INTRODUCTION

Plaintiff Smoking Everywhere, Inc. ("SE"), seeks a preliminary injunction requiring the United States Food and Drug Administration ("FDA") to permit SE to import an electronic cigarette product and its accessories ("E-Cigarettes") for distribution in the United States. SE asserts that FDA lacks jurisdiction to regulate its product, which it claims is a "non-therapeutic" alternative to traditional cigarettes. SE is not entitled to this relief. It has no likelihood of success on the merits, it has not established an irreparable injury, and the balance of interests does not weigh in its favor.

In the proceeding following SE's attempt to import two shipments of E-Cigarettes, FDA found that SE's product met the definition of both a drug and device under the Federal Food, Drug, and Cosmetic Act ("FDCA"). FDA made this determination after examining the product, the claims made in the product labeling, and information SE submitted to FDA. FDA has similarly determined that other nicotine-containing products, such as gums, transdermal patches, nasal sprays, inhalers, lollipops, lozenges, and hand gels, are within its jurisdiction. Manufacturers and distributors of some of these products have obtained FDA approval to market their products legally in the United States. SE has chosen not to submit an application for approval of its product, which would require it to submit data showing that the product is safe and effective. As an unapproved drug or device, distribution of E-Cigarettes in commerce in the United States is prohibited. Thus, FDA properly concluded that the shipments of E-Cigarettes at issue here may be refused admission into the United States.

In addition to challenging FDA's basic jurisdiction to regulate E-Cigarettes, SE argues that Import Alert 66-41 ("IA 66-41") is a rule that should have been published for notice and

comment rulemaking. In late March and early April 2009, FDA amended IA 66-41, adding electronic cigarettes manufactured by three Chinese firms.

Plaintiff's challenge to the amendment to the import alert is not well founded. This import alert contains a list of drug products that are not approved for distribution in the United States and that may be detained by FDA field personnel pending the submission of testimony or other evidence by the importer and a final decision whether the products should be released into commerce or refused admission. The import alert is simply an administrative means for FDA to communicate efficiently with its personnel, and it relates only to detention. Detention is a preliminary step in an import proceeding; the ultimate purpose of the proceeding is to determine whether a product should be refused admission to the United States. Accordingly, IA 66-41 is not a binding, substantive rule that is required to be published for notice and comment rulemaking under the Administrative Procedure Act ("APA").

In any event, SE has failed to establish standing to challenge IA 66-41. The shipments referenced in the complaint were detained well before any electronic cigarettes were added to the import alert, and the import alert itself relates only to electronic cigarettes from three specific manufacturers in China, none of which appears to make plaintiff's product.

For these reasons, SE has failed to establish a likelihood of success on the merits of its claims. SE fares no better with respect to the other factors that it must establish in order to justify the issuance of a preliminary injunction from this Court. SE has failed to establish irreparable harm or that the balance of harms weighs in its favor. SE claims injury to its business from FDA's import refusals, but that is the same injury anyone faces

who seeks to distribute an unapproved drug or device. Congress has made clear, in its enactment and subsequent amendments of the FDCA, that the interest of the public in safe and effective drugs and devices supersedes a distributor's hoped-for profits. Accordingly, plaintiff has failed to establish entitlement to a preliminary injunction, and its motion should be denied.

REGULATORY AND FACTUAL BACKGROUND

I. STATUTORY AND REGULATORY SCHEME

A. FDA Authority over Drugs and Devices

The FDCA generally prohibits the introduction into commerce of unapproved drugs and devices. 21 U.S.C. § 355(a); 21 U.S.C. § 331(d). A new drug cannot be marketed in the United States until the drug sponsor submits a new drug application ("NDA") to FDA, obtains the agency's approval, and the approved application is effective. 21 U.S.C. §§ 355(a), (b), 331(d). A product is a "new drug" if it is not generally recognized among qualified experts as safe and effective for the conditions prescribed, recommended, or suggested in its labeling. 21 U.S.C. §§ 321(p). "General recognition" of a drug as safe and effective must rest on a consensus among qualified experts based on adequate and well-controlled clinical trials that are published in the scientific and medical literature. *See Weinberger v. Hynson, Westcott & Dunning, Inc*., 412 U.S. 609, 629 (1973); *Weinberger v. Bentex Pharms., Inc*., 412 U.S. 645, 652 (1973).

To obtain approval, the manufacturer must demonstrate that there is sufficient evidence to find that the drug is in fact both safe and effective for each of the uses recommended in the proposed labeling. 21 U.S.C. § 355(b), (d). Thus, FDA is required to reject an NDA if, *inter alia*, the data fail to show that the product is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" or "will have the effect it purports or is

represented to have." 21 U.S.C. § 355(d).

Though not identical, the statutory requirements for the premarket clearance or approval of devices are similar to the requirements for drug approval. *See* 21 U.S.C. § 360e. The standards and process for FDA clearance or approval depends, among other things, on the device's classification under 21 U.S.C. § 360c. Class III devices are subject to the most stringent regulation: a determination of their safety and effectiveness is made by FDA, based on information submitted by the manufacturer or sponsor in a premarket approval application ("PMA"). 21 U.S.C. § 360e. Devices that entered commerce after the 1976 Medical Device Amendments, 21 U.S.C. §§ 360c-360k, such as E-Cigarettes (*see* SE Memorandum in Support of Preliminary Injunction ("SE Mem.") at 4, "E-cigarettes were first invented in approximately 2004"), are automatically classified by statute in class III, without any rulemaking, unless and until the FDA issues an order finding that the device is "substantially equivalent" to a device previously classified in class I or II, or the agency reclassifies the device into class I or II. *See* 21 U.S.C. § 360c(f)(1)-(3). A device is adulterated under 21 U.S.C. § 351(f)(1)(B) if there is no approved PMA in effect pursuant to 21 U.S.C. § 360e(a), or no approved investigational device exemption ("IDE") under 21 U.S.C. § 360j(g).

The FDCA broadly defines "drug" and "device." The definition of "drug" includes, in relevant part, articles "intended for use in the . . . mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1). "Device" includes "an instrument, apparatus, . . . or other similar or related article, including any component, part, or accessory," that is "intended for use in the . . . mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man"

and that "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

The Supreme Court has directed that these definitions be broadly construed:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates – and equally clearly, broader than any strict medical definition might otherwise allow. . . . [R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

Some products may represent "a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1). For such products, both drug and device authorities would apply. In regulating these products, the FDCA provides that FDA shall determine "the primary mode of action of the combination product," which in turn determines which agency component will be assigned responsibility for premarket review of the product. *Id*. *See* Administrative Record of Nicotine Background Materials ("AR NIC")[1] at NIC 50; "Regulations Restricting the Sale

[1] FDA has submitted three administrative records to the Court. One of these pertains to the two SE shipments of E-cigarettes that were detained by FDA (cited as "AR DET"), one pertains to the Import Alert ("AR IA"), and one (cited above in the text) contains background materials that were relied upon in reaching these two decisions, *i.e.*, the refusal of SE's shipments and the addition of certain electronic cigarettes to IA 66-41. *See* Decl. of Kevin Budich (attached to and authenticating AR NIC).

and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 Fed. Reg. 44396, 44400-03 (Aug. 28, 1996) (hereinafter "Final Rule").

B. FDA's Import Program

Several federal agencies have overlapping and concurrent jurisdiction over imported products. Under the FDCA, FDA may request "samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States . . . ." 21 U.S.C. § 381(a). The FDCA further provides: "If it *appears* from the examination of such samples or *otherwise* that . . . (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in [21 U.S.C. § 381](b)." 21 U.S.C. § 381(a)(3) (emphasis added).[2]

Thus, the FDCA thus does not require FDA to find that an article offered for importation actually is adulterated, misbranded, or in violation of 21 U.S.C. § 355; rather, the agency has "broad authority to prohibit import" of any article that "appears" to violate the FDCA. *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 43 (D.C. Cir. 1982). In addition, because the appearance of a violation may be based on "the examination of such samples or otherwise," 21 U.S.C. § 381(a), FDA can refuse admission to an article based upon its own examination of the product, or on evidence other than sampling and analytical results. *See id.*; *Balmaceda v.*

[2] The statute vests this authority in the Secretary of HHS. 21 U.S.C. § 381(a). The Secretary has delegated that authority to the Commissioner of Food and Drugs. FDA Staff Manual Guide 1410.10. That authority has been redelegated to the Regional Food and Drug Directors and District Directors. FDA Staff Manual Guide 1410.801, para. A.2.

United States, 815 F. Supp. 823, 826-27 (E.D. Pa. 1992), *aff'd sub nom. Fisher Bros. Sales, Inc. v. U.S.*, 46 F.3d 279 (3d Cir. 1995).

FDA coordinates with U.S. Customs and Border Protection ("CBP") to ensure that FDA is notified of FDA-regulated products imported or offered for import into the United States. As a first step, the importer, or his/her representative, files an entry notice and an entry bond with CBP. *See* 21 U.S.C. § 381(b). After CBP notifies FDA of the entry, FDA determines initially whether to admit the product into United States commerce, detain the product based on information it already has, conduct a physical examination, or obtain additional information.

When FDA believes that "it appears that an article may be subject to refusal of admission," FDA may "detain" the product by issuing a notice of detention to notify the owner or consignee of the opportunity for a hearing. 21 C.F.R. § 1.94.[3] In some instances, FDA may detain a product as soon as it is offered for entry into the United States without first examining it or taking a sample. *See* FDA's Regulatory Procedure Manual ("RPM") Chap. 9-6 (avail. at http://www.fda.gov/ora/compliance_ref/rpm/ chapter9/ch.9-6.html). A detention without physical examination (or "DWPE" as it is commonly known) may be based on past history of a particular company, product, or geographic region, or other information indicating that the

[3] Although referred to as "detention," generally neither FDA nor CBP has physical custody or control of the articles; the importer has actual possession and posts a bond with CBP. However, if CBP demands redelivery and the importer is unable to redeliver, CBP may assess liquidated damages pursuant to the entry bond for failure to hold the product intact. *See* 19 C.F.R. § 113.62(d) & (l).

product appears to be violative. *Id.*; *see also* 21 U.S.C. § 381(a).

A hearing on a detention can take many forms, including telephone conversations and letters. *See* RPM Chap. 9-8. The owner or consignee may introduce testimony either orally or in writing in an effort to demonstrate the admissibility of the article. 21 C.F.R. § 1.94; *see also* 21 U.S.C. § 381(a); *Sugarman v. Forbragd*, 267 F. Supp. 817, 823-24 (N.D. Cal. 1967), *aff'd*, 405 F.2d 1189 (9th Cir. 1968), *cert. denied*, 395 U.S. 960 (1969). A decision as to the admissibility of detained goods is made only after the importer has had an opportunity to present testimony and that testimony has been considered. If FDA concludes that the product is in compliance, the shipment may be released into United States commerce. If FDA concludes that a violation appears to exist, the product will be refused admission. *See* 21 U.S.C. § 381(a). An owner/consignee may seek reconsideration of the decision of an FDA field office to refuse admission of a particular shipment. *See* 21 C.F.R. §§ 10.33, 10.75; RPM Chap. 9-9. If the product is ultimately refused, however, the importer is required to either re-export or destroy the article under CBP or other approved supervision. *See* 21 U.S.C. § 381(a).

C. Import Alert Overview

FDA's Division of Import Operations and Policy ("DIOP") may issue "import alerts" to the FDA employees located in FDA district offices who review import entries. RPM Chap. 9-13. This process allows DIOP to disseminate information efficiently and effectively throughout the field and to coordinate FDA's screening efforts. *Id.* (The purpose of import alerts is to "identify and disseminate import information (problems, violative trends, etc.)" to help ensure an "effective import coverage program."); *see also United States v. Food, 2,998 Cases*, 64 F.3d 984, 986 n.2 (5th Cir. 1995) ("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.") (emphasis added). This mechanism is particularly important given the large disparity between the volume of imported products within FDA's jurisdiction and FDA's limited resources. Usually, import alerts inform FDA field personnel that FDA has sufficient evidence or other information to consider refusing admission of future shipments of an imported article. FDA field staff use the information contained in import alerts, along with other information, to help determine whether they will detain articles, which is what initiates the process for determining whether articles are ultimately refused entry.

II. FACTUAL BACKGROUND

A. E-Cigarettes

SE's E-Cigarette product is constructed with a rechargeable, battery-operated, heating element and a replaceable plastic cartridge that contains various chemicals, including liquid nicotine. Compl. ¶¶ 8-9. The heating element vaporizes the liquid, which is inhaled by the user. *Id.* The stainless steel exterior of the product mimics the size, shape, and appearance of a conventional cigarette. *Id.* ¶ 9; Administrative Record of Detention and Refusal ("AR DET") at DET 61. The package labeling and the website (www.SmokingEverywhere.com) referenced in the labeling, *see, e.g.*, AR DET 78-79, state that the product delivers nicotine. *See* AR DET 1-53 (copy of the website as of December 17, 2008, which was evaluated for determining the admissibility of the detained shipments referenced in the complaint); *id.* at 54-63 (product manual); and *id.* at 76 (product packaging).

SE's website contains numerous statements that represent and suggest that E-Cigarettes are substitutes for traditional cigarettes that will deliver the pharmacological effects of nicotine. For example, the promotional materials state: "the smoker gets[] the nicotine hit that smokers crave;" E-Cigarettes "satisfy [smokers'] smoking addiction;" "[s]moking . . . E-Cigarettes will provide . . . the same physical and emotional feelings [smokers'] get in smoking traditional cigarettes;" and "[e]ach cartridge is the equivalent of 20 cigarettes." AR DET 51, 56, 49, 26. The website also represents that E-Cigarettes are a healthier alternative to traditional cigarettes: the "E-Cigarette offers smokers a . . . a much *healthier way* . . . to smoke [and] still get their nicotine;" and the E-Cigarette is "a great alternative to help . . . stop smoking real cigarettes." AR DET 49, 21. FDA reviewed these statements and determined that they constitute drug and

device claims. AR DET 101-02.

B. The Refused Shipments

The complaint alleges that "[i]n or about late 2008 and early 2009," SE received several "Notices of FDA Action" from FDA, including one in which FDA refused admission of the E-Cigarette products. Compl. ¶ 24. SE attached two such notices to its complaint. Compl., Ex. A. FDA has compiled the record of those two shipments. *See* AR DET 1-134; AR NIC 1-80. After the products arrived in late September 2008, FDA issued a "hold" indicating that designated shipment lines of E-Cigarette products were not being admitted at that time pending further review. AR DET 69-70. On October 29, 2008, FDA issued notices of "Detention" stating that the products appear to be unapproved new drugs and/or misbranded drugs or devices. AR DET 88-91. Although SE represents that it was provided no "opportunity to respond to the notice of detention," SE Mem. at 7, FDA provided that opportunity in accordance with its standard procedures; the notices state that the company may provide testimony regarding admissibility by November 19, 2008. AR DET 89, 91.

The company did not respond until November 25, 2008, when it authorized Benjamin England to act on its behalf. AR DET 97-98, 100. In the months that followed, Mr. England made several submissions to FDA regarding arguments against FDA jurisdiction over E-Cigarettes. *See* AR DET 92-96. On December 23, 2008, FDA issued a "Correspondence" to SE stating that, after reviewing SE's response, the entry documents, and the product labeling, including SE's website, the product appeared to be an unapproved drug-device combination product. AR DET 107-11. FDA explained that it believed that E-Cigarettes and its component parts appear to be intended to affect the structure or function of the body, and to prevent,

mitigate, or treat the withdrawal symptoms of nicotine addiction. Because the product has both drug and device features (as an apparatus that delivers nicotine to the body), it appears to be a drug-device combination. FDA further explained that because the product was not approved as either a drug or a device, its marketing in the U.S. would violate the FDCA. AR DET 108-09, 111.

After further communications from Mr. England, in an email to Mr. England on February 11, 2009, FDA confirmed its earlier views and elaborated as follows:

> We believe that when originally offered for importation, this product was explicitly labeled and promoted for "drug" use. In addition, and as described in 21 C.F.R. 201.128, this product is clearly intended for "drug" use by "the circumstances surrounding the distribution of the article." These circumstances include the product's conventional cigarette appearance; its design, formulation, and function to deliver to the body through inhalation of a smoke-like aerosol (resembling conventional cigarette smoke) various volatile chemical substances, including nicotine, produced by the article; and how the product is intended to be manipulated and used like conventional cigarettes to affect the body's structures and functions and/or to treat/mitigate the symptoms of nicotine addiction. In addition, the intended distribution of "Smoking Everywhere E-Cigarette" is targeted to current and potential conventional cigarette smokers, who are knowledgeable about the effects that nicotine has on the structure and function of the body. Moreover, it is clear that the product is intended to deliver nicotine and/or other volatilized chemical substances for inhalation. Thus, as described

> further in 21 C.F.R. 201.128, we think that "[i]t may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, [to be] offered and used for a [drug] purpose . . . ."

AR DET 92. FDA heard nothing more from SE or Mr. England in the following month. Accordingly, on March 16, 2009, FDA issued notices of "Refusal of Admission" for the products. AR DET 112-16. Although plaintiff has alleged that it received a shipment on April 13, 2009, in Miami, Florida, Compl. ¶ 28, it provided no documentation of this shipment, and to date FDA has been unable to locate any information on such a shipment.

C. Import Alert 66-41

Several years ago, FDA issued an import alert related to unapproved and misbranded drugs. *See* Administrative Record of Import Alert 66-41 ("AR IA") at 1-91; IA 66-41 is also available at http://www.fda.gov/ora/fiars/ora_import_ia6641.html. The import alert is directed at the importation of unapproved medical products, which may violate the provisions of the FDCA that require that a new drug be the subject of an effective new drug application and that the product bear adequate directions for use. 21 U.S.C. §§ 355(a), 352(f)(1); *see* AR IA 2-3. The import alert explains that there had been inaccurate reports in the media suggesting that any unapproved drug may be imported for personal use. *Id*. The import alert further explains that although FDA, as an exercise of enforcement discretion, typically does not refuse admission with respect to some limited personal importation, when there is evidence of promotion of unapproved new drugs in the United States, the products should be considered for detention. *Id*.

The import alert advises: "Districts may detain without physical examination any [u]napproved and/or misbranded drug listed in the attachment." AR IA 3. The lengthy

attachment is a list of "Unapproved and/or misbranded new drugs that may be subject to DWPE." AR IA 4-91. The list generally identifies the product type or name along with the overseas manufacturer and the date when the listing was added to the import alert. *Id.*

There are three entries listed for "Electronic Cigarettes and Electronic Cigarette Components." The first, for Shenzhen Kanger Technology Co. Ltd, was added on March 30, 2009. AR IA 85-86. The second, for Desonic Industrial, was added on April 6, 2009. AR IA 86. The third, for Loong Totem Science & Technology, was added on April 7, 2009. AR IA 86. FDA added each of these Chinese manufacturers to IA 66-41 after examining the labeling and promotional material for electronic cigarette products that originated from them. *See* AR IA 92-179.

D. Plaintiff's Allegations

Plaintiff filed this lawsuit on April 28, 2009, approximately six months after FDA's detention of the shipments referenced in the complaint. SE's primary allegation is that because of the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), FDA has no authority to regulate E-Cigarettes. Compl. ¶¶ 14-18, 36-39. SE also alleges that Import Alert 66-41 is a binding, substantive rule that should have been published for notice and comment rulemaking, *id.* ¶¶ 42-46, and that the addition of E-Cigarettes to Import Alert was arbitrary and capricious because FDA treats E-Cigarettes differently from traditional tobacco products. *Id.* ¶¶ 47-50. SE seeks a declaratory judgment finding that the government is without authority to regulate E-Cigarettes and that the addition of E-Cigarettes to Import Alert 66-41 is invalid, and an injunction prohibiting defendants from regulating E-Cigarettes or from enforcing an "import ban" on E-Cigarettes. Compl. at 13.

ARGUMENT

I. STANDARD OF REVIEW

To obtain preliminary injunctive relief, plaintiff must demonstrate that: (1) it has a substantial likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. *E.g.*, *Mova Pharm. Corp v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998). The Court must balance the four factors in deciding whether to grant the injunctive relief. *Id*.

A preliminary injunction is "an extraordinary remedy" and is not to be granted lightly. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996) (citing *Dorfman v. Boozer*, 414 F.2d 1168 (D.C. Cir. 1969)). Moreover, the relief that SE seeks – an order compelling FDA to permit the importation of E-Cigarettes and release E-Cigarettes for distribution in domestic commerce – is a "mandatory injunction" that must be reviewed "with even greater circumspection." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 36 (D.D.C. 2000). Because plaintiff has failed to make any of the showings necessary to justify such extraordinary relief, its motion for a preliminary injunction should be denied.

II. SE HAS NO LIKELIHOOD OF SUCCESS ON THE MERITS

A. FDA Has Properly Exercised Jurisdiction Over E-Cigarettes

1. The Court Should Defer to FDA's Reasonable Application of the FDCA

FDA's decision that E-cigarettes are within its jurisdiction is subject to review by the Court under the APA, and may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly

deferential to the agency. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). "There is a presumption in favor of the validity of administrative action." *Bristol-Myers Squibb*, 923 F. Supp. at 216; *see also Watson Pharm, Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001). The reviewing court must consider whether the agency's decision was based upon a consideration of the relevant factors and whether there has been a clear error of judgment. *Overton Park*, 401 U.S. at 416. However, "under this narrow scope of review, '[t]he court is not empowered to substitute its judgment for that of the agency.'" *Bristol-Myers*, 923 F. Supp. at 216 (quoting *Overton Park*, 401 U.S. at 416).

When the Court is reviewing an agency's construction of statutory provisions, the two-step analysis of *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), governs. First, the Court must inquire "whether Congress has directly spoken to the precise question at issue;" if Congress' intent is clear, the Court "must give effect to [such] unambiguously expressed intent." *Id*. at 842-43. Formulated another way, the Court must initially decide "whether the statute unambiguously forbids the Agency's interpretation." *Barnhart v. Walton*, 535 U.S. 212, 218 (2002). Second, if Congress has not "directly addressed the precise question at issue," the Court may not "impose its own construction on the statute." *Chevron*, 467 U.S. at 843. Rather, it must determine if the agency's interpretation is based on "a permissible construction of the statute." *Id*.

Chevron deference also applies when "Congress delegated authority to the agency generally to make rules carrying the force of law." *Gonzales v. Oregon*, 546 U.S. 243, 255 (2006) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226-27

(2001)). "Delegation of such authority may be shown in a variety of ways." *Mead Corp*., 533 U.S. at 227. With the FDCA, Congress has authorized and directed FDA to decide what drugs and devices may lawfully enter the marketplace, and what medical products may legally enter the United States. *See, e.g.*, 21 U.S.C. §§ 355, 360e, 381(a). Further, the Supreme Court has explained that *Chevron* deference is appropriate when "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue." *Barnhart*, 535 U.S. at 222.

Accordingly, the D.C. Circuit has repeatedly given *Chevron* deference to FDA's interpretation of the FDCA, as well as the agency's own implementing regulations. *See, e.g., Novartis Pharmaceuticals Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006) ("We have held on a number of occasions that FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations unless plainly erroneous or inconsistent with the regulations."); *Mylan v. Thompson*, 389 F.3d 1272, 1281 (D.C. Cir. 2004); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319, 1320 (D.C. Cir. 1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).[4] Furthermore, *Chevron* deference extends to administrative

[4] *See also Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352 (Fed. Cir. 2003) ("Deference is due to an administrative agency's regulations particularly when the subject matter of the regulatory authority is a 'highly detailed' regulatory program to

determinations that are not embodied in rulemaking or formal adjudication. *See Mylan v. Thompson*, 389 F.3d at 1279-80; *Apotex, Inc. v. FDA*, No. 06-5060, 2007 WL 754768 at *1 (D.C. Cir. Feb. 23, 2007) ("the district judge's opinion, which grants *Chevron* deference to the FDA's statutory interpretation of [the FDCA] embodied in FDA approval letters (i.e., informal adjudications), is supported by the Supreme Court's post-*Mead* decision in *Barnhart v. Walton*, 535 U.S. 212, 222, (2002), as well as our own decision in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004)").

2. E-Cigarettes Fall Within the Definitions of Drug and Device

After examination of SE's E-Cigarette product, together with its labeling and promotional material, FDA concluded that the E-Cigarette is a combination drug and device within the meaning of the FDCA. AR DET 112-16; *see also* AR DET 101-02, 107-11, 92. The product itself is a mechanism for delivering vaporized chemicals, including nicotine, into the mouths and lungs of users. The product is promoted as a cigarette substitute that will deliver nicotine and satisfy addiction. Under long-standing FDA interpretation, such statements are "drug claims" that clearly place the product well within the FDCA's definitions of "drug" and "device."

As noted, an article may be a drug or device if it is "intended to affect the structure or any function of the body," or "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1), 321(h). FDA refers to this standard as the

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which the agency has brought its 'specialized expertise'") (quoting *Mead*, 533 U.S. at 235).

"intended use" of the product, and has issued a regulation to address its meaning. The "intended use" of a product refers "to the objective intent of the persons legally responsible for the labeling of drugs." 21 C.F.R. § 201.128. *See also United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 567 (D.N.J. 2004), *order modified by*, 328 F. Supp. 2d 520 (D.N.J. 2004), *aff'd*, 427 F.3d 219 (3d Cir. 2005). Because the standard is an objective one, in determining whether an article is a "drug" based on its intended use, the agency is not bound by the manufacturer's subjective claims of intent, but instead can establish intent on the basis of objective evidence. *See Lane Labs-USA*, 324 F. Supp. 2d at 567; *United States v. Undetermined Quantities of An Article of Drug Labeled as "Exachol,"* 716 F. Supp. 787, 791 (S.D.N.Y. 1989).

FDA's regulation further explains:

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter . . . .

21 C.F.R. § 201.128; *see also* 21 C.F.R. § 801.4 (device intended use regulation). In determining the intended use of a product, FDA may consider the label and labeling of a product, advertising or promotional materials, and "any relevant source." *See, e.g., United States v. Storage Spaces Designated Nos. 8 & 49*, 777 F.2d 1363, 1366 (9th Cir. 1985). To be considered labeling, materials do not have to be attached to the product. *Kordel v. United States*, 335 U.S. 345, 349-50 (1948); *United States v. Urbuteit*, 335 U.S. 355, 357-58 (1948); *United States v. Articles of Drug . . . 5,906 Boxes*, 745 F.2d 105, 114 n.14 (1st Cir. 1984); *United States v. Guardian Chem. Corp.*, 410 F.2d 157, 160-61 (2d Cir. 1969).

Upon review of the product and its labeling and promotional materials, FDA properly

concluded that SE's E-Cigarette is a drug-device product because it appears to be intended both to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. AR DET 112-16; *see also* AR DET 101-02, 107-11, 92. The Court should defer to FDA's reasonable application of the FDCA.

a. Nature of Nicotine

First, there is the nature of the product itself. The mechanism of the E-Cigarette vaporizes a liquid containing various chemicals, including nicotine, for inhalation by the user. Compl. ¶¶ 8-9. Nicotine is recognized by the scientific community as a pharmacological agent, and it is understood by consumers as having drug-like effects. *See* AR NIC 23-57; 61 Fed. Reg. 44701-50, 44811-23.

As noted above, on August 28, 1996, FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed. Reg. 44396. In this Final Rule, FDA found that nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight. *Id*. at 44631-32; *see also id*. at 44701-50. Moreover, the agency concluded that the effects of nicotine on the body are widely known to consumers. *Id*. at 44630, 44811-23. Although, as discussed below, the rule was subsequently overturned on legal grounds, FDA's scientific findings regarding nicotine were undisturbed.

More recently, FDA has confirmed these earlier scientific findings in connection with its determinations that it has jurisdiction over other nicotine-containing products. *See* AR NIC 23-57. It is well understood that people smoke for the pharmacologically

rewarding effects of nicotine. *See* AR NIC 24, 29-30, 33-38, 54. For addicted smokers, the body has adapted to nicotine, and abstinence produces withdrawal and craving. *See* AR NIC 23-24, 26-29, 30-33, 36-37, 50-51. One expert has concluded: "Nicotine clearly alters the structure and function of the body." *See* AR NIC 54.

The scientific and medical communities have determined that nicotine addiction is a disease. *See* AR NIC 49-50. FDA has recognized that the administration of nicotine can mitigate or treat the symptoms of withdrawal during abstinence from tobacco. *See* AR NIC 31-32, 50-52. FDA has approved nicotine replacement therapies in the form of gums, transdermal patches, nasal sprays, inhalers, and lozenges. *See* AR NIC 31, 50; http://www.fda.gov/womens/medicinecharts/smoking.html (contains chart listing approved nicotine replacement therapies as of 2007).

b. E-Cigarettes' Drug and Device Claims

The promotional materials for E-Cigarettes contain claims that represent and suggest that the product will provide the same drug effects as cigarettes:

- The E-cigarette "when puffed on creates a vapor like smoke, just like a real cigarette. This vapor is a result of the nicotine that is found in the cartridge, heating up by the atomizer device and creating vapor smoke . . . This is what the smoker gets, *the nicotine hit that smokers* crave, and the smoke like illusion . . ."

- "Smoking Everywhere E-Cigarette is an electronic smoking device or an electronic cigarette which is also known as E-Cigarette. It is a non-flammable product that uses state of the art classy micro-electronic technology which provides smokers a *real smoking experience* . . ."

- ". . . similar functions to those of a common cigarette which is to refresh smokers and *satisfy their smoking addiction*, thus making them happy and relaxed."

- "Most smokers enjoy the substantial and emotional feelings of smoking. Smoking Everywhere E-Cigarette will provide smokers the *same delight, physical and emotional feelings* they get in smoking traditional cigarettes . . ."

· "Smoking Everywhere E-Cigarette performs just like a traditional cigarette. It looks like, feels like and tastes like a real cigarette and also distributes the *same pleasures of smoking a traditional cigarette . . .*"

· ". . . gives the users the *feeling they get* when they *smoking real cigarette* [sic]."

· "Each cartridge is the *equivalent of 20 cigarettes*."

AR DET 51, 49, 56, 49, 51, 41, 26 (emphasis added).

The dosing instructions for E-Cigarettes provide further evidence that the product is intended to provide the pharmacological effects of nicotine:

· "As you inhale, a tiny battery vaporizes liquid inside the cigarette producing smoke. You insert the Nicotine cartridges of your choice . . . that will release nicotine - or if you choose to skip the nicotine altogether, try our 0mg (None) Nicotine cartridges or you can choose from *High Nicotine (16mg), Medium Nicotine (11mg) or Low Nicotine (6mg).*"

AR DET 25 (emphasis added). These statements demonstrate that the intended use of E-Cigarettes is to affect the structure or function of the body.

SE is also intended to prevent, treat, or mitigate the withdrawal symptoms of nicotine addiction. As discussed above, nicotine addiction is a recognized disease, and nicotine withdrawal is itself an accepted medical condition. *See* AR NIC 49-51. Indeed, FDA currently regulates nicotine gums and patches as nicotine replacement therapies. *See* AR NIC 31, 50. The promotional materials for E-Cigarettes are aimed at nicotine-addicted tobacco users, and promote the product as a healthier alternative to traditional cigarettes:

· "Smoking Everywhere E-Cigarette offers smokers a choice of smoking in a much *healthier way* and the freedom to smoke everywhere. The smokers *still get their nicotine* . . ."

· "Testimonials:
- I heard about smoking everywhere e-cig and I thought is was a *great alternative to help me stop smoking real cigarettes . . .*
- I've been *smoking real cigarettes for over 20 years* and really *wanted to stop* . . . I've

been using it for 3 weeks now and *feel great*."

AR DET 49, 21 (emphasis added).

In sum, nicotine has clearly established pharmacological effects and tobacco users smoke in large measure to sustain their nicotine addiction and to alleviate or prevent nicotine withdrawal symptoms. The promotion of E-Cigarettes as satisfying a craving for nicotine and providing the same physical feeling as smoking establishes that the product is intended to affect the structure or function of the body. The assertion that E-Cigarettes provide a "healthier way" to obtain the effects of nicotine establishes that E-Cigarettes are intended to prevent or alleviate nicotine withdrawal symptoms. Accordingly, FDA reasonably concluded that the totality of the evidence demonstrates that E-Cigarettes are intended to affect the structure or function of the body and intended for use in the mitigation of disease. AR DET 112-16; *see also* AR DET 101-02, 107-11, 92.

3. E-Cigarettes Are Not Exempted from FDA Jurisdiction under *Brown & Williamson*

SE incorrectly argues that the Supreme Court's decision in *FDA v. Brown & Williamson* precludes FDA's jurisdiction over E-Cigarettes. Compl. ¶¶ 14-18, 36-38, SE Mem. at 10-14. In *Brown & Williamson*, the Court, addressing FDA's Final Rule cited above, held that FDA exceeded its statutory authority in asserting jurisdiction over tobacco products, *i.e.*, traditional cigarettes and smokeless tobacco. The Court expressly based its opinion on Congress' establishment of an alternative regulatory system for those products. 529 U.S. at 137-39, 143-58. Because E-Cigarettes are not traditional tobacco products that are governed by alternative regulatory systems, the holding of *Brown & Williamson* is

inapplicable.

The tobacco-specific legislation discussed by the Court included the Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. No. 89-92, 15 U.S.C. §§ 1331 *et seq.*, and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), Pub. L. No. 98-474 (1986), 15 U.S.C. §§ 4401 *et seq.* Among other things, those statutes provided that cigarettes and smokeless tobacco products must bear certain warnings for users. *Id.* §§ 1331, 4402. The statutes also prohibited the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission. *Id.* §§ 1335, 4402(f).

The Court noted that the very products that FDA sought to regulate under the FDCA had been specifically addressed in the FCLAA and CSTHEA. In the Court's view, those statutes demonstrated that Congress had made a specific choice to allow traditional cigarettes and smokeless tobacco products to be legally marketed, subject to certain disclosures and obligations. Under the FDCA, however, the Court noted that these same products could be banned as unsafe. *Brown & Williamson*, 529 U.S. at 135-37, 143. The Court concluded that this was not the result that Congress intended. Because "Congress . . . has foreclosed the removal of tobacco products from the market," the Court stated, "a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation," including FCLAA and CSTHEA. *Id*. at 137, 143. According to the Court, "[i]f they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit" within the FDCA. *Id*. at 143.

Neither the holding nor the reasoning of the case extends to E-Cigarettes, a

non-traditional cigarette alternative. FDA's Final Rule was directed at traditional tobacco products, including cigarettes and smokeless tobacco products. *See* 61 Fed. Reg. at 44616. SE readily admits (in fact, promotes) the facts that E-Cigarettes are not traditional cigarettes:

- "Smoking Everywhere Electronic Cigarette Looks like a traditional cigarette, feels like a traditional cigarette, Taste like a traditional cigarette, But *it isn't a traditional cigarette*."
- ". . . some people may come up to you telling you to put your Electronic Cigarette out (it looks that real), but . . . *it's NOT a real cigarette*, there is NO real smoke, flame, tar or tobacco."

AR DET 49, 25 (emphasis added); *see also* Compl. ¶¶ 8-9; SE Mem. at 4-5. FDA's Final Rule did not encompass products analogous to E-Cigarettes, and thus the Court's decision invalidating that rule is not applicable to E-Cigarettes.

Moreover, the logic and reasoning of *Brown & Williamson* does not extend to E-Cigarettes. Unlike the products at issue in *Brown & Williamson*, there are no statutes regulating E-Cigarettes that would conflict with the agency's exercise of jurisdiction. *Brown & Williamson* addressed Congress' intent for the regulatory treatment of products that had been on the market and subject to federal government regulation for decades. This analysis does not extend to new and innovative products, like E-Cigarettes, that have not been subject to regulation under FCLAA and CSTHEA.

Finally, the conflict between regulatory systems that the Court identified in *Brown & Williamson* is not present here. The Supreme Court believed that, if traditional cigarettes and smokeless tobacco were regulated under the FDCA, they might need to be banned, based on safety concerns, in conflict with Congress' intent, expressed

through other legislation, that they remain on market. Much less is known about the safety of E-Cigarettes, however. It may be possible for E-Cigarettes, upon the submission and review of an appropriate application, to satisfy the FDCA's safety, effectiveness, and labeling requirements and obtain FDA approval, just as FDA has approved other nicotine-containing products, such as gums and transdermal patches. Accordingly, *Brown & Williamson* is not applicable to E-Cigarettes, and that case does not undermine the agency's assertion of jurisdiction here.

4. FDA's Assertion of Jurisdiction over E-Cigarettes is Consistent with FDA's Treatment of Similar Nicotine-Containing Products

FDA has exercised jurisdiction over products analogous to E-Cigarettes. For example, in 1987, the agency exercised jurisdiction over a nicotine product marketed as "Favor Smokeless Cigarettes." AR NIC 10-11. The Favor product was comprised of a plastic tube containing a plug impregnated with nicotine solution that allowed the user to inhale nicotine vapor. The product was marketed as providing "cigarette satisfaction without smoke." AR NIC 1. The marketing materials also claimed that Favor could be used "in places where smoking is not permitted or just doesn't fit in" and could provide "full tobacco pleasure and satisfaction." AR NIC 3. FDA issued a letter to the company explaining that the products were unapproved new drugs, and that FDA was prepared to initiate legal action if the company did not discontinue marketing the products. AR NIC 10-11.

In the years since *Brown & Williamson*, FDA has continued to exercise jurisdiction over nicotine-containing products. For example, in 2002, FDA asserted

jurisdiction over Nicotine Lollipops and Nicotine Lip Balm. *See* AR NIC 12-17. Both products consisted of Nicotine Salicylate combined with flavoring and sweetening ingredients. AR NIC 12, 15. Claims for these products were made on associated websites that included statements such as "help[s] relieve the craving for nicotine." AR NIC 13. Like E-Cigarettes, these products had not been the subject of an application submitted to FDA for approval. FDA issued warning letters to companies distributing the products explaining that the products were unapproved and misbranded drugs. *See* AR NIC 12-17.

Also in 2002, FDA asserted jurisdiction over Nicotine Water, a product that contained water and pharmaceutical grade nicotine. *See* AR NIC 18-22. The manufacturer's website promoted the product as having the "nicotine equivalent of 2 cigarettes" and to "reduce use of tobacco products." AR NIC 20. FDA found that Nicotine Water was an unapproved new drug. *See* AR NIC 21-22.

In 2008, FDA asserted jurisdiction over a nicotine hand gel made from liquified tobacco in a water soluble solution. *See* AR NIC 58-80. The product was promoted as a cigarette alternative that provides "cigarette satisfaction." AR NIC 62. FDA had detained the product, and the importer had requested and obtained a hearing. In an August 2008 letter, FDA informed the importer that FDA had concluded that the product was an unapproved new drug, and FDA intended to refuse entry of the products into the United States. *See* AR NIC 79.

In addition, as noted above, a number of companies distributing nicotine-containing products have not attempted to evade FDA regulation, but have obtained FDA approval of their products. These include gums, transdermal patches, nasal sprays, inhalers, and lozenges. *See* AR NIC 31, 50; http://www.fda.gov/womens/medicinecharts/smoking.html.

For all of these reasons, the Court should defer to FDA's reasonable conclusion, based on the nature of E-cigarettes, the claims made for them, the language of the statute and FDA regulations, and administrative precedent, that E-Cigarettes are drugs and devices under the FDCA. Because E-Cigarettes are not approved under the FDCA, FDA properly excluded SE's shipments of E-Cigarettes from import, and SE's motion for a preliminary injunction should be denied.

B. FDA's Amendment of IA 66-41 was a Permissible Exercise of FDA's Discretion and Did Not Require Notice and Comment Rulemaking

In addition to challenging FDA's authority to regulate E-Cigarettes, SE argues that Import Alert 66-41 is a substantive rule that should have been published for notice and comment rulemaking. Compl. ¶¶ 42-46. SE is wrong, for three reasons. First, in enacting section 21 U.S.C. § 381(a), Congress committed decisions regarding the refusal of entry of drugs and devices to FDA's broad discretion. Indeed, the statutory language, legislative history, and case law support the proposition that FDA's discretion regarding the admissibility of products within its jurisdiction is not subject to judicial review. Even if FDA's import decisions were subject to judicial review, however, they would still be entitled to substantial deference under the broad discretionary standard contained in the statute. Second, plaintiff has failed to establish standing to challenge IA 66-41 because it has failed to show any causal link between the import alert and any injuries it sustained. Finally, the amendment to IA 66-41 did not require publication for notice and comment rulemaking. FDA's amendment of an import alert reflects only information communicated to FDA field personnel pertaining to a preliminary stage in the import proceeding – the *detention* of products – and not to the final decision

regarding the *refusal* of those products from importation. As such, the import alert is not a binding, substantive rule and was not required to be published for notice and comment rulemaking.

1. FDA's Import Decisions Are Committed to Agency Discretion

In FDCA's import provision, Congress directed the agency to refuse the admission of a drug or a device it "appears," *inter alia*, adulterated, misbranded, or in violation of section 355, based on an examination of the samples "or otherwise." *See* 21 U.S.C. § 381(a). In using the terms "appear" and "otherwise," which are undefined, Congress delegated broad discretionary authority to the agency. Courts have recognized that, under the plain language of the statute, Congress committed import refusal decisions to the agency's discretion such that those decisions are unreviewable.

The APA, 5 U.S.C. § 701(a)(2), precludes judicial review when "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion. In such a case, the statute ('law') can be taken to have 'committed' the decisionmaking to the agency's judgment absolutely." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). Here, there is no meaningful way for the Court to review what "appears," in FDA's judgment, to be violative of the FDCA. Indeed, when the "appearance" standard was introduced the Pure Food and Drug Act of 1906, Congress made its intent regarding judicial review clear: "[U]nder this provision, the Secretary . . . has power to decide whether a cargo of goods imported from a foreign country is adulterated or misbranded, . . . *his decision is final*, and the goods must be destroyed or exported and returned *without* further investigation or power of *review*." *See* 40 Cong.

Rec. 9002-9003 (daily ed. June 12, 1906) (statement of Rep. Crumpacker) (emphasis added).

Although the case law on this issue is not abundant, some courts have held that Congress delegated unreviewable discretion to FDA. See *Sugarman v. Forbragd*, 267 F. Supp. at 824, 825 ("There is no provision for judicial review. Clearly, this is an instance where "agency action is committed to agency discretion by law. . . . . Congress intended that the Secretary, or the employees to whom his authority is delegated, should make the final determination whether a food offered for import *appears* to be adulterated - without judicial review.")[5]; *The James J. Hill*, 65 F. Supp. 265, 270 (D. Md. 1946) ("[I]t is clear that in the present case the statute makes no provision for judicial review and creates no personal federal rights as the basis for judicial review, so long as the Secretary acted within the scope of his authority under the Act.").

Other courts, which have not concluded that FDA import decisions are unreviewable, have nevertheless recognized the extreme breadth of FDA's discretion. *See Seabrook Int'l Foods, Inc. v. Harris*, 501 F. Supp. 1086, 1090-91 (D.D.C. 1980) ("The use of the term 'appears' in the statute is a striking and clear indication of Congress' intent to forego formal procedural requirements."), *aff'd sub nom., Cont'l Seafoods, Inc. v. Schweiker*, 674 F.2d

[5] The Ninth Circuit, in affirming the district court in *Sugarman*, held that import refusal decisions under section 381(a) are committed to agency discretion and therefore are not subject to the APA. 405 F.2d at 1190-91. However, it further held that the agency's decision was not arbitrary and capricious, *see id*., apparently indicating that it did conduct some review.

38, 42-43 (D.C. Cir. 1982) (noting "FDA's broad authority to prohibit import of any food that 'appears' to be adulterated"); *K & K Merch. Group v. Shalala*, Civ. No. 95-10082, 1996 WL 183023 at *8 (S.D.N.Y. Apr. 17, 1996) (noting "the wide discretionary power FDA enjoys to determine the factors regarding its decision to grant or refuse admission of imported goods"); *Meserey v. United States*, 447 F. Supp. 548, 555 (D. Nev. 1977) (an FDA order excluding material from import under the appearance standard is committed to FDA's discretion, although the court reviewed the decision to determine whether it was arbitrary and capricious).

In vesting the agency with such broad discretion to refuse to admit certain products into domestic commerce, Congress enabled FDA to act on incomplete information and conserve its resources. Given the vast disparity between FDA's relatively modest resources and the huge volume of imported products within its jurisdiction,[6] as well as the more limited information and regulatory control that FDA has with respect to overseas manufacturers, FDA could not effectively monitor and control the influx of foreign medical products into domestic commerce if the agency were required to prove an actual violation of the FDCA, subject to judicial review, every time it sought to refuse admission to an article offered for import. By granting the agency authority to refuse admission to any product that "appears" adulterated based on actual inspection or "otherwise," Congress empowered the agency to exercise its discretion in a broad and flexible manner, thereby promoting the most efficient and effective use of the agency's limited resources and information.

[6] "In FY 2009, FDA expects . . . a total of more than 18.2 million lines of FDA regulated entries." *See* http://www.fda.gov/oc/oms/ofm/budget/2009/FDA_Online_Appendix.htm.

When, as here, the statute affords no judicial review of FDA's ultimate determination to *refuse* admission of an entry offered for import, then plainly SE should not be able to challenge FDA's preliminary step of identifying certain products as being subject to detention pending a determination of their admissibility. As discussed above, the Import Alert simply provides information to FDA field personnel pertaining to the detention, not refusal, of products offered for importation into the U.S. If a product is detained (whether pursuant to an import alert or otherwise), the importer is given an opportunity to contest the detention and offer proof of the legality of the products sought to be imported. *See* 21 C.F.R. § 1.94; AR DET 89, 91. FDA's interim decisions regarding the allocation of its resources, including what products to identify as being subject to DWPE, what entries to examine or detain, and the means it uses to communicate information, are, like the admissibility decision itself, committed to agency discretion, and should not be subject to review by the Court.

2. Import Alert 66-41 is Not a Substantive Rule that Requires Notice and Comment Rulemaking under the APA

Even if the import alert were subject to judicial review, IA 66-41 is not a substantive rule that FDA was required to issue through notice and comment rulemaking. As an initial matter, however, SE does not have standing to challenge IA 66-41. Standing requires the plaintiff to show, among other things, a "causal connection between the injury and the conduct complained of." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). SE has not provided any evidence that any of its products were detained based on this import alert. The shipments that were documented in Exhibit A to the complaint had been detained in October 2008, more than five months before electronic cigarettes were first listed in IA

66-41. AR IA 88-91. Further, the electronic cigarettes currently listed in IA 66-41 come from three specific manufacturers in China, and SE has not alleged that it receives any products from the listed manufacturers. Thus, on the facts alleged in the complaint, SE has no standing to challenge IA 66-41.

Even if plaintiff had established standing, SE would not be entitled to relief because IA 66-41 is not a substantive rule. Under the APA, the publication of notice and opportunity for comment are only required for a limited subset of agency pronouncements. Rulemaking is required for "legislative" or "substantive" rules. An agency pronouncement does not become a substantive rule "merely because it supplies crisper and more detailed lines than the authority being interpreted." *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). The pronouncement may have a "substantive impact" on the parties being regulated without becoming a substantive rule. *Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537 (D.C. Cir. 1986) (quoting *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666, 668 (D.C. Cir. 1978)).

In *Am. Mining Cong.*, the D.C. Circuit identified four criteria that indicate a rule is legislative (none of which is present in this case): (1) in the absence of the rule, no legislative basis would exist for an enforcement action; (2) the agency has published the rule in the Code of Federal Regulations ("CFR"); (3) the agency explicitly invoked its general legislative authority to pass the rule; (4) the rule effectively amends a prior legislative rule. 995 F.2d at 1112; *see also In re Long-Dist. Tel. Service*, 539 F. Supp.2d 281, 307-11 (D.D.C. 2008) (discussing the requirements of a substantive rule).

Under these principles, IA 66-41 is clearly not a substantive rule. The import alert is a

mechanism for FDA headquarters to communicate information and provide guidelines to FDA field personnel and the regulated industry. In this case, FDA headquarters gathered and analyzed information regarding the marketing of electronic cigarettes originating from three overseas manufacturers. AR IA 92-179. This information showed that drug claims were being made for these particular products. *E.g.*, AR IA 157-59. The import alert pertains only to detention, not the ultimate refusal of entry. AR IA 3. In addition, the districts retain the discretion to make detention decisions on a case-by-case basis and are not required to follow the import alert. Further, every importer has the opportunity, after detention but before the ultimate decision regarding admission or refusal, to present evidence to the agency. 21 C.F.R. § 1.94. Most significantly, the ultimate decision on an entry is based on the statute, not the import alert. *See* 21 U.S.C. § 381(a).

None of the indicia of rulemaking identified in *Am. Mining Cong.* applies to IA 66-41: in its absence, FDA has the same authority granted by the FDCA to detain imported goods; the import alert was not published in the CFR; FDA did not invoke its legislative authority; and the statement did not amend a prior legislative rule. *See* 995 F.2d at 1112. Nor does IA 66-41 have a "binding effect" on private parties or the agency. *See Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 226-27 (D.C. Cir. 2007). To the contrary, because IA 66-41 relates to detention, and not to the final admission or refusal of a product into United States commerce, it has – at most – a "tentative effect." *See Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38-39 (D.C. Cir. 1974); *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 596 (5th Cir. 1995). Also, as the D.C. Circuit has recognized, written guidelines that describe how the agency intends to exercise its discretion, and that are not issued pursuant to notice and comment

rulemaking, "have the not inconsiderable benefits of apprising the regulated community of the agency's intentions as well as informing the exercise of discretion by agents and officers in the field." *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 949 (D.C. Cir. 1987); *see also Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) ("statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power" are "general statements of policy" that do not have to be published for notice and comment) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979)).

Courts have found that, when a pronouncement sets forth a rebuttable presumption that may be challenged in individual proceedings, it is not a binding rule. *Panhandle Producers and Royalty Owners Ass'n v. Econ. Regulatory Admin.*, 847 F.2d 1168, 1174-75 (5th Cir. 1988); *Ryder Truck Lines, Inc. v. United States*, 716 F.2d 1369, 1377-78 (11th Cir. 1983). IA 66-41 does not create binding law because it is not "finally determinative" of whether a particular importation will be admitted or released into United States commerce. *See Pacific Gas & Elec.*, 506 F.2d at 38.

IA 66-41 also does not impose any new obligations or requirements beyond the existing statutory requirements on foreign producers or importers, or on FDA personnel. Importers remain subject to the exact same statutory obligation – that they refrain from importing into the United States medical products that violate the FDCA. And FDA continues to exercise the same authority – to refuse admission to any product that "appears" to be violative of the FDCA. 21 U.S.C. § 381(a). Nothing in the import alert "cabin[s]" the agency's discretion to determine whether to admit or refuse any electronic cigarette. *See Cmty. Nutrition Inst.*, 818 F.2d at 948 ("cabining of an agency's prosecutorial discretion can in fact rise to the level of a substantive,

legislative rule").

Indeed, it is clear from even a cursory examination of the language of IA 66-41 that the alert is – and is meant to be – nothing more than an expression of a non-binding policy on import compliance activities. The import alert provides:

> Note: This import alert contains guidance to FDA field personnel only. It does not establish any requirements, or create any rights or obligations on FDA or on regulated entities.
>
> * * *
>
> GUIDANCE: Districts may detain without physical examination any Unapproved *** and/or misbranded drug *** listed in the attachment.

AR IA 3. The use of the words "Guidance" and "may" clearly demonstrates that the document is not intended to be a binding directive. *See Cathedral Bluffs Shale Oil Co.*, 796 F.2d at 537-38 (the agency's characterization of the pronouncement, and the language of the statement itself, such as the choice between the words "may" and "will," are significant in determining whether the pronouncement is a substantive rule).

The discretionary, non-mandatory language of IA 66-41 distinguishes it from the FDA import alert at issue in *Bellarno Int'l Ltd. v. FDA*, 678 F. Supp. 410 (E.D.N.Y. 1988), relied upon by SE. SE Mem. at 19-21. The import alert in *Bellarno* used the words "automatically" and "shall," *id.* at 415, leading the court to find that it was a mandatory directive, not discretionary guidance, and was binding on both the agency and importers. *Id*. at 414. The court also cited a contemporaneous memorandum issued by the agency which provided: "There should be no exceptions to strict enforcement." *Id.* at 415. Here, by contrast, IA 66-41 employs discretionary, non-mandatory language, providing that "Districts *may* detain . . . ."

The import alert in *Bellarno* also contained requirements for overcoming detention that went beyond satisfaction of the statutory standard, such as establishing a "complete chain of

custody" and a "satisfactory reason for return of the goods." *Id.* at 411-12. When the plaintiff was unable to produce the complete chain of custody, FDA was unwilling to consider alternative evidence, such as testing, to confirm the products' safety and purity. *Id*. at 412. The *Bellarno* court thus found that the agency had created a new and substantive obligation "by requiring the importer to comply with the terms set forth in" the import alert. *Id*. at 414 & n.4. Because none of these factors is present in IA 66-41, the specific facts in *Bellarno* prevent any useful comparison between the two cases.

Furthermore, no court has ever relied on *Bellarno* to hold that an FDA import alert was a substantive rule, with the exception of one case from the same jurisdiction that was stayed almost immediately. Four years after *Bellarno*, the same court applied that decision, holding, in the context of a preliminary injunction, that another FDA import alert violated the APA's rulemaking requirement for substantive rules. *See Benten v. Kessler*, 799 F. Supp. 281, 288-90 (E.D.N.Y. 1992). The Second Circuit stayed the injunction the same day the district court issued it, however, and the Supreme Court summarily rejected the plaintiff's application to vacate the stay. 505 U.S. 1084 (1992) (per curiam). In fact, the Supreme Court specifically held that plaintiffs had "failed to demonstrate a substantial likelihood of success" on the claim that the import alert was improperly issued without notice and comment procedure. *Id.* at 1085. *Bellarno*, therefore, is not compelling precedent.

For all of the reasons set forth above, IA 66-41 is not a legislative rule that required notice and comment rulemaking under the APA. Accordingly, SE has not shown a likelihood of success on the merits.[7]

[7] In addition to the notice and comment argument, SE also argues that the addition of E-

Cigarettes to IA 66-41 was arbitrary and capricious on the grounds that traditional tobacco products are outside of FDA's jurisdiction and they are treated differently from E-Cigarettes. Compl. ¶¶ 47-50. Because SE has not shown that IA 66-41 had anything to do with the refusal of its products, it has no standing to raise this claim. Also, for the same reasons that IA 66-41 is not a substantive rule, it is not final agency action subject to challenge. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). In any event, this is the same as the jurisdiction/authority argument addressed in Section II.A of the argument, and can be rejected for the same reasons.

III. SE HAS NOT SHOWN IT WILL SUFFER IRREPARABLE INJURY ABSENT THE REQUESTED PRELIMINARY INJUNCTION

Not only does SE's claim for preliminary injunctive relief lack substantive merit, SE has failed to demonstrate that it will suffer irreparable harm absent such relief or that the balance of hardships tips in its favor. "The *sine qua non* of granting any preliminary injunctive relief is a clear and convincing showing of irreparable injury to the plaintiff." *Experience Works, Inc. v. Chao*, 267 F. Supp. 2d 93, 96 (D.D.C. 2003). Because the likelihood of success is extremely slim, SE "would have to make a very substantial showing of severe irreparable injury" to prevail on its motion. *National Pharm. Alliance v. Henney*, 47 F. Supp. 2d 37, 41 (D.D.C. 1999). Irreparable injury is a very high standard. *See RCM Technologies, Inc. v. Beacon Hill Staffing Group*, 502 F. Supp.2d 70, 74 (D.D.C. 2007); *Varicon Int'l v. Office of Personnel Mgmt.*, 934 F. Supp. 440, 447 (D.D.C. 1996); *Bristol-Myers*, 923 F. Supp at 220. The injury alleged must be certain, great, actual, and imminent, *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985), and it must be "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981).

SE recognizes, SE Mem. at 9, that, in this Circuit, mere economic loss in and of itself does not constitute irreparable harm unless the financial injury is so great as to "cause extreme hardship to the business, or even threaten destruction of the business." *Gulf Oil*, 514 F. Supp. at 1025; *see also Wisconsin Gas*, 758 F.2d at 674; *Apotex, Inc. v. FDA*, Civ. No. 06-0627, 2006 WL 1030151 at * 17 (D.D.C. Apr. 19, 2006); *Experience Works, Inc.*, 267 F. Supp. 2d at 96; *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001).

Despite that acknowledgment, SE did not, in its preliminary injunction motion, make any attempt to quantify any loss it would allegedly suffer. It simply stated that if its shipments are detained, its "ability to pay its expenses as they come due will be jeopardized, and it will likely be forced to close its business." SE Mem. at 9. SE made no attempt to describe its business by stating how long it had been doing business or how many employees it had, nor did it make any attempt to quantify its sales – past or present, its inventory, or the percentage of the total worldwide sales it would lose if its shipments into the United States are detained. Thus, it is possible that, prior to FDA's actions, SE's sales were so low that there was not really a "business" in place. It is simply impossible to tell from what SE has submitted.

In the complaint, SE alleges that it markets E-cigarettes "and similar products." Compl. ¶ 7. In the administrative proceeding on the detention of one of its shipments, SE represented to FDA that it sells "this product around the world." AR DET 94-95; *see also* AR DET 46 (The E-Cigarette "is expanding it's [sic] distribution channels both nationally and internationally.") Nonetheless, SE makes no attempt to show what portion of its total sales of E-cigarettes are made in the United States, and thus what effect the loss of those sales would have on its overall business.

FDA has pointed out the speculative nature of these allegations. Memorandum in Support of Motion to Establish Briefing Schedule at 2, 3. Although SE submitted a declaration in response to this motion, that declaration does not quantify the amount of business that SE will lose as a result of FDA's actions, nor give any sales figures. Declaration of Elicko Taleb, April 30, 2009. The vague and speculative nature of these allegations is insufficient to establish such irreparable injury that would justify the drastic remedy of a mandatory preliminary injunction.

Wisconsin Gas Co. v. FERC, 758 F.2d. at 675 ("Finally, the allegations made by petitioners are so speculative and hypothetical that it would be difficult to conclude that irreparable injury would occur even if the allegations were supported by evidence. The fact that petitioners have not attempted to provide any substantiation is a clear abuse of this court's time and resources."); *see also United Farm Workers v. Chao*, 593 F. Supp.2d 166, 171 (D.D.C. 2009); *National Ass'n of Mfrs. v. Taylor,* 549 F. Supp.2d 68, 76 (D.D.C. 2008); *Biovail Corp. v.* FDA, 519 F. Supp.2d 39, 44 (D.D.C. 2007); *RCM Technologies, Inc.*, 502 F. Supp.2d at 74. Equally significant to the question of irreparable harm is the amount of time that has passed since SE first became aware of this issue. As reflected in the administrative record, SE was informed of the hold on two of its shipments in October 2008. AR DET 69-70. It was told on October 29 that it could submit information regarding admissibility of these shipments by November 19. AR DET 89, 91. It missed that deadline, but submitted information to FDA in December. AR DET 94-96. On December 23, FDA responded to this submission, and explained why the products were subject to refusal of admission. AR DET 107-11. SE again submitted information to FDA. AR DET 92-94. FDA considered this information and responded on February 11, 2009, again stating that the products were subject to refusal of admission. AR DET 92. FDA heard nothing further from SE, and issued a notice of refusal of admission on March 16, 2009. AR DET 112-16. On March 30, FDA first added certain electronic cigarettes to an import alert that pertains to unapproved new drugs. AR IA 85-86.

SE filed this lawsuit on April 28, approximately six months after first learning of FDA's regulatory concerns regarding this product, about a month and a half after receiving FDA's

notice of refusal of admission, and nearly a month after this type of product was added to an import alert. This delay in seeking relief defeats plaintiff's claim that it has suffered irreparable injury. In *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006), this Court held that Sandoz' delay of less than two months – until the "last minute" – to bring its challenge undercut its claim of irreparable injury. *Id.* at 30-31. *See also Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995) (delay "may, 'standing alone, . . . preclude the granting of preliminary injunctive relief.'") (quoting in part *Majorica, S.A. v. R.H. Macy & Co.*, 762 F.2d 7, 8 (2d Cir. 1985)); *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975) ("Our conclusion that an injunction should not issue is bolstered by the delay of the appellants in seeking one."); *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp.2d 30, 43 (D.D.C. 2000) ("Mylan's delay in bringing this action further undercuts its allegation of irreparable harm.").

IV. THE BALANCE OF HARMS AND THE PUBLIC INTEREST WEIGH HEAVILY AGAINST THE REQUEST FOR INJUNCTIVE RELIEF

The interest of the government and the public in reducing exposure to unapproved, and potentially unsafe and ineffective, drugs and devices substantially outweighs any potential harm to SE. Congress enacted the drug and device provisions of the FDCA to protect consumers from unsafe and ineffective drug products. *Cf. FDA v. Brown & Williamson*, 529 U.S. at 133 (expressly recognizing that the "essential purpose" of the FDCA is to "ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use"). The core objective of the FDCA's drug regulation provisions is to promote public health by regulating drugs for safety and effectiveness. *See* 21 U.S.C. § 393(b)(2) (defining the FDA's mission as including "ensuring that . . . drugs are safe and effective"); *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 50 (D.D.C. 2003) ("There is no question that the legislative intent behind enactment of the original FDCA

was to protect the public from unsafe drugs.") (citing *United States v. Undetermined Quantities of Veterinary Drug*, 22 F.3d 235, 238 (10th Cir.1994)); *In re Establishment Inspection of Wedgewood Vill. Pharmacy, Inc.*, 270 F. Supp. 2d 525, 549 (D.N.J. 2003) ("Congress intended that the FDCA, both in its original form and as amended, allow the FDA broad enforcement powers to fulfill its mandate that it protect the public from unsafe medication.").

Without the submission of an appropriate application for review by FDA, there is no assurance that E-Cigarettes are safe and effective for their intended uses. To be sure, SE would not be able to market its product while an application was pending. However, that is the same burden that the law imposes on every drug and device manufacturer and their distributors awaiting the completion of FDA review of a drug or device application. In enacting the FDCA, Congress made clear that the interest of the public health in safe and effective medical products takes precedence over the economic interests of would-be drug and device manufacturers.

CONCLUSION

For the foregoing reasons, SE's motion for a preliminary injunction should be denied.

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May 11, 2009

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