

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TOTALLY WICKED-E.LIQUID (USA), INC.,)
4907 14th Street West)
Bradenton, Florida 34207,)

Plaintiff,)

v.)

CASE NO. _____

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

and)

U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)
KATHLEEN SEBELIUS, Secretary of Health)
and Human Services,)
200 Independence Avenue, S.W.,)
Washington, D.C. 20201,)

Defendants.)

VERIFIED COMPLAINT
(TEMPORARY RESTRAINING ORDER REQUESTED)

Plaintiff Totally Wicked-E.Liquid (USA), Inc. ("TWI"), for its Verified Complaint against the United States Food and Drug Administration, Margaret A. Hamburg, Commissioner for Food and Drugs (collectively, "FDA"), the United States Department of Health and Human Services, and Kathleen Sebelius, Secretary of Health and Human Services (collectively, "DHHS"), hereby alleges as follows:

NATURE OF THE ACTION

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 bar the FDA from exceeding its statutory authority by improperly attempting to regulate TWI's electronic cigarettes—products that are derived from tobacco—and accessories as drugs, devices, or drug-device combination products under the federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and to prohibit the FDA from barring the importation of TWI's electronic cigarettes into the United States.

PARTIES

2. Plaintiff TWI is a privately held Florida corporation with its principal place of business located at 4907 14th Street West, Bradenton, Florida 34207. TWI is an importer and distributor of electronic cigarettes and electronic 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 drugs and medical devices 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, S.W., Washington, D.C. 20201.

JURISDICTION AND VENUE

4. This Court has original subject matter jurisdiction over this matter 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, Commissioner Hamburg, and Secretary Sebelius in their official capacities, as each is an agency or official of the United States.

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

FACTUAL ALLEGATIONS

A. TWI's Electronic Cigarettes

7. TWI, a Florida corporation, is a business that is wholly dedicated to the importation and distribution of electronic cigarettes in the United States. During the period between its founding in early 2009 and the detention of its products in October 2010, TWI imported and sold approximately 60,000 electronic cigarette kits in the United States.

8. An electronic cigarette is an alternative to traditional smoked tobacco products and is designed to replicate the adult experience of smoking without combustion or the inhalation of many of the cancerous byproducts that results from smoking traditional cigarettes. Electronic cigarettes function by vaporizing a liquid nicotine mixture that, in the case of TWI'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, ash, known carcinogenic byproducts, or smell found in traditional cigarettes.

9. Electronic cigarettes are composed of three basic parts: the cartridge, the heating element (also called the "atomizer"), and the battery and electronics. The cartridge is a disposable plastic container that contains liquid nicotine and serves as the mouthpiece of the electronic cigarette. The liquid nicotine cartridges imported and distributed by TWI are of pharmaceutical-grade quality and are produced in Ireland. The heating element serves to vaporize the naturally derived nicotine that is ultimately inhaled by the user. Finally, the battery and electronics power the heating element and monitor air flow. On many of the models

imported and distributed by TWI, each of the parts of an electronic cigarette is designed to look like an actual cigarette, thereby further mimicking the traditional smoking experience.

10. When a user inhales on an electronic cigarette, the air flow is detected by the device's electronics and the heating element is activated, vaporizing the natural liquid nicotine. The user then inhales the nicotine vapor, which contains a flavoring designed to stimulate the flavor and feel of smoking a traditional cigarette.

11. TWI does not, and has never, marketed or advertised its electronic cigarettes for any therapeutic purpose, as a smoking cessation aid, or as a product designed to affect the structure or function of the body of man. Instead, TWI markets, labels, and sells its electronic cigarette products and accessories solely to provide adult consumers with an alternative smoking experience that excludes many of inconveniences and negative externalities associated with smoking traditional cigarettes.

12. TWI imports one hundred percent of its supply of electronic cigarettes from overseas manufacturers and is not aware of any domestic manufacturer of electronic cigarettes or their component parts. TWI's contracts with its suppliers require TWI to purchase a minimum amount of electronic cigarettes each month. One hundred percent of TWI's revenue is derived from the importation and distribution of electronic cigarettes and accessories.

B. FDA's Attempted Regulation of Electronic Cigarettes as Unauthorized Drugs, Devices, or Drug-Device Combination Products.

13. Throughout most of the FDA's history, the FDA explicitly and repeatedly disclaimed the authority and jurisdiction to regulate tobacco products as nicotine delivery mechanisms. Prior to 2009, Congress, on several occasions, debated whether to extend FDA's jurisdiction to include tobacco products. Each time, however, Congress concluded that FDA should not have jurisdiction over tobacco products.

14. In approximately 1995, the FDA changed its historic position and asserted for the first time that it had jurisdiction to regulate cigarettes and tobacco products as a nicotine delivery device. FDA then proposed and adopted binding regulations relating to the marketing and sale of cigarettes and tobacco products.

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

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

17. While thwarted by the Supreme Court in its initial attempts to regulate cigarettes and tobacco products, beginning in approximately 2008 and continuing through the present, FDA nevertheless has attempted to regulate the importation, distribution, and sale of electronic cigarettes in the United States. The electronic cigarette industry remains in its infancy, as the creation of electronic cigarettes was only recently made possible by advances in micro-atomizer technology. Indeed, the FDA's regulatory interest in electronic cigarettes has coincided with a period of exponential growth in the electronic cigarette industry in the United States.

18. FDA's interest in electronic cigarettes led to the apparent adoption of a new internal FDA policy that includes the classification of electronic cigarettes and accessories as unapproved new drugs, devices, and/or drug-device combination products based on the inherent characteristics of electronic cigarettes and their accessories. In 2009 and 2010, the FDA made repeated public statements that it now considered electronic cigarettes to be drug-device

combination products that fell within the FDA's regulatory purview under Chapter V of the FDCA.

19. Upon information and belief, in early 2009, the FDA added electronic cigarettes to Import Alert 66-41 and thereby directed U.S. Customs and Border Protection to reject the entry of electronic cigarettes and their accessories into the United States. An import alert advises FDA field offices of potential issues relating to particular products. Specifically, Import Alert 66-41 stated that electronic cigarettes were unapproved drugs and/or misbranded drugs. FDA's action in this respect constitutes a substantive, binding regulation.

20. Upon information and belief, at no time before the FDA added electronic cigarettes and accessories to Import Alert 66-41 was the proposed action published in the Federal Register. Neither was TWI or any other manufacturer, importer, or distributor of electronic cigarettes allowed to participate in FDA's rulemaking process by submitting its written views or being allowed to make oral arguments before the FDA. With the exception of the litigation described below, no such opportunity has ever formally been afforded any such entity since the addition of electronic cigarettes to the FDA's import alerts.

21. Following several seizures of its products on grounds that they constituted unapproved new drugs and/or devices, on April 28, 2009, Smoking Everywhere, Inc., another importer and distributor of electronic cigarettes, filed a lawsuit, Smoking Everywhere, Inc. v. Food and Drug Administration, Case No. 1:09-cv-771 (RJL), in this Court. Smoking Everywhere's action sought a declaratory judgment and a preliminary and permanent injunction against FDA's misclassification and repeated seizures of its products. The undersigned attorneys for TWI represented Smoking Everywhere in that action.

22. While Smoking Everywhere's motion for preliminary injunction against the FDA was pending, on June 22, 2009, the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 ("Tobacco Act"), was enacted. The Tobacco Act amended the FDCA to explicitly grant to the FDA for the first time statutory authority to regulate "tobacco products" and the advertising and promotion of such products. The Tobacco Act defines "tobacco product" in relevant part as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr)(1). The term "tobacco product" thus encompasses electronic cigarettes, such as those imported and distributed by TWI, that contain nicotine naturally derived from tobacco leaves. The term "tobacco product" explicitly excludes "an article that is a drug under [21 U.S.C. § 321(g)(1)], a device under [21 U.S.C. § 321(h)], or a combination product described in [21 U.S.C. § 353(g)]."

23. The Tobacco Act also provides that "tobacco products" are to be regulated by the FDA under the new Chapter IX of the FDCA and "shall not be subject to the provisions" of Chapter V ("Drugs and Devices"). 21 U.S.C. § 387a(a). Further, the FDA is expressly prohibited from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products" and from "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. § 387g(d)(3).

24. Following the enactment of the Tobacco Act, this Court granted a preliminary injunction in the action brought by Smoking Everywhere. In its opinion, the Court observed as follows:

FDA says that the electronic cigarettes marketed by plaintiffs are a drug-device combination and should therefore be excluded from the Tobacco Act's definition of "tobacco product" because the labeling and promotional materials "represent and suggest that the product will provide the same drug effects as

cigarettes." . . . Because plaintiffs' electronic cigarettes are to be used, like conventional cigarettes, as a means for delivering nicotine and because consumers and scientists widely believe that nicotine has drug-like effects . . . , FDA contends that plaintiffs' electronic cigarettes are intended to affect the structure or function of the body As a result, they qualify as a drug-device combination, not as a tobacco product. Put simply, this argument is bootstrapping run amuck.

That electronic cigarettes are devices for delivering nicotine and are intended to have the same effect on the structure and function of the body as cigarettes is hardly a basis for classifying electronic cigarettes as a drug-device combination, thereby excluding them from the definition of "tobacco product." If it were, then traditional cigarettes would be excluded as well. Indeed, any tobacco product containing nicotine and claiming to have some pharmacological effect would be excluded. Because this result would effectively dismantle the existing regulatory wall Congress erected between tobacco products and drug-device combinations, I can easily infer that Congress *did not* intend tobacco products to be drugs merely because they deliver nicotine.

....

. . . FDA does not contend that the electronic cigarettes marketed by plaintiffs are intended to affect the structure or function of the body in any way materially different from traditional cigarettes. Indeed, by FDA's own admission, Smoking Everywhere markets its product as providing "the same drug effects on the structure and function of the human body as cigarettes." . . . Likewise, NJOY markets its product as providing "all the pleasures of smoking." . . . Because plaintiffs sell their electronic cigarette products for customary recreational use, those products (just like traditional cigarettes) are properly excluded from the meaning of drug or device under the FDCA.

Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 69-70, 73 (D.D.C. 2010).

25. The District Court went on to note:

In sum, absent substantial evidence of the manufacturer's objective intent that its electronic cigarettes affect the structure or function of the body in a way distinguishable from "customarily marketed" tobacco products or that its electronic cigarettes have the therapeutic purpose of treating nicotine withdrawal, there is no basis for FDA to treat electronic cigarettes, as they are marketed by the plaintiffs in this case, as a drug-device combination when all they purport to do is offer consumers the same recreational effects as a regular cigarette. Thus, the plaintiffs are substantially likely to succeed on their claim that FDA cannot regulate and thereby exclude their electronic cigarettes from the United States on the basis that those products are an unapproved drug-device combination under the FDCA.

....

This case appears to be yet another example of FDA's aggressive efforts to regulate recreational nicotine products as drugs or devices under the FDCA. Ironically, notwithstanding that Congress has now taken the unprecedented step of granting FDA jurisdiction over those products, FDA remains undeterred. Unfortunately, its tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that I find, at first blush, to be unreasonable and unacceptable.

Id. at 75, 78.

26. Following the District Court's granting of a preliminary injunction in the Smoking Everywhere action, the FDA appealed. The United States Court of Appeals for the District of Columbia Circuit affirmed the District Court's decision on December 7, 2010, holding that, "[t]ogether, Brown & Williamson and the Tobacco Act establish that the FDA cannot regulate customarily marketed tobacco products under the FDCA's drug/device provisions." Sottera, Inc. v. FDA, 627 F.3d 891, 2010 U.S. App. LEXIS 24883, at *18 (D.C. Cir. 2010).

C. FDA's Seizure of TWI's Electronic Cigarettes and Accessories

27. Despite the resounding refutation of the FDA's policy with regard to electronic cigarettes by both this Court and the Court of Appeals for the District of Columbia Circuit, the FDA has continued its unlawful seizures of imported electronic cigarettes on the grounds that these products constitute drugs, devices, or combination products subject to FDA regulation under Chapter V of the FDCA.

28. On or about October 8, 2010, at the direction of the FDA, U.S. Customs and Border Protection detained a shipment of electronic cigarettes and accessories being imported into the United States through Miami International Airport by TWI.

29. On or about October 26, 2010, TWI received a "Notice of FDA Action" relating to the shipment that advised that the electronic cigarettes contained in the shipment were "subject

to refusal" pursuant to the FDCA because they appeared to be misbranded drugs or devices in violation of FDCA Section 502(o) [21 U.S.C. § 352(o)] and because they appeared to be unapproved new drugs in violation of FDCA Section 505(a) [21 U.S.C. § 355(a)]. (A true and correct copy of the Notice of FDA Action is attached hereto as Exhibit A.)

30. On November 29, 2010, TWI submitted a formal response to the Notice of FDA Action. In its response, TWI noted that both its product packaging and labeling state that its electronic cigarettes and accessories are "an alternative to smoking a traditional tobacco based cigarette" and do not constitute a nicotine replacement therapy. TWI also emphasized that the bottom of every page on TWI's website contains the following disclaimer:

WARNING: the electronic cigarette will not cure a smoker's addiction to nicotine; the electronic cigarette serves the same purpose as a tobacco cigarette—it delivers its user nicotine. If you do suffer from the disease of Tobacco/Nicotine Dependence Syndrome and want to take steps to give up smoking or cut down the quantity of cigarettes you currently smoke[, w]e recommend you visit your health care provider to discuss NRT (Nicotine Replacement Therapy) or a nicotine harm reduction program.

(A true and correct copy of the November 29, 2010 Letter from Jason Cropper, TWI's Managing Director, to Magda M. Karlsen, FDA Compliance Officer, is attached hereto as Exhibit B.)

31. In its submission, TWI also requested that, to the extent that FDA contends that its decision is based on any particular claims or representations made by TWI with respect to its products, the FDA enumerate those claims so that could be modified or eliminated by TWI, as appropriate.

32. Within hours of TWI's transmittal of its response letter to FDA, FDA Compliance Officer Magda Karlsen forwarded an analysis of the shipment that had been performed by the FDA's Center for Drug Evaluation and Research ("Center for Drugs"). In its analysis of TWI's

products, the Center for Drugs concluded that TWI's products constitute drugs and devices under the FDCA:

The labeling claims . . . for the "totally wicked" products indicate that they are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease. They suggest that "totally wicked" products are substitutes for traditional cigarettes and that they are capable of delivering nicotine, which is recognized by the scientific community as a pharmacological agent and is understood by consumers to have drug-like effects. . . . The inclusion of labeling claims stating that the "totally wicked" products will deliver a vapor or mist for inhalation by the user, which may or may not include nicotine; that these articles replicate the physical pleasures of smoking; and satisfy cravings for nicotine establish that the articles are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease. Moreover, the marketing of these articles targets the knowledge and expectations of conventional tobacco users that these articles are suitable for these uses when one cannot, or chooses not to, smoke. The scientific and medical communities have determined that nicotine addiction is a disease and that nicotine withdrawal is itself a recognized medical condition. Thus, these labeling claims fit within the "drug" and "device" definitions in the Act.

(A true and correct copy of the November 29, 2010 Email from Magda Karlsen, FDA Compliance Officer, to Jason Cropper, TWI Managing Director, is attached hereto as Exhibit C.)

33. Following its receipt of the Center for Drugs' analysis, on or about December 1, 2010, TWI sent further correspondence to the FDA requesting direction as to any further action that TWI could take with respect to its labeling, advertising, or website that could lead the FDA to conclude that TWI's products do not fall with the definition of drugs, devices, or combination products. TWI also asked for guidance on whether there was any other FDA department or official to which the Center for Drugs' analysis could be appealed. (A true and correct copy of the December 1, 2010 letter from Jason Cropper, TWI Managing Director, to Magda Karlsen, FDA Compliance Officer, is attached hereto as Exhibit D.)

34. Despite the December 1, 2010 letter and several follow-up emails that have since been sent to Compliance Officer Karlsen, TWI has received no further communications from

FDA regarding the possibility of appealing the Center for Drugs' analysis or steps TWI may take to avoid further rejections of its imports by FDA.

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

36. Upon information and belief, the FDA will continue to order that all overseas shipments of TWI's electronic cigarettes be denied entry into the United States until such time as TWI's electronic cigarettes have been approved by the FDA as a new drug within the meaning of Section 201 of the FDCA. [21 U.S.C. § 321(p)]

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

38. FDA's rejection of TWI's electronic cigarettes and accessories and its continued policy of classifying electronic cigarettes as drugs, devices, or drug-device combination products under the FDCA directly threatens the continued viability of TWI as an ongoing business. Absent a reversal of FDA's policy, TWI will remain unable to import any electronic cigarette products into the United States. TWI's current inventory of electronic cigarettes is limited to only a few weeks' supply remaining. Once that supply is exhausted, TWI will be required to close its doors in the event that it is unable to obtain further shipments of electronic cigarettes. Further, in the event that TWI is not soon able to re-commence its importation of electronic

cigarettes into the United States, TWI will be forced to breach its minimum-quantity supply contracts with its suppliers.

39. No avenue for redress is available to TWI other than review of FDA's actions in this Court and the granting of declaratory and injunctive relief. TWI's attempts to obtain internal administrative review of the decision by the FDA's Center for Drugs have been refused and/or ignored.

40. FDA's actions in barring TWI's imports of electronic cigarettes and the analysis conducted by FDA's Center for Drugs directly contradict the binding authority established by this Court and the Court of Appeals for the District of Columbia Circuit. FDA's actions in barring TWI's imports, in addition to being *ultra vires*, are thus the very definition of "arbitrary and capricious."

41. TWI seeks a temporary restraining order, preliminary injunction, and permanent injunction that: (a) enjoin Defendants from enforcing any import ban on TWI's electronic cigarettes and accessories arising out of their purported classification as a drug, device, or drug-device combination product under the FDCA, or from enforcing Import Alert 66-41 with respect to TWI's electronic cigarettes and accessories; (b) declare that Defendants are without statutory authority to regulate TWI's electronic cigarettes and accessories as a drug, device, or drug-device combination product under the FDCA; and (c) order the release of any of TWI's electronic cigarettes and electronic cigarette accessories currently detained by the United States.

COUNT I
(Declaratory Judgment)

42. TWI incorporates by reference the allegations of paragraphs 1 - 41, above, as if fully set forth herein.

43. Defendants' classification of TWI's electronic cigarettes and accessories as drugs, devices, and/or drug-device combination products under the FDCA is *ultra vires* and unlawful. Defendants' actions are, therefore, "arbitrary and capricious," "not in accordance with law," and "in excess of statutory jurisdiction, authority, and limitations." 5 U.S.C. § 706(2)(A), (C). The Court must, therefore, set aside the FDA's actions undertaken pursuant to its erroneous findings.

44. Defendants' actions are egregiously arbitrary and capricious in so much as they run directly contrary to the ruling of this Court in Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62 (D.D.C. 2010), and the ruling of the Court of Appeals for the District of Columbia Circuit in Sottera, Inc. v. FDA, 627 F.3d 891, 2010 U.S. App. LEXIS 24883 (D.C. Cir. 2010).

45. TWI has been seriously injured and faces the immediate threat of future irreparable harm as a direct and proximate result of Defendants' unlawful acts.

46. TWI has already been seriously harmed in that one shipment of electronic cigarettes and accessories has been detained and denied entry into the United States based on the FDA's erroneous interpretation of its authority. TWI continues to face the threat of irreparable harm in that: (a) TWI receives 100 percent of its revenue from imported electronic cigarettes and does not have a domestic supplier currently available to it; (b) TWI will lose its ability to fulfill its contractual obligations with its overseas suppliers in the event that it is not permitted to continue importing electronic cigarettes in the near future; (c) the FDA's import ban threatens the continued viability of TWI, which will be forced to close its doors in the immediate future in the event that it is not able to resume importing electronic cigarettes and accessories.

47. TWI requests that the Court: (1) declare that the actions of the FDA as set forth herein are unlawful, contrary to binding precedent, arbitrary and capricious, and *ultra vires*; (2) enter a judgment in favor of TWI; and (3) enjoin and prohibit FDA from detaining or refusing

admission into the United States of TWI's electronic cigarettes and electronic cigarette accessories on the ground that those products constitute unapproved drugs, devices, or drug-device combination products under the FDCA.

COUNT II
(Violation of Administrative Procedures Act)

48. TWI incorporates by reference the allegations of paragraphs 1-47, above, as if fully set forth herein.

49. 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.

50. 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 effects a substantive change in the law must be adopted pursuant to the required notice and comment procedures of the Administrative Procedures Act ("APA"). 5 U.S.C. §§ 553, *et seq.*

51. Import Alert 66-41, which, *inter alia*, directed U.S. Customs and Border Protection 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 TWI and others in the electronic cigarette industry.

52. The FDA did not provide opportunity for notice and comment pursuant to the APA before classifying electronic cigarettes as a new drug, device, 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.

53. The FDA's failure to comply with the observance of the procedures required by law is a violation of the APA and thus renders the FDA's actions unlawful. 5 U.S.C. § 706(2)(D).

54. In addition, the FDA has not established a rational nexus between the addition of electronic 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.

55. Prior to 2009, the FDA had a custom and practice of not interfering with the importation of electronic cigarettes and other tobacco products as customarily marketed. With its addition of electronic cigarettes to Import Alert 66-41, the FDA has departed from precedent without cause, good reason, or notice.

56. The FDA's addition of electronic 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.

57. The FDA's addition of electronic 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 for uses associated with traditional tobacco products.

58. The FDA's addition of electronic cigarettes to Import Alert 66-41 and, upon information and belief, the failure to remove electronic cigarettes from Import Alert 66-41, is an arbitrary and capricious agency action that is in excess of statutory jurisdiction, authority, and limitations because the FDA's interpretation of its authority over electronic cigarettes has explicitly been held unlawful both by this Court and the Court of Appeals for the District of Columbia Circuit.

59. The FDA's arbitrary and capricious conduct has both directly and proximately caused, and is continuing to threaten, substantial and irreparable injury to TWI.

60. TWI has already been seriously harmed in that one shipment of electronic cigarettes and accessories has been detained and denied entry into the United States based on the FDA's erroneous interpretation of its authority. TWI continues to face the threat of irreparable harm in that: (a) TWI receives 100 percent of its revenue from imported electronic cigarettes and does not have a domestic supplier currently available to it; (b) TWI will lose its ability to fulfill its contractual obligations with its overseas suppliers in the event that it is not permitted to continue importing electronic cigarettes in the near future; (c) the FDA's import ban threatens the continued viability of SE, which will be forced to close its doors in the immediate future in the event that it is not able to resume importing electronic cigarettes and accessories.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Enter a temporary restraining order, a preliminary injunction, and a permanent injunction that enjoins Defendants from enforcing any import ban on TWI's electronic cigarettes arising out of their purported classification as a drug, device, or drug-device combination product under the FDCA, or from enforcing Import Alert 66-41 with respect to TWI's electronic cigarettes and electronic cigarette accessories;

B. Enter a declaratory judgment that Defendants are without statutory authority to regulate TWI's electronic cigarettes and accessories as a drug, device, or drug-device


combination product under the FDCA, and that the addition of electronic cigarettes to Import Alert 66-41 is invalid, unlawful, and *ultra vires* of Defendants' authority; and

C. Order the release of any of TWI's electronic cigarettes and electronic cigarette accessories currently detained or seized by the United States pursuant to the FDA's unlawful declaration that it has jurisdiction over electronic cigarettes and electronic cigarette accessories under the FDA's authority to regulate drugs, devices, and drug-device combination products;

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

E. Award such other and further relief as is necessary and appropriate.

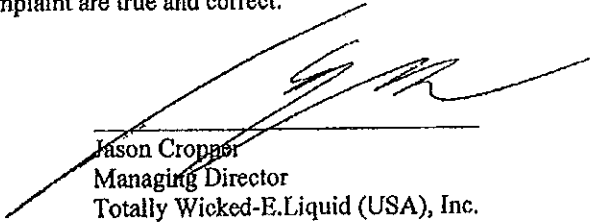
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*Counsel for Plaintiff Totally Wicked-
E.Liquid (USA), Inc.*

VERIFICATION

I verify under penalty of perjury under the laws of the United States of America that the facts set forth in the foregoing Verified Complaint are true and correct.



Jason Cropper
Managing Director
Totally Wicked-E.Liquid (USA), Inc.

Executed this 11TH day of February, 2011

EXHIBIT A

United States Food and Drug Administration

Florida District Office

Notice of FDA Action

Entry Number: XXX-0174491-2

Notice Number: 2
October 26, 2010

Importer:
Totally Wicked E.Liquid Usa, Inc.
4907 14th St W

Bradenton, FL 34207-2402

Port of Entry: 5206, Miami Int'l. Airport, FL
Carrier: UPS AIR FREIGHT SERVICES INC; BVA-0102902-0. Disclaimed to FDA.
Date Received: October 18, 2010
Arrival Date:
Filer of Record: Interamerican Customs Broker & Forwarders, Inc., Miami, FL 33166
Consignee: Totally Wicked E.Liquid Usa, Inc., Bradenton, FL 34207-2402

HOLD DESIGNATED

Summary of Current Status of Individual Lines

Document:	1	AWB: 40637561101		
Line ACS/FDA	Product Description	Quantity	Current Status	
* -/001	Electronic nicotine imitation cigarettes. Original Entry# BVA-0102902-0 disclaimed to FDA.	22 CT	Detained 10-25-2010	

* = 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.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Notice of FDA Action
Entry Number: XXX-0174491-2

Notice Number: 2
Page: 2

Line ACS/FDA	Product Description	Respond By
--/001	Electronic nicotine imitation cigarettes. Original Entry# BVA-0102902-0 disclaimed to FDA.	November 30, 2010

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. This office has forwarded information regarding this shipment of electronic cigarettes to the Center for Drugs for their review. This office will advise you of the outcome of the review once completed.

Please direct your response to:

Magda M. Karlsen, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
6601 NW 25th Street, Rm 241
Miami, FL 33122

(305) 626-2800 ext. 921
(305) 626-2693 (FAX)
MAGDA.KARLSEN@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

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

EXHIBIT B



Totally Wicked

Via Facsimile and Electronic Mail

November 29, 2010

Magda M. Karlsen
Compliance Officer
Florida District Office
U.S. Food and Drug Administration
6601 N.W. 25th Street, Room 241
Miami, Florida 33122
MAGDA.KARLSEN@FDA.HHS.GOV
Fax: (305) 526-2693

RE: Detention of Electronic Cigarettes (Entry Number XXX-0174491-2)

Dear Ms. Karlsen:

This letter shall serve as the response letter to the Notice of FDA Action ("Notice") issued to Totally Wicked-E.Liquid (USA), Inc. ("TWI") on October 26, 2010. The Notice states that the above-referenced shipment of electronic cigarettes and accessories has been detained by the FDA and is subject to refusal pursuant to the Food, Drug & Cosmetic Act ("FDCA"). The Notice alleges that the electronic cigarettes are in violation of Sections 502(o), 510(j)-(k), and 801(c) of the FDCA because they are "misbranded." The Notice also alleges that the electronic cigarettes appear to be an "unapproved new drug" in violation of Sections 505(a) and 810(a)(3) of the FDCA.

It is the position of TWI that the FDA's categorization of TWI's electronic cigarettes as a misbranded or unapproved new drug in violation of Chapter 5 of the FDCA is unwarranted. The FDA may only assert jurisdiction over a product the FDA claims to be a drug if the product is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or 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)(1).

Here, I do not understand what statements made by TWI the FDA could possibly purport to rely on to conclude that either of the above requirements is met. TWI expressly states both in its product packaging and labeling that its electronic cigarettes and accessories are "an alternative to smoking a traditional tobacco based cigarette" and do not constitute a nicotine replacement therapy. Further, TWI's website (www.totallywicked-eliquid.com) contains the following disclaimer at the bottom of every page:

Totally Wicked-E.Liquid (USA) Inc.
4907 14th Street West, Bradenton
Florida, 34207.

Tel: 1-888-741-9425
email: info@totallywicked-eliquid.com
web: www.totallywicked-eliquid.com



TOTALLY WICKED

WARNING: the electronic cigarette will not cure a smoker's addiction to nicotine; the electronic cigarette serves the same purpose as a tobacco cigarette—it delivers its user nicotine. If you do suffer from the disease of Tobacco/Nicotine Dependence Syndrome and want to take steps to give up smoking or cut down the quantity of cigarettes you currently smoke, we recommend you visit your health care provider to discuss NRT (Nicotine Replacement Therapy) or a nicotine harm reduction program.

Please Note: We are not a pharmaceutical company and we do not produce medical products.

TWI is unaware of any representations that the seized products constitute a nicotine replacement therapy, will assist a user in decreasing his or her dependence on nicotine, or will alleviate nicotine withdrawal symptoms. In short, TWI does not intend, nor does it claim, that its electronic cigarettes can be used for therapeutic purposes or for the purpose of altering the structure or a function of the body. Rather, TWI's electronic cigarettes, which utilize tobacco that is naturally derived from tobacco leaves, are designed and marketed simply as an alternative smoking experience to traditional cigarettes without the accompanying drawbacks of fire, carcinogens, and second-hand smoke. TWI markets its products in the same way that traditional cigarettes have customarily been marketed—for recreational use only.

Additionally, the FDA's attempt to exercise jurisdiction over TWI's electronic cigarettes as an unapproved or misbranded new drug runs contrary to the plain language of the FDCA. While TWI does not contest the FDA's ability to regulate electronic cigarettes as "tobacco products" under 21 U.S.C. § 321(rr)(1), the FDA is specifically prohibited from regulating tobacco products as "drugs" under Chapter 5 of the FDCA. See 21 U.S.C. § 321(rr)(2)-(3). Indeed, in Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62 (D.D.C. 2010), the Court held that "Congress *did not* intend tobacco products to be drugs merely because they deliver nicotine." *Id.* at 70. The Court went on to explain that Congress's enactment of the Family Smoking Prevention and Tobacco Control Act in 2009 "in effect, serves as an implicit acknowledgment by Congress that FDA's jurisdiction over drugs and devices does not, and never did, extend to tobacco products, like electronic cigarettes, that are marketed in customary fashion for purely recreational purposes." *Id.* at 72.

Based on the foregoing, it is TWI's position that the FDA lacks statutory authority to refuse the subject shipments of TWI's electronic cigarettes. However, to the extent that the FDA contends that its decision is based on any particular claims or representations made by TWI with respect to its products, I request that you kindly enumerate or direct me to such claims or

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email: info@totallywicked-liquid.com
web: www.totallywicked-liquid.com

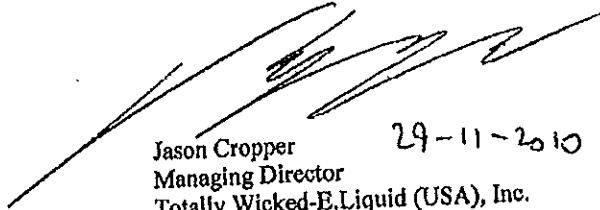


Totally Wicked

representations so that they can be modified or eliminated, as appropriate, so as to permit TWI to continue importing its electronic cigarettes into the United States in full compliance with the FDCA and all applicable regulations.

Also, since I understand from the Notice that information regarding the shipment is currently being reviewed by the Center for Drugs, I would also like to ask by what date we might expect the ultimate findings and conclusions of that review.

Respectfully submitted,



Jason Cropper
Managing Director
Totally Wicked-E.Liquid (USA), Inc.

29-11-2010

Totally Wicked-E.Liquid (USA) Inc.
4907 14th Street West, Bradenton
Florida, 34207.

Tel: 1-888-761-9425
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EXHIBIT C

From: Karlsen, Magda <Magda.Karlsen@fda.hhs.gov>
Subject: RE: Response To Notice of FDA action (entry number xxx-0174491-2)
To: "Jason Cropper" <pillbox3840@yahoo.com>
Date: Monday, 29 November, 2010, 20:56

Jason,

I received the review from the Center for Drugs regarding entry XXX-0174491-2. below is their review.

Magda M. Karlsen
Compliance Officer

We have reviewed the labeling, including the internet website listed on the label (www.totallywicked-eliquid.com) for Entry No. #XXX-0174491-2, regarding several articles intended for marketing in the United States under the name "totally wicked." Based on our review, these articles are constructed with a rechargeable battery-operated heating element and a replaceable cartridge that contains, or is capable of containing, various chemicals, including nicotine. Nicotine and/or other chemicals are intended to be volatilized when the user inhales through these electronic cigarette articles, just as they would when using conventional tobacco-containing cigarettes. Each "totally wicked" product is intended to heat air as it is drawn through it by the user. This heated air purportedly volatilizes the chemicals contained in the replaceable cartridge component of these articles. The volatilized chemicals are then inhaled by the user. These products are designed to look like and to be used (inhaled) in the same way that a smoker uses conventional cigarettes.

The following statements appear on the labeling, which includes the internet website www.totallywicked-eliquid.com, related to the articles in this entry:

"A short testimonial: . . . When I first tried an e-cigarette, I was such a heavy smoker that I couldn't get satisfied, and found myself switching back and forth between analogs and my e-cig. That changed immediately once I tried Totally Wicked E.Smoking Liquid. I haven't touched an analog since that day, and can't imagine myself ever wanting to again."

"The Electronic Cigarette-Helping a new user with her COPD . . . Testimonial: I've been a smoker for 35 years. When I picked up an E-Cig, I never went back to smoking! I can't say enough good about how it has helped my COPD . . ."

"FDA Lunacy: Cigarette a Product We Know Will Kill 400,000 People This Year - APPROVED; Electronic Cigarette a Product that May Well Help Prevent Many of Those People from Dying: BANNED . . . Yesterday, the FDA held a major press conference to announce that there are traces of tobacco-specific nitrosamines in electronic cigarette cartridges and that diethylene glycol was detected in one cartridge. Based on those findings, the FDA expressed grave concern over the safety of the product - which is being used by thousands of smokers, literally hundreds of whom have testified that it is more effective than NRT in helping them to stay off cigarettes . . ."

"FDA smoke screen on e-cigarettes . . . At a time when the government is ostensibly trying to cut health costs, why is it trying to ban something that might help people quit smoking tobacco, perhaps the most devastating health problem in the U.S.?"

2/9/2011

"Debate continues over e-cigarettes . . . As the debate over the electronic cigarette continues, the device has found at least three true believers in Jackson County. Mildred "Mikay" Barrentine, 30, along with Pat Manning, 37, and 45-year-old Linda Lockwood, the latter two of Altha, are enthusiastic about the e-cigarette. All three are long-time heavy smokers who have given up traditional cigarettes in favor of "vaping," users' common term for this alternative to smoking. Although e-cigarettes are not marketed or proven in studies as a smoke cessation device, all three say it has worked for them."

CDER considers these claims to be "drug" claims under the Federal Food, Drug, and Cosmetic Act (the Act). The "drug" definition in section 201(g) (as well as the "device" definition in section 201(h)) of the Act (21 U.S.C. §§ 321(g) and (h)) encompasses articles intended either to affect the structure or any function of the body or to cure, mitigate, treat, or prevent disease.

The labeling claims noted above for the "totally wicked" products indicate that they are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease. They suggest that "totally wicked" products are substitutes for traditional cigarettes and that they are capable of delivering nicotine, which is recognized by the scientific community as a pharmacological agent and is understood by consumers as having drug-like effects. It is also well understood that people smoke for the pharmacologically rewarding effects of nicotine, such as alleviation of stress and negative mood, enhancement of thinking, and increased alertness. For an addicted smoker, the body has adapted to nicotine, and abstinence produces withdrawal and craving. As a result, people also smoke to avoid the negative effects of nicotine withdrawal, such as anxiety, difficulty concentrating, negative mood, increased appetite, insomnia and irritability. The inclusion of labeling claims stating that the "totally wicked" products will deliver a vapor or mist for inhalation by the user, which may or may not include nicotine; that these articles replicate the physical pleasures of smoking; and satisfy cravings for nicotine establish that the articles are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease. Moreover, the marketing of these articles targets the knowledge and expectations of conventional tobacco users that these articles are suitable for these uses when one cannot, or chooses not to, smoke. The scientific and medical communities have determined that nicotine addiction is a disease and that nicotine withdrawal is itself a recognized medical condition. Thus, these labeling claims fit within the "drug" and "device" definitions in the Act.

Based on the foregoing, the "totally wicked" products appear to be, or are comprised of, "drug" and "device" components that are intended both to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. Therefore, the "totally wicked" products appear to be subject to both "drug" and "device" authorities under the Act.

Since we are not aware of any data establishing the "totally wicked" products as generally recognized among scientific experts as safe and effective for the "drug" uses described above and in the labeling, they appear to be "new drugs," under section 201(p) of the Act (21 U.S.C. § 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. The "totally wicked" products are not so approved, and their marketing in the United States would violate this section of the Act.

Under the device provisions of the Act, the "totally wicked" products also appear to be adulterated devices under section 501(f)(1)(B) of the Act (21 U.S.C. § 351(f)(1)(B)), because there is no approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. § 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. § 360j(g)). In addition, the "totally wicked" products appear to be misbranded under section 502(o) of the Act (21 U.S.C. § 352(o)), because the agency was not notified under section 510(k) of the Act (21 U.S.C. § 360(k)) that these products were intended to be introduced into commercial distribution.

For your information, our assessment of "totally wicked" products considered the existing statutes affecting tobacco products, i.e., the Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 15 U.S.C. §§ 1331 et seq., and the Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 98-474 (1986), 15 U.S.C. §§ 4401 et seq. Since "totally wicked" products do not appear to contain any tobacco leaf or stem, they are not subject to these statutes. The enactment (June 22, 2009) of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") (P.L. 111-31) also does not affect this assessment of the regulatory status of this product because that statute exempts "drugs," "devices," and "combination products" from the scope of the tobacco products that are subject to that Act.

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. § 381(a)), the marketing of the "totally wicked" products and their components appear to violate sections 505, and 501(f)(1)(B) and 502(o) of the Act (21 U.S.C. §§ 355 and 351(f)(1)(B) and 352(o)), as described above, and we support the District's detention and refusal of the referenced import entry citing these violations.

Magda M. Karlsen
Compliance Officer

From: Jason Cropper [mailto:pillbox3840@yahoo.com]
Sent: Monday, November 29, 2010 8:59 AM
To: Karlsen, Magda
Cc: pillbox3840@yahoo.com
Subject: Response To Notice of FDA action (entry number xxx-0174491-2)

Dear Ms Karlsen

Please find attached our response to your recent Notice of FDA Action (xxx-0174491-2) in relation to the holding of our shipment in Miami. A facsimile copy is also being sent.

Please advise, by return of email, that you have received this document.

Yours faithfully

Jason Cropper
Managing Director

Totally Wicked E-Liquid
<http://www.totallywicked-liquid.co.uk/>
<http://www.totallywicked-liquid.com/>

The Electronic Cigarette Company
<http://www.theelectroniccigarette.co.uk/>

2/9/2011

EXHIBIT D



Totally Wicked

via Facsimile and Electronic Mail

December 1, 2010

Magda M. Karlsen
Compliance Officer
Florida District Office
U.S. Food and Drug Administration
8600 N.W. 36th Street, Suite 700
Miami, Florida 33166

RE: Refusal of Entry of Electronic Cigarettes (Entry Number XXX-0174491-2)

Dear Ms. Karlsen:

As a follow-up to our email correspondence of November 29 and 30, 2010, it is the understanding of Totally Wicked-E.Liquid (USA), Inc. ("TWI") that the above-referenced shipment has been refused entry into the United States. I understand, based on your email of November 29, 2010, that the FDA's Center for Drugs considers TWI's electronic cigarette products to be both "drugs" and "devices" under Chapter 5 of the Food, Drug & Cosmetic Act ("FDCA"). I also understand it to be FDA's position that TWI's electronic cigarettes do not fall within the definition of "tobacco products" as such are defined in 21 U.S.C. § 321(rr)(1) because FDA reads the Family Smoking Prevention and Tobacco Control Act as exempting "drugs," "devices," and "combination products" from the scope of tobacco products that are subject to that Act.

Please correct me if I have misstated FDA's position with respect to any of the above. If I have not, based on the above, can you please tell me whether, in the opinion of FDA, there are any further actions that TWI can take with respect to its labeling, advertising, or website that would lead the FDA to conclude that TWI's products do not fall within the definition of "drugs," "devices," or "combination products"? Or is it FDA's position (as I understand to be the case) that the very nature of the products themselves requires them to be defined in this fashion, regardless of whether, for example, the statements found on TWI's website that are referenced in your November 29, 2010 email are removed?

Further, while I understand, based on your November 29, 2010 email, that the analysis provided therein came directly from the Center for Drug Evaluation and Research, can you please identify if there is any FDA department or official within FDA to whom TWI can appeal the decision and rationale set forth in the November 29, 2010 email? I would like to ensure that we have done everything we possibly can to see if the FDA will be willing to reconsider its decision to refuse entry of the shipment into the United States.

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Totally Wicked

Thank you in advance for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Jason Cropper', written in a cursive, fluid style.

Jason Cropper
Managing Director
Totally Wicked-E.Liquid (USA), Inc

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