UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVELTY DISTRIBUTORS, INC. d/b/a GREENFIELD LABS,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 08-00635 (RMC)**
MICHELLE LEONHART, Acting Administrator, Drug Enforcement Administration, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

Novelty Distributors, Inc. ("Novelty"), challenges the pre-hearing suspension by the Drug Enforcement Agency ("DEA") of Novelty's registration to distribute ephedrine and pseudoephedrine, both of which are list I chemicals subject to DEA regulation. It seeks a preliminary injunction enjoining the suspension pending a final decision by DEA. DEA contests jurisdiction in the district court, insisting that only the court of appeals can review its actions under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, *et seq.* (2008), and in the alternative, argues that a preliminary injunction is not warranted under the applicable standard. The Court finds that Novelty's challenge is properly presented in the district court, but it has not satisfied the standards for a preliminary injunction.

I. STATUTORY BACKGROUND

Both ephedrine and pseudoephedrine are list I chemicals which are often diverted for

use in the clandestine manufacture of methamphetamine, a controlled substance.[1] In response, Congress passed the Chemical Diversion and Trafficking Act of 1988 ("CDTA"), Pub. L. 100-690; 102 Stat. 4312 (repealed in part 1992); the Domestic Chemical Diversion Control Act of 1993, Pub. L. 103-200; 107 Stat. 2333; and the Combat Methamphetamine Epidemic Act of 2005, Publ. L. 109-177; 120 Stat. 256 (2006), all of which have imposed upon distributors and sellers of list I chemicals various duties to control theft, loss, and other illegal diversions of list I chemicals to clandestine laboratories.

DEA regulates ephedrine and pseudoephedrine pursuant to the CSA, as amended by, *inter alia*, the CDTA. 21 U.S.C. § 802(34)(C), (K). Any individual or entity who wishes to import, export, or distribute list I chemicals must first register with DEA. 21 U.S.C. §§ 802(38), 843(a)(9); *see also* 21 C.F.R. § 1309.21. Collectively, these statutes require list I chemical distributors to take affirmative steps to prevent illegal diversion of their products by proper handling, storage, and tracking. 21 U.S.C. §§ 830(a), (b)(1), 823(h); *see also* 21 C.F.R. §§ 1310, 1310.05(a), 1309.71-73. DEA has the authority to conduct inspections of registrants' places of business where regulated persons lawfully distribute list I chemicals. 21 U.S.C. § 822(f); 21 C.F.R. § 1316.03.

DEA can revoke or suspend a party's registration for a variety of reasons. *See* 21 U.S.C. § 824(a) (articulating five grounds for revocation or suspension). Prior to suspending or

[1] Under the CSA, controlled substances are categorized into five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision. *See* 21 U.S.C. § 812(a). Congress prepared the initial schedules by statute, placing a number of substances in one of the five schedules, but provided for those schedules to be amended by the Attorney General pursuant to 21 U.S.C. § 811. *See id.* § 812(c). Schedule I substances are "the most stringently controlled" because they have "no currently accepted medical use in treatment in the United States," have "a lack of accepted safety for use . . . under medical supervision," and have "a high potential for abuse." *John Doe, Inc. v. Drug Enforcement Admin.*, 484 F.3d 561, 563 (D.C. Cir. 2007) (citing 21 U.S.C. § 812(b)(1)).

revoking a party's registration, DEA must issue an order to show cause containing DEA's basis for the proceedings and it must provide an administrative hearing within 30 days. *See id.* § 824(c).

In cases where DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," DEA can suspend that party's registration immediately, prior to an administrative hearing. 21 U.S.C. § 824(d). As with suspensions under § 824(a), DEA must provide the basis for its immediate suspension under § 824(d) in an order to show cause, and the registrant is entitled to request an expedited administrative hearing. *See id.*; 21 C.F.R. §§ 1309.44(a), 1309.44(c). A suspension under § 824(d) remains in effect until: (1) DEA issues a final order ending it; (2) it is withdrawn by the Attorney General; or (3) it is dissolved by a "court of competent jurisdiction." *Id.* § 824(d).

II. FACTUAL BACKGROUND

As a distributor of ephedrine and pseudophedrine, Novelty must obtain a registration from DEA every year to distribute list I chemicals. In order to verify that distributors of controlled substances are complying with the various obligations imposed by statute and DEA regulations, DEA routinely conducts administrative inspection of distributors' facilities and records. Mot. to Dismiss, Barnhill Decl. ¶ 33 [Dkt. # 33-3]. Pursuant to this authority, DEA investigators went to Novelty's facility in Greenfield, Indiana, to execute an administrative search warrant on July 9, 2007. *Id.* Although Novelty allowed DEA investigators to use a conference room on their premises as a workspace, on July 11, 2007, while the investigators had vacated the workspace for lunch, Novelty installed a video-recorder on a tripod at the far end of the conference room to record their deliberations. *See* Pl.'s Mem. in Support of Mot. for Partial Summ. J. ("Pl.'s Mem.") at 3-4 [Dkt. # 30-3]. DEA agents unplugged the camera upon returning from lunch and thereafter refused to

allow Novelty to videotape its deliberations.[2] *Id*. at 5.

The inspection went poorly. Novelty allegedly failed for three days to provide records it was legally required to maintain. *See* Mot. to Dismiss, Barnhill Decl. ¶ 35. The records that Novelty did produce were "coded," such that DEA investigators could not discern what products Novelty was distributing, or to whom it was distributing those products. *Id.* ¶ 36. Novelty representative Ryan Polk informed DEA investigators that it would need more time to produce "uncoded" records from which DEA could trace sales of particular chemicals from Novelty to specific retail customers, so Novelty and DEA agreed that Novelty would produce only records for the time between January 1 and July 9, 2007, rather than the entire two-year audit period. *Id.* The necessary records were not fully produced until July 18, 2007. *Id.* ¶ 38.

Based upon its investigation, DEA concluded that there was reason to believe that Novelty had committed several separate and independent statutory and regulatory violations. Defs.' Mem. in Support of Mot. to Dismiss at 6 [Dkt. # 33-2]. It also concluded that these practices posed a serious risk that list I controlled substances would be diverted to the illegal manufacture of methamphetamine. *Id.* And given the apparent failure of effective safeguards against diversion and the numerous unregistered sites from which Novelty allegedly distributed chemicals, DEA further concluded that Novelty's continued registration posed an imminent danger to the public health and safety. *Id.*

DEA suspended Novelty's registration by Order dated January 17, 2008, pursuant to 21 U.S.C. § 824(d). *Id.* Novelty requested an expedited administrative hearing which commenced

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[2] DEA's insistence that the video equipment be removed underlies a First Amendment claim in the instant complaint.

on March 24, 2008 and continued intermittently for eight days, concluding on April 2, 2008. Mot. to Dismiss, Barber Decl. ¶ 3 [Dkt. # 33-4]. By decision dated May 21, 2008, a DEA Administrative Law Judge ("ALJ") recommended that DEA reinstate Novelty's registration. *See In the Matter of Novelty Distribs.*, No. 08-33 (D.E.A. May 21, 2008) (the "DEA ALJ Decision") [Dkt. # 29-2 (redacted)]. DEA has not yet issued a final determination regarding Novelty's suspension.

In the meantime, on April 9, 2008, Novelty filed the instant complaint against DEA. *See* Dkt. # 1. It seeks declaratory and injunctive relief on the grounds (i) that DEA acted arbitrarily and capriciously in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and the CSA by suspending Novelty's registration without prior notice or an opportunity to be heard; (ii) that DEA's suspension unlawfully deprived Novelty of its property interest in its registration without due process of law in violation of the Fifth Amendment, U.S. Const. amend. V; and (iii) that DEA violated Novelty's First Amendment rights, U.S. Const. amend. I, by refusing to allow Novelty to record its deliberations during the administrative search.

III. ANALYSIS

Pending before the Court is Novelty's motion for summary judgment on the issue of jurisdiction and Novelty's motion for a preliminary injunction.

A. Summary Judgment on Jurisdiction

1. *Legal Standards for Summary Judgment*

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment must be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Anderson v. Liberty*

Lobby, Inc., 477 U.S. 242, 247 (1986); *see also Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). Moreover, summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Id.* at 675. If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

2. *Jurisdiction*

Whether this Court has jurisdiction to hear Novelty's complaint depends in the first instance on the provisions of 21 U.S.C. § 824(d) which states:

> The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or

dissolved by a court of competent jurisdiction.

The argument between the parties really devolves as to whether a district court, and not a court of appeals, can be a "court of competent jurisdiction" referenced in the statute.

Citing 21 U.S.C. § 877, DEA argues that only a court of appeals can review "final determinations, findings, and conclusions of the Attorney General under this subchapter. . . . Because no part of this review process involves the district court, this Court lacks jurisdiction over Novelty's claims." Defs.' Mem. in Support of Mot. to Dismiss at 8 (citing *John Doe, Inc. v. Drug Enforcement Admin.*, 484 F.3d at 568-70).

Rather than supporting DEA's argument, *John Doe* demonstrates that only the district court can have jurisdiction at any time prior to a final DEA decision. In *John Doe*, the plaintiff, a drug manufacturer, sought to import a generic version of the drug Marinol for testing in order to obtain Food and Drug Administration ("FDA") approval. 484 F.3d at 563. Both Marinol and the plaintiff's generic drug contained the active ingredient dronabinol which is a schedule I drug under the CSA, *id.*, and is therefore "subject to very strict controls" by DEA, *id.* (citing 21 U.S.C. § 812(b)(1)). DEA did, however, after extensive testing and approval by the FDA, assign the precise synthetic formulation for Marinol, which was specifically approved by the FDA, a schedule III listing, thereby reducing the restrictions on its production and distribution. *Id.* at 563-64. When the plaintiff applied for a permit to import its generic version of Marinol, it registered the drug as a schedule III substance. *Id.* at 564. When DEA learned that the drug that the plaintiff sought to import was not Marinol, but rather a generic version of Marinol which may therefore have a slightly different chemical composition, it denied the plaintiff's request for a permit to import its drug, deeming it to be a schedule I substance like all other dronabinol-containing drugs other than Marinol.

Id. The plaintiff sought immediate redress in both the district court and the court of appeals. *Id.*

The D.C. Circuit first held that DEA's denial of the plaintiff's permit was "sufficiently final to confer jurisdiction" on the court of appeals for review. *Id.* at 567. Only after it had concluded that DEA's denial of the permit was a final determination did it move on to consider whether jurisdiction properly lay in the district court or in the court of appeals. *See id.* at 568. It held that jurisdiction lay solely in the court of appeals, not the district court. *Id.* at 570. In so holding, the D.C. Circuit rejected the reasoning adopted by several district courts for exercising jurisdiction over review of DEA actions. *Id.* at 568-69. Those district courts relied in part on the Supreme Court's decision in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479 (1991), which held that a narrow grant of individualized review, vested exclusively in the court of appeals, did not preclude district court jurisdiction over a class action claiming a pattern or practice of constitutional violations by the Immigration and Naturalization Service. *John Doe*, 484 F.3d at 568. The D.C. Circuit reasoned that *McNary* was distinguishable from the subsequent district court cases relying on it, in large part because "*McNary* cannot be divorced from the Court's obvious concern that, absent district court review of the *McNary* plaintiffs' claims, meaningful judicial review would have been entirely foreclosed." *Id.* at 569 ("Were we to hold otherwise and instead require respondents to avail themselves of the limited judicial review procedures set forth in § 210(e) of the [Immigration and Nationality Act], meaningful judicial review of their statutory and constitutional claims would be foreclosed.") (citation omitted). The district court cases whose reasoning the D.C. Circuit rejected, however, did not deal with situations where the aggrieved parties would be foreclosed from seeking any judicial review of their claims if the district courts were denied jurisdiction. *Compare McNary*, 498 U.S. at 484 *with PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24 (D.D.C. 2001); *Novelty,*

Inc. v. Tandy, No. 04-1502, 2006 U.S. Dist. LEXIS 57270 (S.D. Ind. Aug. 15, 2006); *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002).

The D.C. Circuit did not otherwise find "the . . . reasons district courts have given for exercising jurisdiction . . . persuasive." *John Doe*, 484 F.3d at 569. First, it explained that the district courts incorrectly concluded that the "applicability of 21 U.S.C. § 877 turns on whether the DEA complied with the procedural requirements for final agency 'determinations, findings, and conclusions,'" *id.* (rejecting the reasoning in *PDK Labs*, 134 F. Supp. 2d at 29, and *Novelty*, 2006 U.S. Dist. LEXIS 57270, at *10-27); rather, the Circuit held that its "jurisdiction under a direct-review statute has never depended on agency compliance with procedural requirements." *John Doe*, 484 F.3d at 569. The D.C. Circuit also rejected the conclusions of some district courts that the lack of a comprehensive administrative record is sufficient cause to narrow the scope of the courts of appeals' jurisdiction under 21 U.S.C. § 877, and therefore confer jurisdiction on the district courts, noting that "this court [of appeals] regularly reviews agency action with a limited or even non-existent administrative record under direct-review statutes analogous to 21 U.S.C. § 877." *Id.* at 570 (citations omitted) (rejecting the conclusions in *Oregon*, 192 F. Supp. 2d at 1085-86; *Novelty*, 2006 U.S. Dist. LEXIS 57170, at *26-27). And finally, the D.C. Circuit reasoned that narrowing the scope of 21 U.S.C. § 877 to grant exclusive jurisdiction with the court of appeals only after a final agency "determination, finding or conclusion," but not after a final agency "action" would encourage dissatisfied claimants to engage in forum shopping and "gun-jumping" by "going directly to the district court to develop their case instead of exhausting their administrative remedies before the agency." *John Doe*, 484 F.3d at 570.

Nothing in 21 U.S.C. § 877 or the D.C. Circuit's decision in *John Doe* strips this

Court of jurisdiction to decide Novelty's present motion for a preliminary injunction. *John Doe* makes clear that "finality is a statutory jurisdictional prerequisite [for a court of appeals to have jurisdiction over a § 824(d) appeal] rather than merely a precaution related to concreteness and institutional capacity." *Id.* at 567. In other words, the D.C. Circuit has held that it has no jurisdiction prior to issuance of a final agency decision.

Each of the district court cases that the D.C. Circuit rejected in *John Doe* are distinguishable from the present case. Each of those cases dealt with whether the district courts, rather than the courts of appeals, can ever have jurisdiction under 21 U.S.C. § 877 to hear a challenge to a final agency action; none of them presented the issue of whether the district courts have jurisdiction over a challenge to an agency action that is admittedly not final. *Compare PDK Labs, Inc.*, 134 F. Supp. 2d at 29; *Novelty*, Inc., 2006 U.S. Dist. LEXIS 57270, at *8-11; *Oregon*, 192 F. Supp. 2d at 1085. The parties concede that the suspension of Novelty's registration in the present case is neither a "final agency action" under the APA, 5 U.S.C. § 704, nor a "final determination[], finding[] or conclusion[]" under the CSA, 21 U.S.C. § 877. *See* Defs.' Mem. in Support of Mot. to Dismiss at 9. Furthermore, there is no question that Novelty's motion for a preliminary injunction is not a request for a final judgment on the merits, but rather a request for temporary relief pending a final agency determination regarding its suspension. *See*, *e.g.*, *Nat'l Org. for Women, Wash., D.C. Chapter v. Social Sec. Admin. of the Dep't of Health & Human Servs.*, 736 F.2d 727, 733 (D.C. Cir. 1984) (noting that "the appeals before us emanate, not from a final disposition of the controversy by the District Court, but from a preliminary injunction designed to preserve the status quo pending that court's decision on the merits"); *Zuber v. Allen*, F.2d 660, 676 (D.C. Cir. 1968) ("a preliminary injunction does not constitute a final judgment on the merits").

In addition, unlike *PDK Labs*, 134 F. Supp. 2d 24, and *Novelty*, 2006 U.S. Dist. LEXIS 57270, there is no allegation in the present case that DEA failed to comply with its procedural requirements when suspending Novelty's registration; after its suspension, Novelty was granted an expedited administrative hearing in accordance with 21 C.F.R. § 1309.44(c). Thus, Novelty is not seeking district court review on the basis that DEA failed to comply with its procedural requirements. Nor has Novelty claimed that the district court should have jurisdiction because there is an incomplete administrative record upon which the court of appeals would be forced to rely. To the contrary, Novelty has filed the DEA ALJ Decision recommending the continued registration of Novelty. *See* Dkt. # 29 (redacted). And, Novelty's motion for a preliminary injunction is not a disguised attempt at forum shopping or gun-jumping by going directly to the district court before exhausting its administrative remedies, but is rather a request for temporary injunctive relief from its pre-hearing suspension, which the court of appeals lacks jurisdiction to consider, until such time as DEA issues a final agency determination regarding the suspension or revocation of its registration, which the court of appeals can hear on appeal. While there is no question that DEA has the authority, pursuant to 21 U.S.C. § 824(d), to suspend Novelty's registration prior to an administrative hearing if it has reason to believe that Novelty's continued operation would pose "an imminent danger to the public health or safety," § 824(d) provides for judicial review of such a suspension at "the conclusion of such [administrative] proceedings . . . unless sooner . . . dissolved by a court of competent jurisdiction." Who can act "sooner" than a final agency determination, which is the jurisdictional prerequisite for courts of appeals, if not a district court?

The courts in *Norman Bridge Co. v. Banner*, 529 F.2d 822 (5th Cir. 1976) and *Neil*

Laboratories, Inc. v. Ashcroft, 217 F. Supp. 2d 80 (D.D.C. 2002), rightly concluded that it is indeed the district court that has jurisdiction to hear a party's requests for relief, such as the preliminary injunction sought in the present case, prior to a final agency determination. And contrary to Defendants' assertions, these cases are not inapposite to the D.C. Circuit's decision in *John Doe*, 484 F.3d 561. In *Norman Bridge*, like the present case, the plaintiff challenged DEA's immediate suspension of the plaintiff drug company's license to dispense controlled substances and requested that DEA relinquish possession of the drugs it had seized from the plaintiff's inventory. 529 F. 2d at 824. The district court issued a temporary restraining order, ordering DEA to halt enforcement of the suspension pending a hearing on a motion for a preliminary injunction (which was granted), and then pending a final agency determination. *Id.* at 825-27. On appeal, the Fifth Circuit explained:

> The appellants fail to notice that what we have in this case is a *statutory scheme specifically mandated by Congress*. Apparently in an effort to preserve constitutional safeguards with reference to the seizure of property or the deprivation of professional status without notice, Congress was careful to prescribe two requirements for the suspension of registration and the seizure of property without notice, 21 U.S.C. § 824. Such a suspension . . . may be invoked *only* to avoid imminent danger to the public health and safety. In the absence of that factor there can be no suspension and no seizure without notice and an opportunity to be heard. Moreover, when such action is taken, it survives only so long as it goes undissolved by a court of competent jurisdiction.

Id. at 828 (emphasis in original). The Fifth Circuit concluded that because "it would be a distortion of the statutory scheme to hold that the Court first had to allow the drug inventory to be dismantled and the customers to be dispersed[,] . . . we hold that the temporary restraining order . . . was validly entered." *Id.* at 829. Likewise, the district court in *Neil Laboratories*, reviewing similar facts to

those in the present case, noted that "the plain language of the CSA signifies that a registrant subject to immediate suspension of registration may seek judicial review by a district court before the suspension becomes final." 217 F. Supp. 2d at 84 n.6. This Court agrees that the language of 21 U.S.C. § 824(d) implies that it is the district court that is the "court of competent jurisdiction" to review challenges to an immediate DEA suspension imposed prior to an administrative hearing and a final agency determination. The Court also agrees with the Fifth Circuit that the CSA's statutory scheme, and § 824(d) in particular, was designed to ensure that a party is not deprived of its property interest in its registration without due process of law in violation of the Fifth Amendment. *See Norman Bridge*, 529 F.2d at 828. Accordingly, this Court has jurisdiction to consider Novelty's motion for a preliminary injunction against DEA's suspension of Novelty's registration pending a final agency determination on the matter.

B. Preliminary Injunction

Because Novelty's motion for preliminary injunction properly lies in this Court, the Court must now consider its merits.

A court must consider four factors in deciding whether to issue a preliminary injunction:

1. whether the movant has shown a substantial likelihood of success on the merits;

2. whether the movant would suffer irreparable injury if the injunction is not granted;

3. whether the issuance of a preliminary injunction would cause substantial harm to other interested parties; and

4. whether the public interest would be served by the issuance of an injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998). The foregoing factors should be balanced on a "sliding scale," i.e., a lesser showing on one factor can be surmounted by a greater showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667, 670 (D.C. Cir. 2005). Even so, in order to justify intruding into the ordinary litigation process by issuing a preliminary injunction, it is critical that a movant 1) make a substantial showing of likelihood of success on the merits, *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999), and 2) make a showing of at least some injury. *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995). An order granting an injunction shall set forth reasons for its issuance and shall be reasonably specific in its terms. Fed. R. Civ. P. 65(d). A preliminary injunction is "an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004).

The Court finds that Novelty has not met the burden necessary for this Court to issue a preliminary injunction. Significantly, Novelty has not shown a substantial likelihood of success on the merits. The underlying question on the merits is whether DEA acted arbitrarily and capriciously in suspending Novelty's registration based on a preliminary finding that its continued operation posed an "imminent danger to public health or safety." *See* 21 U.S.C. § 824(d). DEA executed an administrative search warrant of Novelty's facilities and reviewed the records that Novelty provided to it. Mot. to Dismiss, Barnhill Decl. ¶¶ 33-38. DEA's suspension was based largely on its evaluation of those records and DEA interviews of Novelty employees. Defs.' Resp. to Mot. for Prelim. Inj. at 23 [Dkt. # 21]. Based on the information gleaned primarily from those

two sources – Novelty's records and employee interviews – DEA found that Novelty had committed six independent violations of federal law relating to distribution of the list 1 chemicals ephedrine and pseudophedrine. *See* Mot. to Dismiss, Barnhill Decl. ¶ 40; Defs.' Resp. to Mot. for Prelim. Inj. at 6-8. Notable among them were that Novelty's procedures for safeguarding list 1 chemicals did not comply with applicable law, and that an audit of Novelty's inventory revealed that 1) Novelty sold more ephedrine products than it should have had in its inventory and 2) Novelty's suppliers' purchase summaries did not match Novelty's purchase records. *See* Mot. to Dismiss, Barnhill Decl. ¶ 40; *see also* DEA ALJ Decision at 87. For the present purposes, DEA's most significant conclusion relating to these alleged violations was that Novelty failed to maintain effective controls against diversion of ephedrine for the illegal manufacture of methamphetamine. *See* DEA ALJ Decision at 65; Defs.' Mem. in Support of Mot. to Dismiss at 6. As explained above, this conclusion was informed by a diligent search of Novelty's records and interviews of its employees, as well as a subsequent analysis of those records. *See* Mot. to Dismiss, Barnhill Decl. ¶¶ 33-38; Defs.' Resp. to Mot. for Prelim. Inj. at 23.

Novelty contends, however, that DEA made certain erroneous conclusions of fact which flawed its determination that immediate suspension was necessary. While Novelty may ultimately prove to be correct, the Court cannot agree that DEA made a "'*clear* error of judgment.'" *See Me. Pub. Utils. Comm'n v. FERC*, 454 F.3d 278, 286 (D.C. Cir. 2006) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415-16 (1971)) (emphasis added). DEA made its determination to suspend Novelty's registration based on the facts revealed by the agents' investigation which were arguably supported by the records provided to them. While its initial findings of fact may turn out to be incorrect in certain respects after completion of a thorough

investigation and review of the evidence presented at the administrative hearing, DEA's analysis and conclusions were reasoned, not arbitrary and capricious. Under the "'highly deferential'" standard required to be accorded to agency decisions under the APA, *see id.* (citing *Sithe/Independence Power Partners v. FERC*, 165 F.3d 944, 948 (D.C. Cir. 1999)), it is unlikely that Novelty will succeed on the merits of its claim that DEA acted arbitrarily and capriciously in exercising its discretion to suspend Novelty's registration.

Novelty's argument that it is suffering great harm is compelling. While it is, as Defendants argue, speculative whether Novelty will go out of business if the suspension is not lifted, the Court accepts Novelty's assertion as to the specific injuries that Novelty has suffered and will suffer in the future absent a Court order enjoining the suspension.[3] *See* Pl.'s Mot. for Prelim. Inj. at 18-21.

However, Novelty distributes a list 1 chemical, ephedrine, which is an active ingredient in methamphetamine, a dangerous illegal drug that is a scourge on our society. Congress recognized the danger that methamphetamine poses, and in response, crafted a statutory scheme that comports with Due Process requirements and that balances the property interests of distributors with the need to protect the public from the illicit production and distribution of methamphetamine, as well as the danger that such distribution poses to the public. Through its review of Novelty's records and interviews of Novelty's employees, DEA agents concluded that Novelty's continued registration,

[3] It is worth noting that DEA expects to issue a final decision by August 2008, *see* Mot. to Dismiss, Barber Decl. ¶ 6, approximately two months from the present date. In light of the fact that DEA served the Suspension Order on January 28, 2008, Defs.' Resp. to Mot. for Prelim. Inj. at 16, and Novelty did not file its Complaint in this Court until April 9, 2008, it seems unlikely that the harm, while no doubt increasing with time, will reach a level beyond repair as a result of an additional two months of suspension if Novelty had not reached such dire straits before the instant Complaint was filed.

and therefore its continued right to distribute ephedrine, posed an imminent threat to the public health and safety because it failed to maintain effective controls against diversion of ephedrine for the illegal manufacture of methamphetamine. *See* DEA ALJ Decision at 65; Defs.' Mem. in Support of Mot. to Dismiss at 6. If errors were made during the agents' review of the records or the audit of Novelty's accounts, as is suggested by the DEA ALJ Decision, *see* DEA ALJ Decision at 82-99, DEA's initial analysis and conclusions should be reviewed, and if necessary, corrected, by the agency in its final determination. If Novelty is dissatisfied with the agency's final determination, it is free to appeal that determination to the court of appeals pursuant to 21 U.S.C. § 877. This Court will not disturb DEA's initial findings at this juncture in the proceedings.

IV. CONCLUSION

For the reasons set forth above, this Court, not the court of appeals, has jurisdiction to consider Novelty's motion for a preliminary injunction enjoining DEA from suspending Novelty's license pending a final agency determination. Novelty's motion for summary judgment on the issue of jurisdiction will therefore be granted in part and denied in part. The Court finds, however, that DEA did not act arbitrarily and capriciously in suspending Novelty's registration for posing an imminent danger to the public health or safety. Novelty therefore does not have an equitable right to preliminary injunctive relief. A memorializing order accompanies this memorandum opinion.

Date: June 17, 2008

/s/
ROSEMARY M. COLLYER
United States District Judge