

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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|------------------------------|---|---------------------------------|
| NEIL LABORATORIES, INC., | : | |
| | : | |
| Plaintiff, | : | |
| | : | Civil Action No.: 02-0428 (RMU) |
| v. | : | |
| | : | Document Nos.: 13, 15, 16 |
| JOHN ASHCROFT, U.S. Attorney | : | |
| General <i>et al.</i> , | : | |
| | : | |
| Defendants. | : | |

MEMORANDUM OPINION

**GRANTING THE DEFENDANTS’ CROSS-MOTION FOR SUMMARY JUDGMENT;
DENYING THE PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT¹**

I. INTRODUCTION

This agency-review matter is before the court on the plaintiff’s and defendants’ cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56(c). Neil Laboratories (“Neil Labs” or “the plaintiff”), brought this suit alleging that John Ashcroft, acting in his official capacity as the U.S. Attorney General; the Department of Justice; Asa Hutchinson, acting in her official capacity as Administrator of the Drug Enforcement Agency; and the Drug Enforcement Agency (collectively, “the DEA” or “the defendants”) wrongfully suspended Neil Labs’ registration to sell List I chemicals under the Controlled Substances Act (“CSA”), 21 U.S.C. § 801 *et seq.* The plaintiff, in its motion for summary judgment, argues that the DEA’s action violated the Administrative Procedure Act (“APA”), 5 U.S.C § 701 *et. seq.*, the CSA, and the Fifth Amendment. For the reasons that follow, the court affirms the DEA’s decision, grants

¹ The court treats the plaintiff’s motion as one for summary judgment because the plaintiff requests full relief by way of the motion and submits with the motion a statement of material facts not in dispute, pursuant to Local Civil Rule 56.1.

the defendants' cross-motion for summary judgment, and denies the plaintiff's motion for summary judgment.

II. BACKGROUND

Neil Labs was a registered manufacturer and distributor of List I chemicals, including ephedrine and pseudoephedrine. Defs.' Material Facts ¶ 7. Between February 1999 and April 2001, the DEA issued 29 warning letters to Neil Labs identifying various instances in which pseudoephedrine tablets sold by Neil Labs had been diverted to illicit methamphetamine production.² *Id.* ¶ 14. During this period the DEA also reviewed Neil Labs' customer list and discovered that the DEA had taken enforcement action against 18 out of the 45 distributors that Neil Labs served across the nation.³ *Id.* ¶ 18 (citing Suspension Order ¶¶ 8-12). Consequently, Neil Labs became a subject of the DEA's nationwide "Operation Mountain Express III," an investigation into the diversion of chemicals for the manufacture of methamphetamine. *Id.* ¶¶ 29, 32.

The DEA's investigation focused on Mantu Patel, a Neil Labs employee and the brother of Neil Labs' President and Chief Executive Officer, Bharat Patel. *Id.* ¶¶ 21, 32-41. In 2000, Neil Labs identified Mantu Patel as one of seven "key personnel." *Id.* ¶ 22.

² Neil Labs offers no evidence showing that it investigated the customers implicated by these letters. Rather, Neil Labs asserts that even if it "were to receive a warning letter with a specific lot number [to indicate which wholesale distributor issued the product], the company has no way of knowing which of the distributor's customers diverted the product or if, in fact, a consumer diverted the product." Pl.'s Opp'n at 20. Neil Labs' attempt to justify its complete disregard of the DEA's warning letters and its assumption of the risk of selling to illegal manufacturers of controlled substances is not compelling.

³ The DEA alleges that they have taken enforcement actions against many of the 45 distributors because of the distributors' regulatory failures, identification of their product at clandestine laboratory sites, and association with known diverters of listed chemical products. Defs.' Material Facts ¶ 18. Neil Labs states that it is not able to verify this information. Pl.'s Resp. to Defs.' Material Facts ("Pl.'s Resp.") ¶ 18.

He was one of the four original incorporators of Neil Labs in 1990, was the company's fourth largest shareholder, and served as Neil Labs' Plant Manager. *Id.* ¶¶ 23-25. Mantu Patel was also the second highest paid employee after Bharat Patel's wife. *Id.* ¶ 26.

In January 2001, the DEA developed a confidential source ("CS") who provided important intelligence regarding Neil Labs' distribution practices. *Id.* ¶ 32. Also, after negotiated with the CS, Mantu Patel shipped listed chemicals to the CS by secreting the listed chemical in two shipments of non-controlled substances.⁴ *Id.* ¶ 37. Neil Labs does not dispute that Mantu Patel twice shipped listed chemicals to the CS in this manner.

Pl.'s Resp. ¶ 37. In July 2001, the DEA intercepted a shipment from Neil Labs, in which a bag containing about four kilograms of a listed chemical was labeled as a non-listed chemical and secreted within the non-listed chemicals. Suspension Order ¶ 19; Defs.' Material Facts ¶ 37.

Between May and November 2001, the DEA received four requests to import shipments of listed products from several foreign companies on behalf of Neil Labs. Defs.' Material Facts ¶¶ 54-57. The DEA alleges that it approved these requests and delayed issuing a suspension order against Neil Labs in an attempt to advance its criminal investigation by further monitoring Neil Labs' distribution practices. *Id.* ¶ 58.

In early September 2001, the CS informed Bharat Patel that he planned to sell List I products to Mexican drug dealers, though the exact nature of this conversation is a bit unclear. *Id.* ¶ 38. Two weeks after this conversation, the DEA renewed Neil Labs'

⁴ In their submissions, both the plaintiff and the defendants specify that the hidden listed chemical was pseudoephedrine. Defs.' Material Facts ¶ 37; Pl.'s Resp. ¶ 37. The Suspension Order, however, specifies that the hidden listed chemical was ephedrine. Suspension Order ¶¶ 19-20. Both are list one chemicals because both are used in the illicit manufacture of methamphetamine. 21 U.S.C. § 802(34)(C), (K).

registration to manufacture and distribute List I chemicals, including ephedrine and pseudoephedrine. *Id.* ¶ 43; Compl. ¶ 22. On January 7, 2002, the CS held a final conversation with Bharat Patel to discuss the sale of pseudoephedrine. Defs.’ Material Facts ¶ 39. During this conversation, Bharat Patel informed the CS that Mantu Patel would not be involved in the negotiations.⁵ *Id.* The DEA’s investigation culminated on January 16, 2002 when the DEA issued an Order to Show Cause and Immediate Suspension of Registration (“Suspension Order”). *Id.* ¶ 59. The Suspension Order suspended Neil Labs’ DEA registration to manufacture and distribute products containing ephedrine and pseudoephedrine, explaining that “Neil Labs’ continued registration . . . would constitute an imminent danger to public health and safety because of the substantial likelihood that Neil Labs will continue distributing ephedrine and pseudoephedrine ultimately to purchasers who use these products in the illicit manufacture of methamphetamine.” Suspension Order at 6.

Neil Labs filed its complaint in this case on March 6, 2002 and on the following day filed a motion for a preliminary injunction. Subsequently, however, the parties agreed to consolidate the merits with the preliminary injunction issue. Order dated Mar. 22, 2002; Defs.’ Mot. for Summ. J. at n.1. Neil Labs now moves for summary judgment, asking the court to determine that in issuing the Suspension Order, the DEA violated the APA and the CSA. Pl.’s Opp’n at 10. The DEA filed a cross-motion for summary judgment, asking the court to rule that the Suspension Order is proper. Defs.’ Mot. for

⁵ The defendants allege that during this conversation, Bharat Patel displayed his interest in continuing to sell List I chemicals to the CS. Defs.’ Material Facts ¶ 39. Neil Labs does not deny or confirm this assertion. Pl.’s Resp. ¶ 39.

Summ. J. at 1.

III. ANALYSIS

Preliminarily, the court must determine whether the Suspension Order meets the basic requirements set forth in the CSA. The CSA requires

the Attorney General . . . [to] serve upon the . . . registrant an order to show cause why registration should not be denied, revoked or suspended The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order

21 U.S.C. § 824(c). The court holds that the suspension order meets these technical requirements. Next the court addresses the merits of the parties' arguments and determines that the DEA, in issuing the Suspension Order, violate neither the APA nor the CSA. Finally, as no material facts are in dispute, the court grants the defendants' cross-motion for summary judgment.

A. Legal Standard for Motions for Summary Judgment

Summary judgment is appropriate 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); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are “material,” a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A “genuine issue” is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

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. To prevail on a motion for summary judgment, the moving party must show that the nonmoving party "fail[ed] 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*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the nonmoving party, a moving party may succeed on summary judgment. *Id.*

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); *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir. 1993). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Greene*, 164 F.3d 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 (internal citations omitted).

B. Legal Standard for Review of the DEA's Suspension Order Pursuant to the APA

The APA allows "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . [to be] entitled to judicial review

thereof.” 5 U.S.C. § 702.⁶ The scope of judicial review under the APA is fairly limited. The agency action in review is “entitled to a presumption of regularity.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). The reviewing court may set aside agency actions, findings, and conclusions when they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). To determine whether agency action is arbitrary or capricious, the court must consider whether:

the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Veh. Mfgs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). In making this determination, the reviewing court may not “substitute its judgment for that of the agency.” *Id.* Rather, the court must determine whether the agency considered relevant data and articulated an explanation establishing a “rational connection between the facts found and the choice made.” *Burlington Trucklines v. United States*, 371 U.S. 156, 168 (1962).

⁶ Generally, the disputed agency action must be “final agency action.” 5 U.S.C. § 704. This requirement, however, may be avoided when “review is sought . . . pursuant to specific authorization in the substantive statute” *Id.* This court agrees with the Fifth Circuit’s determination 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 order becomes final. 21 U.S.C. § 824(d) (providing that a court of competent jurisdiction may dissolve a suspension order); *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823-24 (5th Cir. 1976). Thus, the court has the authority to review the agency action although it is not final agency action.

C. The Controlled Substances Act

The CSA purports to “control the flow of controlled substances through registration of and record keeping by all those within the ‘legitimate distributional chain’” *In re Burka*, 684 F. Supp. 1300, 1302 (E.D. Pa. 1998). In an attempt to curtail the diversion of chemicals used for the illicit manufacture of controlled substances, the CSA allows the DEA to regulate the distribution and sale of these chemicals. 21 U.S.C. § 872(f); 21 U.S.C. § 802(34).

The CSA classifies the chemicals at issue, ephedrine and pseudoephedrine, as List I chemicals. 21 U.S.C. § 802(34)(C), (K). While a List I chemical has some legitimate uses, the statute defines it as a chemical “used in manufacturing a controlled substance . . . [and] important to the manufacture of the controlled substances” 21 U.S.C. § 802(34). Once the DEA issues a registration allowing an applicant to distribute List I chemicals, the Attorney General is authorized to revoke the registration. 21 U.S.C. § 824. Specifically, the CSA allows “[t]he Attorney General . . . , *in his discretion*, [to] suspend any registration . . . in cases where he finds that there is an imminent danger to the public health or safety.” 21 U.S.C. § 824(d) (emphasis added).

D. Summary Judgment is Appropriate Because the DEA’s Actions Did Not Violate the APA or the CSA

Neil Labs asks the court to vacate the DEA’s suspension order, arguing that the DEA suspended its registration in violation of the APA and the CSA.⁷ Compl. ¶¶ 30-43. Opposing the plaintiff’s motion, the DEA requests summary judgment in its favor, arguing that the suspension order did not violate the APA or the CSA. Because no

⁷ The plaintiff also claims that because the suspension order was not lawful, the DEA’s seizure of Neil Labs’ property violated the Fifth Amendment. Compl. ¶¶ 44-48. Because the court deems the order lawful, the court does not reach this claim.

material facts are in dispute, the court grants the defendants' cross-motion for summary judgment and denied the plaintiff's motion. FED. R. CIV. P. 56(c). First, the court determines that the DEA has shown a rational basis for its finding of imminent danger. Second, the court disagrees with the plaintiff's arguments in defense of the DEA's allegations and attributes the actions of Mantu Patel to the plaintiff.

1. Neil Labs' Diversion Activities Created Imminent Danger

The plaintiff argues that the DEA Suspension Order violates the APA and the CSA because Neil Labs' continued registration did not present an imminent danger to public health and safety. Pl.'s Opp'n at 10-14. To support this argument, Neil Labs analogizes its situation to that in a case in which a court enjoined the DEA from enforcing a suspension order. *Norman Bridge*, 529 F.2d at 824-26. The court determines, however, that the DEA reasonably concluded that, due to Neil Labs' violations of the CSA, Neil Labs' continued operation could cause imminent danger to the public. 21 U.S.C. § 824(d).

The Suspension Order issued to Neil Labs cites several key incidents uncovered by the DEA's investigation. Suspension Order. After negotiating with the CS, Mantu Patel, an employee of Neil Labs, shipped listed chemicals from Neil Labs to the CS by secreting the listed chemical in two shipments of non-controlled substances. Defs.' Material Facts ¶ 37. Neil Labs does not dispute that Mantu Patel twice shipped listed chemicals to the CS in this manner. Pl.'s Resp. ¶ 37. In July 2001, the DEA intercepted a shipment from Neil Labs, in which a bag containing about four kilograms of a listed chemical was labeled as a non-listed chemical and secreted within the non-listed chemicals. Suspension Order ¶ 19; Defs.' Material Facts ¶ 37.

In addition, Between May 2001 and November 2001, the DEA received several requests from foreign drug companies who requested permission to import pseudoephedrine and ephedrine on behalf of Neil Labs. Defs.’ Material Facts ¶¶ 54-57. The DEA approved the import requests and delayed issuing the Suspension Order at that time so it could continue its investigation. *Id.* ¶ 58.

The plaintiff argues that, as in *Norman Bridge*, the six-month delay in the DEA’s issuance of the suspension order precludes a determination of imminent danger. Pl.’s Opp’n at 10-14. In *Norman Bridge*, the DEA issued a suspension order for a pharmaceutical company based on the company president’s guilty plea to an indictment for dispensing the controlled substance Didrex to an individual and the company’s record-keeping violations. *Norman Bridge*, 529 F.2d at 823. The president’s guilty plea and the record-keeping violations apparently occurred six and seven months, respectively, before the DEA issued its order. *Id.* at 824-26, 829. The district court enjoined the DEA’s actions, explaining that the seven-month delay demonstrated that in fact the company did not pose an imminent danger to the public because “[g]enuine apprehension of imminent danger to public health and safety could reasonably have been expected to cause prompt notice and an equally prompt hearing.” *Id.* at 826, 829.

The plaintiff fails to appreciate that *Norman Bridge* is distinguishable from the case at bar. Unlike the situation in *Norman Bridge*, the DEA suspected Neil Labs of being an active participant in the chain of production for methamphetamine. Defs.’ Material Facts ¶¶ 29-38. Moreover, Neil Labs received approximately 30 warning letters from the DEA, between February 4, 1999 and March 11, 2002, that identified various instances in which Neil Labs’ product had been diverted to illicit uses. *Id.* ¶ 14. The DEA also had taken action against many of Neil Labs’ customers as a result of either

regulatory failures or identification of Neil Labs' product in clandestine laboratory sites. *Id.* ¶ 18 (citing Suspension Order ¶¶ 8-12). Most significantly, in contrast to the DEA's *unexplained* seven-month delay in issuing the suspension order to Norman Bridge, the DEA's six-month delay in issuing the suspension order to Neil Labs is justified by its ongoing criminal investigation. *Id.* ¶ 43.

If the DEA had delayed its suspension order for Neil Labs without explanation, this case would be similar to *Norman Bridge*. *Norman Bridge*, 529 F.2d at 829. Yet, in the case at bar, the DEA presents a reasonable explanation for the six-month delay: the need to conduct a criminal investigation. Defs.' Material Facts ¶ 43. Also, the CSA explicitly provides the Attorney General with *discretion* in deciding whether to issue a suspension order. 21 U.S.C. § 824(d). Accordingly, because the DEA provided a rational connection between the facts and the conclusion that Neil Labs' continued registration would constitute imminent danger to the public, the court must show deference to the agency. *Burlington Trucklines*, 371 U.S. at 168. The court concludes that the DEA did not abuse its discretion and therefore affirms the agency's finding of imminent danger. *Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 415.

2. The Actions of Mantu Patel Can Be Attributed to Neil Laboratories

In response to the DEA's allegations, the plaintiff also argues that it is not responsible for the actions of Mantu Patel because he is not a "key employee." Pl.'s Opp'n at 6-7. Because Neil Labs' most egregious CSA violations are attributable to Mantu Patel's actions, whether the DEA can consider his actions in evaluating Neil Labs' fitness for registration is significant.

In addressing whether employer liability exists for employee violations of the CSA, the DEA has held the "conduct of owners, agents, and/or key employees

constitute[s] a basis for revoking the registrations of corporate registrants upon a finding that the continued registration would be inconsistent with the public interest.” *Daniel Family Pharmacy*, DEA Dkt. No. 96-38, 64 Fed. Reg. 5314, 5317 (1999); *see also Alfred Khalily, Inc, d.b.a. Alfa Chemical*, DEA Dkt. No. 98-11, 64 Fed. Reg. 31289, 31292 (1999). The DEA explained that the conduct of employees, stockholders, and owners are relevant in determining the fitness of an applicant for registration because a store operates under their control. *Alfred Khalily*, 64 Fed. Reg. at 31292. Similarly, because Neil Labs operates under the control of its agents, the court must determine whether the actions of Neil Labs’ agent, Mantu Patel, serve as a basis for revoking the company’s registration.

The basic facts surrounding Mantu Patel’s employment are undisputed. In September 2000, Neil Labs identified Mantu Patel as one of seven “key personnel.” Defs.’ Material Facts ¶ 22. He also was one of the original 1990 incorporators of Neil Labs, served as a department head, was the second-highest paid employee in the company, and was the fourth-largest shareholder. *Id.* ¶¶ 22-26. Based on these undisputed facts, the court concludes that Mantu Patel was a key employee and, therefore, the DEA appropriately considered his conduct in evaluating Neil Labs’ fitness for DEA registration.

In sum, the court concludes that the DEA did not violate the CSA or the APA, and thus the DEA is entitled to a favorable judgment as a matter of law. *Celotex*, 477 U.S. at 322.

IV. CONCLUSION

For all these reasons, the court denies the plaintiff’s motion for summary judgment and grants the defendants’ motion for summary judgment. An order directing

the parties in a manner consistent with this Memorandum Opinion is separately and contemporaneously issued this _____ day of August 2002.

Ricardo M. Urbina
United States District Judge

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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| General <i>et al.</i> , | : | |
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| Defendants. | : | |

ORDER

**GRANTING THE DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT;
DENYING THE PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

For the reasons stated in this court's Memorandum Opinion separately and contemporaneously issued this ____ day of August 2002, it is

ORDERED that the defendants' cross-motion for summary judgment is **GRANTED**; and it is

FURTHER ORDERED that the plaintiff's motion for summary judgment is **DENIED**; and it is

ORDERED that the plaintiff's motion to file a surreply is **GRANTED**.

SO ORDERED.

Ricardo M. Urbina
United States District Judge

**Service List in *Neil Laboratories, Inc. v. John Ashcroft*
Civil Action No. 02-0428 (RMU)**

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