16, 2008
Arrival Date: September 28, 2008

Filer of Record: TNT Express WORLDWIDE, Los Angeles, CA 90045
Consignee: Smoking Everywhere Llc, Fort Lauderdale, FL 33351-7984

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line	ACS/FDA	Product Description	Quantity	Current Status
*	001	001	Electronic Cigarette E-Cigarette Kit	12 BX	Refuse 03-13-2009

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Notice of FDA Action
Entry Number: DO7-1112224-5

Notice Number 4
Page: 2

Line ACS/FDA	Product Description
001/001	Electronic Cigarette E-Cigarette Kit

Refused : 7,200 NO

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article appears to be a new drug without an approved new drug application. PRODUCT APPEARS TO BE A COMBINATION DRUG-DEVICE PRODUCT THAT REQUIRES PRE-APPROVAL, REGISTRATION AND LISTING WITH FDA.

For the District Director of Customs:

Chih-Shang J. Shen, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700
San Pedro, CA 90731

(310) 971-2363
(310) 971-2363 (FAX)
JIM.SHEN@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

CBP LAX
11099 S. La Cienega Blvd.
Los Angeles, CA 90045-6115

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: AT

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. _____

VERIFICATION OF ELICKO TALEB TO COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND TEMPORARY RESTRAINING ORDER

Elicko Taleb, under penalty of perjury, declares and verifies that he is the President and Chief Executive Officer of Smoking Everywhere Inc., Plaintiff in the above-named action, and that he has read the foregoing *Verified Complaint for Declaratory and Injunctive Relief and Temporary Restraining Order* and knows the contents thereof.

I declare under penalty of perjury that the foregoing is true and correct.

BY: _____

SWORN TO BEFORE ME and subscribed in my presence this ____ day of April, 2009.

_____

Notary Public