UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE, INC., Plaintiff, v. ALBERTO R. GONZALEZ, Attorney General of the United States, *et al.*, Defendants.	Civil Action No. 06-966 (CKK)

MEMORANDUM OPINION
(June 29, 2006)

Plaintiff John Doe, Inc., a manufacturer of generic pharmaceutical products, brings this action for preliminary and permanent mandatory injunctive relief based on a contention that the decision of Defendants Alberto R. Gonzales,[1] the Attorney General of the United States; the United States Department of Justice ("DOJ"); Karen P. Tandy, the Administrator of the United States Drug

[1] Plaintiff, in both the caption for their Complaint and in the Complaint itself, refers to the Attorney General under the incorrect spelling "Alberto R. Gonzalez." *See* Compl. at 1 & ¶ 2. A variety of jurisdictions have issued conflicting decisions regarding whether a court may *sua sponte* correct a party's name in a caption. *Compare Mitchell v. Newryder*, 245 F. Supp. 2d 200, 201 n.1 (D.Me. 2003) ("Neither side has moved to correct the caption and this court does not, as a rule, *sua sponte* correct misspellings of party names."); *Bellows v. Amoco Oil Co.*, 118 F.3d 268, 270 n.1 (5th Cir. 1997) (keeping original misspelling when never corrected by the parties) *with Fearing v. St. Paul Police Dep't*, No. 02-4744 (ADM/JSM), 2005 WL 014733, at *1 n.1 (D.Minn. Apr. 20, 2005) (*sua sponte* correcting misspelled name in caption); *Swarn v. Pizza King*, No. IP 01-1150-C-T/K, 2001 WL 1712507, at *1 n.2 (S.D.Ind. Dec. 6, 2001) (*sua sponte* correcting misspelled caption). This Court, finding no explicit rule that would allow it to *sua sponte* substitute the correct spelling, shall maintain the incorrect spelling in the caption until the parties seek to amend the pleadings. *Cf.* C. Wright, *The Law of Federal Courts* § 54, pp. 347-48, n. 5 (4th ed. 1983) (noting that the Supreme Court, and the official Reports, have continuously misspelled cases such as *Minersville Sch. Dist. v. Gobitis*, 310 U.S. 586, 60 S.Ct. 1010, 84 L.Ed. 1375 (1940) (parties' name was "Gobitas"); *Dred Scott v. Sandford*, 19 How. 393, 60 U.S. 393, 15 L.Ed. 691 (1857) (party's name was "Sanford"); *Swift v. Tyson*, 16 Pet. 1, 41 U.S. 1, 10 L.Ed 865 (1842) (party's name was "Tysen"); and *McCulloch v. Maryland*, 4 Wheat. 316, 17 U.S. 316, 4 L.Ed. 579 (1819) (party's name was "McCulloh")).

Enforcement Administration ("DEA"); and the DEA itself (collectively, "Defendants") to deny Plaintiff its April 18, 2006 application to import Dronabinol in sesame oil, encapsulated in a soft gelatin capsule, was (1) in excess of the DEA's statutory authority, *see* Compl. ¶¶ 50-52 (Count I – Agency Action in Excess of Statutory Authority); (2) contrary to law, arbitrary and capricious, and in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, *see* Compl. ¶¶ 53-55 (Count II – APA Claim); and (3) a deprivation of a liberty and property interest without due process, in violation of the 5th Amendment, *see id.* ¶¶ 56-59 (Count III – Agency Action in Violation of 5th Amendment). In response, Defendants assert that Plaintiff's allegations are without merit, as the "product" that Plaintiff is seeking to import is properly categorized as a Schedule I controlled substance, not a Schedule III substance as claimed by Plaintiffs.

Currently before the Court are Plaintiff's Motion for Preliminary Mandatory Injunctive Relief, Defendants' Opposition, Plaintiff's Reply, Defendants' Surreply, and Plaintiff's Surrebuttal. Upon a searching examination of the parties' filings, the attached exhibits, the relevant case law, and the Administrative Record herein, the Court concludes that it lacks subject-matter jurisdiction over this dispute. As such, the Court shall dismiss without prejudice Plaintiff's Complaint and Motion for Mandatory Injunctive Relief.

I: BACKGROUND

A. The Regulatory Framework for Controlled Substances

1. The CSA and the DEA's Five Schedules of Controlled Substances

The DEA regulates controlled substances through the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. § 801 *et seq.*, as well as DEA regulations promulgated thereunder. In recognition of the fact that certain controlled substances have "useful and medical purpose[s]," *see id.* § 801(1), Congress has authorized the Attorney General to regulate their distribution within a

closed system. The Attorney General has delegated his regulatory authority under the Act to the Administrator of the DEA. *See* 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b). As part of its statutory responsibilities under the CSA, the DEA is authorized to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. The CSA also provides authority for the Administrator of the DEA to "promulgate and enforce any rules, regulations, and procedures which [s]he may deem necessary and appropriate for the efficient execution of his functions under [the Act]." *Id.* § 871(b). Pursuant to this authority, the DEA has issued extensive regulations implementing the CSA, which are found in 21 C.F.R. §§ 1300-1316.

The DEA's rules and regulations itemize all controlled substances on a list of five "schedules." *See* 21 U.S.C. § 812; 21 C.F.R. § 1308 (listing Schedules I–V). Schedule I controlled substances have the most stringent regulations and requirements because they have "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for use . . . under medical supervision," and "a high potential for abuse." 21 U.S.C. § 812(b)(1). Among other things, Schedule I controlled substances may not be prescribed and dispensed for medical use, and human consumption of such Schedule I substances is limited to "the confines of a Government-approved research project." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 491, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001). In contrast, controlled substances falling within Schedules II through V have accepted medical uses and decreasing potential for both abuse and physical/psychological dependence. *See* 21 U.S.C. § 812(b)(2)-(5). For example, to be classified on Schedule III, a substance must have a lower potential for abuse than the substances in Schedule I and II; to be a Schedule III controlled substance, the drug must have a currently accepted medical use in treatment in the United States and abuse of the drug may lead to moderate or low physical

dependence or high psychological dependence. *See id.* § 812(b)(3).

2. The Importation of Controlled Substances

The importation of controlled substances into the United States is governed by statute, which explicitly recognizes importation for medical and scientific uses and grants the Attorney General the authority to issue permits for such importation. *See, e.g.*, *id.* §§ 952, 958. As such, the CSA requires any person or company that manufactures, distributes, or imports a controlled substance to obtain – on an annual basis – a registration from the Attorney General. *See id.* §§ 822(a)(1), 958. Moreover, persons and companies registered with the DEA to handle controlled substances are only authorized to engage in such activities "to the extent authorized by their registration and in conformity with other provisions of [the CSA]." *Id.* § 822(b); *see also id.* § 958(b) ("Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration."). Indeed, it is a felony violation of the CSA to import any controlled substance except as authorized by the Act. *See id.* § 960; *see also* Decl. of Demetra Ashley, Deputy Section Chief of the DEA's Drug and Chemical Evaluation Section, DEA Headquarters (hereinafter, "Ashley Decl."), attached as Ex. A to Defs.' Opp'n, at ¶ 9 (the registration "specifies not only the Schedule, but the particular controlled substance(s), each [registrant] is authorized to possess").

a. Schedule I Controlled Substances

In deciding whether to grant an application to import a Schedule I controlled substance, the DEA must apply the criteria set forth in 21 U.S.C. § 823(a).[2] *See id.* § 958(a) ("The Attorney

[2] For reasons that shall soon become evident, the Court is only focusing on the difference between Schedule I and Schedule III controlled substances. As discussed below, the thrust of this suit is based around Plaintiff's contention that the drug/product at issue should be treated like a Schedule III controlled substance, not a Schedule I controlled substance. As such, the only relevant

General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(a) of this title shall be considered."). In determining the public interest pursuant to a request to import a Schedule I controlled substance, the DEA weighs the following factors:

> 1. maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
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> 2. compliance with applicable State and local law;
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> 3. promotion of technical advances in the art of manufacturing these substances and the development of new substances;
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> 4. prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
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> 5. past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> 6. such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a)(1)-(6). Moreover, under the applicable regulations for registration as a handler of a Schedule I controlled substance, the DEA must publish the applicant's petition in the *Federal Register* and provide notice of the application to each registered manufacturer of that controlled substance and any other applicants for registration for the same substance. *See* 21 C.F.R. §

Schedules for this dispute are Schedules I and III.

1301.34(a).

In addition to the registration requirement, a separate provision of the CSA sets forth additional prerequisites for the importation of a Schedule I controlled substance. Pursuant to 21 U.S.C. § 952(a), a particularized determination must be made with respect to the specific shipment proposed to be imported. Section 952(a) generally prohibits the importation of Schedule I controlled substances, except under certain circumstances. *See id.* § 952(a)(1)-(3). Where the applicant seeks to import a Schedule I controlled substance for research, the applicant must demonstrate – and the DEA must determine – that such importation is "necessary to provide for the medical, scientific, or other legitimate needs of the United States," and the amount of the proposed importation "is in limited quantities exclusively for scientific, analytical, or research uses." *Id.* § 952(a)(2)(C).

Section 952(a) also provides that the proposed import comply with the import regulations promulgated by the DEA. Those regulations provide that no person shall import any Schedule I or II controlled substance, or any controlled substance that the Administrator has specifically designated, "unless and until such person is properly registered under the Act . . . and the Administrator has issued him a permit to do so pursuant to § 1312.13." 21 C.F.R. § 1312.11. A separate import permit is required for each "consignment of controlled substances to be imported." 21 C.F.R. § 3211.11(c).

b. Schedule III Controlled Substances

In contrast to Schedule I controlled substances, in deciding whether to grant an application to import a Schedule III controlled substance, the DEA must apply the criteria set forth in 21 U.S.C. § 823(d). *See id.* § 958(c)(1) ("The Attorney General shall register an applicant to import or export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration

is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(d) of this title shall be considered."). In determining the public interest pursuant to a request to import a Schedule III controlled substance, the DEA weighs the following factors:

> 1. maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
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> 2. compliance with applicable State and local law;
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> 3. promotion of technical advances in the art of manufacturing these substances and the development of new substances;
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> 4. prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
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> 5. past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
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> 6. such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(d)(1)-(6).

In addition to the registration requirement, a separate provision of the CSA sets forth additional prerequisites for the importation of a Schedule III controlled substance. Pursuant to 21 U.S.C. § 952(b), a particularized determination must be made with respect to the specific shipment proposed to be imported. Section 952(b) provides:

> [i]t shall be unlawful to import . . . into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, unless such nonnarcotic controlled substance (1) is imported for medical, scientific, or other legitimate uses and (2) is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe . . . .

Id. § 952(b).

Similar to the requirements to import a Schedule I controlled substance, Section 952(b) also provides that the proposed import comply with the import regulations promulgated by the DEA. Those regulations provide that no person shall import "any narcotic controlled substance listed in Schedule III or any non-narcotic controlled substance in Schedule III which the Administrator has specifically designated by regulation in § 1312.30 of this part . . unless and until such person is properly registered under the Act . . . and the Administrator has issued him a permit to do so pursuant to § 1312.13." 21 C.F.R. § 1312.11. A separate import permit is required for each "consignment of controlled substances to be imported." *Id.* § 3211.11(c).

3. The Import Application Process

As noted, registrants seeking to import controlled substances must first obtain a permit from the Administrator of the DEA. *See id.* § 1312.11. Applications for import permits must be submitted on DEA Form 357. *Id.* § 1312.12. The application must contain, *inter alia*, (1) the date of execution; (2) the registration number of the importer; (3) and a detailed description of each controlled substance to be imported, including the drug name, dosage form, National Drug Code ("NDC") number, the Administration Controlled Substance Code Number, and quantity and size of the packages or containers. *Id.* The "Administration Controlled Substances Code Number" is "a unique four-digit number" assigned to a controlled substance "which appears on Certificates of Registration." Defs.' Opp'n, Ex. A (Ashley Decl.) ¶ 10; *see also* 21 C.F.R. § 1308.03(a). "Applicants for import and export permits must include the appropriate code number on the application." *Id.*

The Administrator "may" issue an import permit authorizing the "importation of any controlled substance listed in Schedule I . . . or any narcotic drug listed in Schedule III[,]" 21 C.F.R. § 1312.13(a), or the importation of "such non-narcotic substances in Schedule III as [s]he shall

designate by regulation in § 1312.30 of this part," *id.* § 1312.13(b), if (s)he finds:

> 1. That the substance is crude opium, poppy, straw, concentrate of poppy straw, or coca leaves, in such quantity as the Administrator finds necessary to provide for medical, scientific, or other legitimate purposes;
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> 2. That the substance is necessary to provide for medical and scientific needs or other legitimate needs of the United States during an emergency where domestic supplies of such substance or drug are found to be inadequate, or in any case in which the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by registration of additional manufacturers under section 303 of the Controlled Substances Act (21 U.S.C. 823); or
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> 3. That the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).
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> 4. That the importation of the controlled substance is for ballistics or other analytical or scientific purposes, and that the importation of that substance is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

Id. § 1312.13(a). A permit is not valid after the date specified therein. *See id.* § 1312.16(b). The Administrator, however, is authorized to cancel a permit at any time for proper cause. *Id.* § 1312.16(a).

Any applicant denied an import permit may request a hearing within thirty (30) days after the denial of its application. *Id.* § 1312.44. The Administrator "shall hold such hearing" if requested and provide notice of the date and time of the hearing to the denied applicant at least thirty (30) days before the hearing. *Id.* § 1312.46. The Administrator has the burden of demonstrating at the hearing that the applicant did not satisfy the requirements for an import permit. *Id.* § 1312.45. As soon as practicable following the hearing and certification of record, the Administrator shall issue

a final order that sets forth his findings of fact and conclusions of law. *Id.* § 1312.47.

B. Plaintiff and Its Interest in Developing a Generic Form of Marinol®

Plaintiff is a generic drug manufacturer incorporated and based in the United States. *See* Aff. of the President & CEO of John Doe, Inc. (hereinafter, "President Aff."), attached as Ex. A to Pl.'s Mot. for Prelim. Inj., at ¶ 6. In order to continue to offer lower-cost alternatives to brand-name pharmaceuticals, Plaintiff pursues partnerships or collaborative relationships with other companies, a process that has allowed Plaintiff – since its inception – to bring to market numerous lower cost generic drug products. *Id.* ¶ 11.

As with any pharmaceutical company, product development is a key component of Plaintiff's success, and Plaintiff invests substantial time, effort, and expense identifying opportunities for generic drug development and manufacture. *Id.* ¶¶ 12-13. For more than one year, Plaintiff has dedicated a substantial amount of time, effort, and financial resources to develop a generic equivalent of Marinol®, which is a product that is already approved by the FDA to treat (1) nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to other treatments; and (2) appetite loss associated with weight loss in individuals with acquired immunodeficiency syndrome ("AIDS"). *Id.* ¶¶ 17, 25-29. There are presently no generic competitors to Marinol® on the market in the United States. *Id.* ¶ 19. According to Plaintiff, its research has indicated that the company will obtain a considerable share of the generic Marinol® market (which currently has annual sales of upwards of $170 million, *id.* ¶ 21) provided that it is the first company to obtain FDA approval of its generic version of Marinol®, and provided that it will be able to sell its product at 50% of the price charged for Marinol®, thereby saving the public tens

of millions of dollars annually, *id.*[3]

The generic chemical name of Marinol® is Dronabinol, and – when used for medical purposes – the product is encapsulated in a soft gelatin capsule in sesame oil. *Id.* ¶ 15. The active pharmaceutical ingredient is a synthetic version of a naturally-occurring compound known as delta-9-tetrahydrocannabinol or delta-9-THC. *Id.* ¶ 16. Plaintiff has identified a market for generic Marinol® and, due to its resource allocation needs, Plaintiff was required to partner with a firm that could formulate the product in order to pursue its business goals. *Id.* ¶¶ 21-22.

Initially, Plaintiff approached several companies in the United States that possessed the requisite technology but was unable to reach an agreement with them to formulate the product for Plaintiff. *Id.* ¶ 23. Ultimately, Plaintiff was introduced to a foreign company ("ForeignCo"), that had the requisite experience to formulate a generic Marinol® product. *Id.* ¶ 24. Plaintiff thereafter executed a manufacturing agreement with ForeignCo in 2005. *Id.* ¶¶ 25-27.

C. Problems Encountered Between Plaintiff and the DEA Regarding Plaintiff's Plans

1. The FDA Approval Process

a. *The Abbreviated New Drug Application (ANDA)*

In order to effectuate its business strategy of eventually bringing a generic version of Marinol® to the U.S. market, Plaintiff first must obtain FDA approval of its "product." The procedure for obtaining FDA approval of generic drugs was simplified when, in 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), also known as the Hatch-Waxman Amendments. In contrast to new drugs, which are approved by the FDA following an extensive investigation into their safety and efficacy, including

[3] The cost of 60 capsules of Marinol® is $1,263.81. *See* Pl.'s Mot. for Prelim. Inj., Ex. A (President Aff.) ¶ 20.

submission of a New Drug Application ("NDA"), generic manufacturers such as Plaintiff may file an Abbreviated New Drug Application ("ANDA") that relies on the testing conducted by the original manufacturer. The generic manufacturer must only establish that the generic drug is the "bioequivalent" of the brand name drug. *See* 21 U.S.C. § 355(j)(2)(A), (j)(8); *see also Collagenex Pharm., Inc. v. Thompson*, No. Civ. A. 03-1405(RMC), 2003 WL 21697344, at *1-*2 (D.D.C. July 22, 2003) (discussing the ANDA process).

b. *The Steps Taken By Plaintiff in Anticipation of a Future ANDA Submission*

Given the requirements of Hatch-Waxman, Plaintiff's generic Marinol® must be bioequivalent to Marinol® in order to be approved. Plaintiff believes that it will be able to show that the generic Marinol® it seeks to import is bioequivalent to Marinol® and therefore substantially identical. *See* Pl.'s Mot. for Prelim. Inj., Ex. A (President Aff.) ¶ 29. As such, on March 23, 2005, Plaintiff entered into a Contract Product Development and Manufacturing Agreement with, among others, ForeignCo to design a custom process for the development of the generic equivalent of Marinol® (the "Manufacturing Agreement"). *Id.* ¶ 25. Plaintiff also began contracting with approved third parties for raw material supplies, analytical laboratory work, and packaging, with the ultimate goal of obtaining FDA approval of its ANDA. *Id.* ¶ 27.

Plaintiff and its business partners set a schedule for obtaining approval from the FDA of the ANDA for a generic equivalent of Marinol® as soon as possible in order to obtain the first ANDA approval in the market. *Id.* ¶ 29. In furtherance of these goals, ForeignCo is required to manufacture various "batches" of the product, and ship them to Plaintiff in the United States. *Id.* Plaintiff will then package the product and conduct various laboratory and clinical testing to substantiate that the generic product it is submitting for FDA approval is the "bioequivalent" of

Marinol®. *Id.* Accordingly, the importation of the batches of finished product is crucial for Plaintiff's plans; absent importation, Plaintiff will be unable to complete its research and ultimately obtain FDA approval. *Id.*

Before Plaintiff can actually submit its ultimate ANDA to the FDA, Plaintiff "must package and bottle the drug at its facilities, conduct stability tests and show bioequivalence with the reference listed drug, Marinol in biostudies. Then it must assemble information from this testing and submit an ANDA." *See generally* Decl. of Matthew Strait, Chief of the DEA's Quota and United Nations Reporting Unit (hereinafter, "Strait Decl."), attached as Ex. B to Defs.' Opp'n; *see also id.*, Ex. 1 (5/9/06 Letter from Plaintiff to Brian Bayley). In order to demonstrate bioequivalence, Plaintiff must conduct not only a pilot study but, thereafter, at least one additional clinical trial of a larger number of human subjects sufficient to demonstrate bioequivalence. *See* Compl., Ex. B ("Review and Evaluation of Protocol for *In Vivo* Pilot Bioequivalence Study of Dronabinol in Healthy Human Volunteers under Fasting Conditions"). Assuming that Plaintiff encounters no setbacks in its testing and preparation of its ANDA, it is likely that its eventual ANDA will be pending before the FDA for quite some time as, "[o]n average, it takes more than 20 months for a new generic drug to be approved by the FDA." *See* FDA White Paper: New FDA Initiative on "Improving Access to Generic Drugs" (June 12, 2003), *reprinted at* www.fda.gov/initatives/generics/whitepaper.html.

2. The Legal Status of Marinol® and THC Under the CSA

In enacting the CSA, Congress set forth the initial schedules of controlled substances in 21 U.S.C. § 812(c). *See Gettman v. Drug Enforcement Admin.*, 290 F.3d 430, 432 (D.C. Cir. 2002). Under the CSA, the DEA is responsible for modifications to the schedules and for publishing an updated list of the current schedules on an annual basis. *Id.*; *see also* 21 U.S.C. § 812(c) n.1. The

current (applicable) schedules are published in 21 C.F.R §§ 1308.11-1308.15. Alongside each listed substance is the "DEA Controlled Substances Code Number," which is used, *inter alia*, for identification purposes on applications for registration with the DEA. *See* 21 C.F.R. § 1308.11(a).

Importantly, "tetrahydrocannabinols" ("THC") – the major psychoactive component of Cannibas sativa L. (i.e., marijuana) – is listed in Schedule I. *Id.* § 1308.11(d)(3). THC is assigned the DEA Controlled Substances Code Number "7370." *Id.* However, one specific isomer of THC – Marinol® – is listed as a Schedule III controlled substance: specifically, "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product." *Id.* § 1308.13(g)(1).[4] This FDA-approved product (i.e., Marinol®) is assigned DEA Controlled Substances Code Number "7369." *Id.*

Marinol® was originally a Schedule I controlled substance; however, on May 31, 1985, the "FDA approved for marketing the product Marinol – which contains synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules – for the treatment of nausea and vomiting associated with cancer chemotherapy." 64 Fed. Reg. 35928. Following this approval, the DEA issued a final rule on May 13, 1986 that transferred "FDA-approved products of the same formulation as Marinol from schedule I to schedule II of the CSA in accordance with 21 U.S.C. 811(a)." *Id.* (also noting that "[f]or simplicity within this document, the term 'Marinol' will be used hereafter to refer to Marinol and any other products, which may be approved by FDA in the future, that have the same formulation as Marinol"). However, "[t]he transfer of Marinol to schedule II did not affect the CSA classification of pure dronabinol, which – as a tetrahydrocannabinol with no currently accepted medical use in treatment in the United States – remains a schedule I controlled substance." *Id.* The

[4] "Dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of Δ^9-(trans)-tetrahydrocannabinol [Δ^9-(trans)-THC]." *See* 64 Fed. Reg. 35928 (1999).

FDA expanded Marinol's® indications on December 22, 1992 to include the treatment of anorexia associated with weight loss in patients with AIDS. *Id.*

Following a 1995 petition and a notice-and-comment process, the DEA concluded that "Marinol® should be transferred from schedule II to schedule III" on July 2, 1999. *Id.* This change allowed, among other things, five prescription refills in six months and lessened record keeping requirements and distribution restrictions. *Id.* The DEA based this decision "on the scientific and medical evaluation and scheduling recommendations of the Assistant Secretary for Health, and . . . on the DEA's independent review," finding, pursuant to 21 U.S.C. § 811(a) and 811(b) that:

1. Based on information now available, Marinol® has potential for abuse less than drugs or other substances in schedules I and II.

2. Marinol® is a FDA-approved drug product and currently accepted medical use in treatment in the United States; and

3. Abuse of Marinol® may lead to moderate [to] low physical dependence or high psychological dependence.

Id. Following the issuance of this final rule transferring Marinol® from Schedule II to Schedule III, "import and export permits for Marinol® will be required in accordance with 21 CFR 1312.30. All importation and exportation of Marinol® shall be in compliance with part 1312 of Title 21 of the CFR." *Id.*

3. Plaintiff Attempts to Import Batches of the Finished Product from ForeignCo

a. *Plaintiff Is Registered With the DEA*

In order to effectuate its business plan to ultimately bring generic Marinol® to market in the United States, Plaintiff submitted an application to the DEA on or about June 25, 2005 pursuant to 21 C.F.R. § 1312.13 for registration for a permit to import certain controlled substances that it apparently believed were listed in Schedules III, IIIN (non-narcotic), and IV. *See* Aff. of the

Manager of Plaintiff's Controlled Substances and Security (hereinafter, "Security Manager Aff."), attached as Ex. B to Pl.'s Mot. for Prelim. Inj., at ¶ 3. Included within this application was a request that Plaintiff be registered to import "Dronabinol, Schedule 3," *see* A.R. at 94 (6/25/06 Plaintiff Application for Registration Under Controlled Substances Act of 1970) which Plaintiff identified with DEA Controlled Substances Code Number "7369," *see id.* at 93. As noted above, Controlled Substances Code Number "7369" corresponds with Marinol® – i.e., "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product." 21 C.F.R. § 1308.13(g)(1). On December 22, 2005, the DEA issued Plaintiff DEA Registration No. RL0332623 for the "Dronabinol, Schedule 3" identified on its application. *See* Pl.'s Mot. for Prelim. Inj., Ex. C (12/22/05 DEA Controlled Substance Registration Certificate Issued to Plaintiff).

b. *Plaintiff's First Import Permit Is Granted*

Following Plaintiff's registration with the DEA, Plaintiff submitted an application on February 28, 2006 with the DEA (Form 357) to import 400 "Dronabinol 2.5mg Capsules in Sesame Oil," "CSA Drug Code: 7369"; 400 "Dronabinol 5mg Capsules in Sesame Oil," "CSA Drug Code: 7369"; and 400 "Dronabinol 10mg Capsules in Sesame Oil," "CSA Drug Code: 7369." A.R. at 110 (2/28/06 First Plaintiff Import Permit Application). Plaintiff certified on the application that the substances "are imported exclusively for scientific purposes," which were described as "Internal Analytical Method Development and Validation." *Id.*

The DEA granted Plaintiff's first import permit application, issuing Permit No. 4624 to Plaintiff on March 22, 2006. *See* A.R. at 111 (3/22/06 Permit to Import). Pursuant to 21 C.F.R. § 1312.13(e), the permit stated that "the Administrator [of the DEA] was satisfied that the consignment proposed to be imported is required for legitimate purposes." *Id.* The batches were

imported and received by Plaintiff on April 24, 2006. *See* Pl.'s Mot. for Prelim. Inj., Ex. A (President Aff.) ¶ 33.

c. *Plaintiff's Second Import Permit Is Denied*

Because "[n]ot more than one shipment shall be made on a single import permit," 21 C.F.R. § 1213(e), Plaintiff filed a second application (Form 357) with the DEA on April 18, 2006. *See* Pl.'s Mot. for Prelim. Inj., Ex. B (Security Manager Aff.) ¶ 6; A.R. at 112 (4/18/06 Second Plaintiff Import Permit Application). This second import permit application requested that Plaintiff be permitted to import 175,000 capsules of "Dronabinol, 2.5mg Capsules in Sesame Oil," "CSA Drug Code: 7369"; 170,000 capsules of Dronabinol 5mg Capsules in Sesame Oil," "CSA Drug Code: 7369"; and 175,000 capsules of "Dronabinol 10mg Capsules in Sesame Oil," "CSA Drug Code: 7369." A.R. at 112. Plaintiff once again certified on the application that the substances "are imported exclusively for scientific purposes," which were described as "Internal Analytical Method Development and Validation." *Id.*

However, this time the large quantity and purpose identified on Plaintiff's April 18, 2006 application "raised a red flag" within the Import/Export Unit ("ODEI") in DEA Headquarters. *See* Defs.' Opp'n, Ex. B (Strait Aff.) ¶ 15. On May 5, 2006, the Chief of ODEI and Chief of the Quota and United Nations Reporting Unit contacted Plaintiff "to obtain more details regarding the application." *Id.* ¶ 16. During that conversation, the DEA explained to Plaintiff that, to import generic Marinol® product under its Schedule IIIN registration, the product had to be FDA-approved. *See* Pl.'s Mot. for Prelim. Inj., Ex. B (Security Manager Aff.) ¶ 7. The DEA concluded that Plaintiff was seeking a permit to import a Schedule I controlled substance (i.e., Dronabinol/an attempted formulation of generic Marinol®) by incorrectly – whether intentionally or not – listing that substance as a Schedule III controlled substance (i.e., the specific product Marinol®, which has

been approved by the FDA) on its import permit; as such, the DEA believed that Plaintiff's registration to import "Dronabinol, Schedule 3" was improperly issued. *See* Defs.' Opp'n, Ex. B (Strait Aff.) ¶ 16; *see also id.*, Ex. C (Decl. of Cheryl E. Brown, Supervisor of the Philadelphia Diversion Group #1 of the DEA (hereinafter, "Brown Aff.")) ¶ 19. That is, the DEA believed that the substance/product sought to be imported by Plaintiff should be given DEA Controlled Substances Code Number 7370 and Schedule I status, not DEA Controlled Substances Code Number 7369 and Schedule III status. The DEA advised Plaintiff that its April 18, 2006 "application for an import permit was being cancelled" and that the earlier-granted permit to import its product had been issued in error. *See* Defs.' Opp'n, Ex. B (Strait Aff.) ¶ 16. The DEA further advised Plaintiff "that dronabinol is a Schedule I controlled substance unless in an FDA-approved product and that Plaintiff would need to apply for registration as a Schedule I importer." *Id.* ¶ 17; *see also* A.R. at 117-18 (6/12/06 Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA Office of Diversion Control, to Plaintiff's President) (echoing these DEA findings in writing).

Later in that same conversation, DEA officials requested that Plaintiff submit a letter explaining in detail its contemplated plans for its synthetic Dronabinol "so that [the DEA] could provide specific guidance as to how the Company should be . . . registered for its proposed activities." *Id.* ¶ 18. Plaintiff, although it had agreed to do so, never provided the requested classification. *Id.* ¶ 21. Instead, Plaintiff's President and CEO contacted a senior attorney in the DEA's Office of Chief Counsel and requested that he intervene. *See* A.R. at 113-116 (5/9/06 Letter from Plaintiff's President to Brian Bayley, United States Department of Justice, Drug Enforcement Administration). In Plaintiff's letter to the DEA's Office of Chief Counsel, Plaintiff insisted that it should be permitted to import its product as a Schedule III controlled substance and that the DEA's

interpretation of its regulations was in error. *See* Defs.' Opp'n, Ex. B (Strait Aff.) ¶ 23.

Following Plaintiff's letter, the DEA responded with a letter on June 12, 2006 drafted by Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA Office of Diversion Control. *See* A.R. at 117-18. The DEA's June 12, 2006 communication noted: "Although the final agency action by the Drug Enforcement Agency (DEA) occurred on May 5, 2006, this letter provides Plaintiff with written notice of the basis for the denial and explains Plaintiff's procedural rights." *Id.* at 117. According to the DEA, the following procedures were available to Plaintiff should it choose to contest the DEA's determination vis-á-vis its April 18, 2006 import permit application:

> 1. Within 30 days after the date of receipt of this denial, you may file with the Administrator of DEA a written request for a hearing in the form set forth in Section 1316.47, Title 21, Chapter 2, Code of Federal Regulations. (See 21 C.F.R. § 1312.44(a)).
>
> 2. Within 30 days after the date of receipt of this denial you may file with the Administrator a waiver of hearing together with a written statement regarding your position on the matters of fact and law involved. (See 21 C.F.R. § 1312.44(b)).
>
> 3. Should you decline to file a request for a hearing or should you so file and fail to appear at the hearing, you shall be deemed to have waived the opportunity for a hearing and the Deputy Administrator of DEA may cancel such hearing, if scheduled, and enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (See 21 C.F.R. §§ 1312.44(c) and 1312.44(d)).

Id.

D. Plaintiff Brings This Action

Rather than pursue its administrative remedies as set forth in the DEA's May 5, 2006 phone call and its June 12, 2006 communication, Plaintiff filed a Complaint and concurrent Motion for Preliminary Injunction in this Court on May 24, 2006. Plaintiff's Complaint contends that the DEA's denial of its April 18, 2006 application to import Dronabinol in sesame oil, encapsulated in a

soft gelatin capsule, was (1) in excess of the DEA's statutory authority, *see* Compl. ¶¶ 50-52 (Count I – Agency Action in Excess of Statutory Authority); (2) contrary to law, arbitrary and capricious, and in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, *see* Compl. ¶¶ 53-55 (Count II – APA Claim); and (3) a deprivation of a liberty and property interest without due process, in violation of the 5th Amendment, *see id.* ¶¶ 56-59 (Count III – Agency Action in Violation of 5th Amendment). Given the alleged significant, irreparable harm it faces in the marketplace if importation is delayed or denied, as well as the strong public interest in providing the market with less-expensive generic drugs, Plaintiff asserts that a preliminary injunction should be entered that would compel the DEA "to issue a permit to Plaintiff to import Dronabinol in sesame oil encapsulated in soft gelatin capsule in the dosage strengths and quantities set forth in Plaintiff's Form 357 submitted on April 18, 2006." Compl. at 13 (Prayer for Relief); *see also* Pl.'s Mot. for Prelim. Inj. at 15-18.

II: DISCUSSION

Prior to commencing any discussion vis-á-vis the merits of Plaintiff's actual claims, the Court must examine an argument first raised by Defendants in their Surreply; namely, Defendants' contention that "[s]ubject-matter jurisdiction over Plaintiff's claims lies exclusively with the Court of Appeals for the D.C. Circuit." *See* Defs.' Surreply at 3. While federal courts have jurisdiction to review agency action under 28 U.S.C. § 1331, that jurisdiction must be exercised in accordance with the procedures established by Congress. Given that the thrust of Plaintiff's Motion for a Preliminary Injunction is almost entirely directed at an argument that the DEA's actions were "arbitrary, capricious, and not in accordance with the law," *see* Pl.'s Mot. for Prelim. Inj. at 11-14, and is essentially silent as to the inextricably intertwined allegations in Plaintiff's other two counts, the Court must analyze two crucial issues prior to any discussion of the merits of Plaintiff's motion:

(1) Was the DEA's May 5, 2006 denial of Plaintiff's import permit request a "final agency action" sufficient to satisfy the APA's jurisdictional prerequisite to judicial review?; and (2) If the DEA's actions were sufficient to satisfy the jurisdictional prerequisite for APA review, does this particular court have subject-matter jurisdiction over this dispute?

A. The Finality Requirement Under the APA

"Agency action" is defined by the APA as "the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). It is well-established that, in the context of APA review, "an agency action must be final in order to be judicially reviewable." *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 13 (D.C. Cir. 2005) (citing *Ctr. for Law and Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1165 (D.C. Cir. 2005) ("APA bars review prior to final agency action.")); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003) ("If there was no final agency action here, there is no doubt that appellant would lack a cause of action under the APA."); *see also* 5 U.S.C. § 704 ("[a]gency action made reviewable by statute and final agency action for which there is no adequate remedy in a court are subject to judicial review"). "The requirement of a final agency action has been considered jurisdictional. If the agency action is not final, the court cannot reach the merits of the dispute." *DRG Funding Corp. v. Sec'y of Housing & Urban Dev.*, 76 F.3d 1212 (D.C. Cir. 1996) (citing *Pub. Citizen v. Office of the U.S. Trade Reps.*, 970 F.2d 916, 918 (D.C. Cir. 1992)); *see also Ticor Title Ins. Co. v. Fed. Trade Comm'n*, 814 F.2d 731, 745 (D.C. Cir. 1987) (Williams, J., concurring).[5]

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[5] "Review of nonfinal agency action is available in 'the most exceptional circumstances,'" and the "classic and oft-quoted formulation" of that standard comes from Judge Leventhal in *Ass'n of Nat'l Advertisers, Inc. v. Fed. Trade Comm'n*, 627 F.2d 1151, 1180 (D.C. Cir. 1981), stating that a federal court may take jurisdictional before final agency action only in a case of "clear right,"

As described by the D.C. Circuit recently in *National Association of Home Builders v. Norton*, 415 F.3d 8, 13 (D.C. Cir. 2005), the Supreme Court has established a two-part test to determine when an agency action is reviewable as "final." First, the action under review "must mark the 'consummation' of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 1778, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997) (citing *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 68 S.Ct. 431, 437, 92 L.Ed.2d 568 (1948)); *see also Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, --- F.3d ----, 2006 WL 1715358, at *8 (D.C. Cir. June 23, 2006). Second, the action must "be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett*, 520 U.S. at 178, 117 S.Ct. 1154 (quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71, 91 S.Ct. 203, 27 L.Ed.2d 203 (1970)). Earlier, different verbal formulations have also been used to determine whether agency action is "final" within Section 704's meaning, including factors such as: (1) whether the action was a "definitive" statement of the agency's position; (2) whether it had a direct and immediate effect on the day-to-day business of the party affected; and (3) whether analysis of the action is legal or factual in nature. *See Fed. Trade Comm'n v. Standard Oil Co.*, 449 U.S. 232, 239, 101 S.Ct. 488, 66 L.Ed.2d 416 (1980) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 151-54, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)); *see also Her Majesty the Queen in Right of Ontario v. Envtl. Prot. Agency*, 912 F.2d 1525, 1531 (D.C. Cir. 1990) ("The [finality] inquiry seeks to distinguish between a tentative agency position from the situation where 'the agency views its

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such as "outright violation of a clear statutory provision" or "violation of basic rights established by a structural flaw, and not requiring in any way a consideration of interrelated aspects of the merits." *Ticor*, 814 F.2d at 749 (Williams, J.). Plaintiff does not argue, nor do these circumstances suggest, that this rare and exceptional end-run around the finality requirement applies in this case.

deliberative process as sufficiently final to demand compliance with its announced position.'") (quoting *Ciba-Geigy Corp. v. Envtl. Prot. Agency*, 801 F.2d 430, 436 (D.C. Cir. 1986)). Whatever exact formulation is actually employed, the end result of the court's finality analysis should be the same. *See DRG Funding Corp.*, 76 F.3d at 1214.

It appears upon initial glance as though strong arguments exist as to why the DEA's May 5, 2006 denial of Plaintiff's import permit request should be labeled a "final agency action" for the purpose of APA review. However, upon a more searching examination of the DEA's actions in the context of the CSA's judicial review provisions, equally strong countervailing considerations argue against such a conclusion.

1. Arguments in Favor of Finality

At least two major arguments exist in support of a finding that the DEA's May 5, 2006 denial of Plaintiff's import permit request – issued during a telephonic conversation with Plaintiff – was sufficiently final to establish jurisdiction for judicial review under the APA. First, "[a]n agency's characterization of an administrative action, though not dispositive of reviewability, may provide guidance[.]" *Am. Portland Cement Alliance v. Envt'l Prot. Agency*, 101 F.3d 772, 776 (D.C. Cir. 1996) (citing *Telecomm. Research & Action Ctr. v. Fed. Commc'ns Comm'n*, 800 F.2d 1181, 1186 (D.C. Cir. 1986)); *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (per curium) (the language used by an agency is an important consideration in finality determinations). In this case, the DEA – in its June 12, 2006 letter to Plaintiff sent by Rannazzisi – emphasized that "the final agency action by the Drug Enforcement Agency (DEA) occurred on May 5, 2006[.]" A.R. at 117. Moreover, during the conference call held on the record between the Court and the parties on June 6, 2006, counsel for both Plaintiff and the Government agreed that final agency action had occurred. *See* 6/6/06 Hrg. Tr. at 26:11-25 (counsel for Plaintiff noted: "we

believe that's final agency action and sufficient for the court to decide the issue"); 27:6-9 (counsel for the Government remarked: "we do believe that the telephone conversation that we referenced was a final decision on the application"). Accordingly, to the extent that the Court may consider the agency's characterization of its May 5, 2006 decision, such a characterization weighs in favor of concluding that the ruling was "final" for the purposes of APA review.

Second, an application of the Supreme Court's two-part test in *Bennett* supports – in part – the conclusion that the DEA's action in this case is best described as "final" for the purposes of this APA jurisdictional review. Here, the DEA's denial of Plaintiff's import permit application is not tentative; rather, the DEA has explicitly stated that the import permit request "was being cancelled," Defs.' Opp'n, Ex. B (Strait Aff.) ¶ 16, and that the end result of any further administrative process would simply re-affirm the DEA's May 5, 2006 cancellation, *id*. ¶ 17. As such, this is not a situation where notice-and-comment rule-making is taking place, or where a rule or policy is being held out for consideration but is not yet in effect; instead, Plaintiff's request has been definitively denied. Moreover, the DEA's May 5, 2006 decision certainly "determined" Plaintiff's rights and obligations, and "legal consequences" will flow from that agency action. For example, if Plaintiff were to choose to continue importing its product from ForeignCo, Plaintiff could be charged with a felony, *see* 21 U.S.C. § 960, or face other penalties that would affect its ability to engage in business. Accordingly, it is clear that the DEA's denial has directly and immediately affected the day-to-day business of Plaintiff: prior to May 5, 2006, Plaintiff could import its product from ForeignCo and proceed with its efforts to obtain an ANDA for its attempted generic version of Marinol®; following May 5, 2006, Plaintiff faces significant obstacles in its importation efforts and its attempt to obtain an ANDA (namely, it must now obtain a Schedule I registration to import the product, *see* Defs.' Opp'n at 21 n.9).

2. Arguments Against Finality

However, other equally important considerations weigh against a conclusion that the action taken by the DEA on May 5, 2006 was "final" for the purposes of APA review. First, while the parties in this matter may well characterize the DEA's May 5, 2006 action as "final," such a characterization is certainly not determinative. *See Sierra Club v. Whitman*, Civ. Action No. 00-2206 (CKK/JMF), 2002 WL 393069, at *4 (D.D.C. Mar. 11, 2002) (Facciola, J.) ("It is for the District Court, and not EPA, to decide whether EPA has actually taken final action.").

Second, and more importantly, the D.C. Circuit has "held repeatedly and across agency contexts that an order will be considered final to the extent that it 'imposes an obligation, denies a right, or fixes some legal relationship, *usually at the consummation of an administrative process*.'" *Meredith v. Fed. Mine Safety & Health Review Comm'n*, 177 F.3d 1042, 1047 (D.C. Cir. 1999) (quoting *Transwestern Pipeline Co. v. Fed. Energy Regulatory Comm'n*, 59 F.3d 222, 226 (D.C. Cir. 1995)) (emphasis added). As discussed in *Ticor Title*, "if an agency proceeding is still at an early stage and the party seeking review has the right to administrative review, a court may decline review for failure to exhaust administrative remedies." *Indep. Petroleum Ass'n of Am. v. Babbitt*, 971 F. Supp. 19, 29 (D.D.C. 1997) (characterizing *Ticor Title*). As Judge Harry T. Edwards stressed, "[j]udicial intervention may not be necessary because the agency can correct any initial errors at subsequent stages of the process; moreover, the agency's position on important issues of fact and law may not be fully crystalized or adopted in final form." *Ticor Title Ins. Co.*, 814 F.2d at 735 (Edwards, J.) (citing E. Gellhorn & B. Boyer, *Administrative Law and Process*, 316-19 (1981)). As Judge Stephen F. Williams also succinctly noted, "exhaustion is directed to the steps a litigant must take, finality looks to the conclusion of activity by the agency." *Id.* at 746 (Williams,

J., concurring).

Here, as detailed in the DEA's June 12, 2006 letter to Plaintiff, *see* A.R. at 117-18, and set forth in 21 C.F.R. § 1312.44, Plaintiff does have several administrative avenues still available that may well reverse the DEA's May 5, 2006 decision. *See DRG Funding Corp.*, 76 F.3d at 1215 ("When completion of an agency's processes may obviate the need for judicial review, it is a good sign that an intermediate agency decision is not final."; concluding that an agency's decision to collect a debt by offset was not final because if the agency's "administrative review ends with the conclusion that the corporation has no debt to [the agency], the corporation will have no reason to seek a judicial determination of the proper procedure for collecting one"); *see also Bellsouth Corp. v. Fed. Commc'ns Comm'n*, 17 F.3d at 1487, 1489-90 (D.C. Cir. 1994). For instance, the DEA's June 12, 2006 letter explicitly notifies Plaintiff that "[t]he following procedures are available to you": (1) Plaintiff may file a written request for a hearing with the Administrator, *see* 21 C.F.R. § 1312.33(a); (2) Plaintiff may submit a written statement regarding its position on the matters of fact and law to the Administrator while waiving its opportunity for a hearing, *id.* § 1312.33(b); or (c) Plaintiff can waive its right to a hearing and/or its right to submit any supporting documentation, *id.* § 1312.33(d). If Plaintiff waives its right to a hearing, "the Administrator may . . . issue his final order pursuant to § 1312.47 without a hearing." *Id.* Section 1312.47 ("Final order") provides:

> As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the issuance or denial of the application for and import, export, or transshipment permit. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon the applicant.

Id. § 1312.47. As such, in many ways, it appears as though the DEA's determination vis-á-vis Plaintiff's import permit application is currently far from "final." Indeed, Section 1312.47, entitled "Final order," seems to contemplate that – at best – the agency's May 5, 2006 determination was

tentative and interlocutory, with several steps remaining until APA finality is reached and an authoritative decision issued by the DEA. *Cf.* 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling *not directly reviewable* is subject to review on the review of *the final agency action*.") (emphasis added).

Concluding that the DEA's May 5, 2006 action was not final, and compelling Plaintiff to either engage in the administrative process or waive its rights and wait for a "final order" with "the findings of fact and conclusions of law upon which the order is based" might well prove an effective choice for the resolution of this case. For instance, the wait to conclude the administrative process here is not exceptionally long, now less than thirty (30) days, and therefore not particularly "harmful" to Plaintiff's alleged interests; moreover, allowing for the conclusion of the process – even if it does not result in a reversal that could moot this suit – could prove beneficial because the reviewing court would then have the DEA's factual and legal conclusions clearly set forth in an extensive manner that would enable the court to conduct a full APA review under a complete administrative record. *See Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 582-83 (D.C. Cir. 2001) (emphasizing the need for a complete administrative record prior to judicial review in the context of the APA); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). Indeed, a review of the present record indicates that this may well be the best course. Here, this Court has required, and the Government has submitted, a 118-page Administrative Record. A review of that Record indicates that virtually all of the documents are simply photocopies of (allegedly) applicable statutes and regulations, and the record is largely devoid of an explicit analysis by the DEA laying out its reasoning. Such an analysis, which would result from a true "Final order" as contemplated in 21 C.F.R. § 1312.47, would certainly aid APA review.

3. Other Considerations

While finality is certainly distinct from a requirement that a plaintiff must exhaust his or her administrative remedies, *see Ticor Title Ins. Co.*, 814 F.2d at 745-46 (Williams, J., concurring) ("while exhaustion and ripeness are judge-made prudential doctrines, finality is, where applicable, a jurisdictional requirement"), here, Plaintiff filed a Complaint and Motion for a Preliminary Injunction in this Court after admittedly failing to exhaust its administrative remedies. *See* Pl.'s Reply at 16-18 (arguing that the exhaustion requirement should be waived given its interests in immediate judicial review due to its claimed irreparable injury). To the extent that exhaustion may be permissibly considered with respect to this Court's jurisdiction, the Court notes two points.

First, Plaintiff has effectively been told by the DEA that any administrative remedy appeal would result in the same decision as effectuated by the DEA on May 5, 2006 – i.e., denial of Plaintiff's import permit application. *See* Defs.' Opp'n at 18 (noting that "[t]hrough [the administrative] process, Plaintiff would be informed *again* that [its] April 18, 2006 application was denied because the product Plaintiff sought to import is a schedule I controlled substance that Plaintiff is not registered to handle") (citing *id.*, Ex. B (Strait Aff.) ¶ 17) (emphasis in original). While not necessarily a valid excuse to avoid exhaustion of required administrative remedies in this Circuit, *see Indep. Petroleum Ass'n of Am.*, 971 F. Supp. at 29 ("the court is unconvinced that this approach is consistent with the law of the D.C. Circuit"), some circuits have held that "futility" of administrative review can provide "finality" and an excuse for failure to exhaust. *See, e.g.*, *Air One Helicopters, Inc. v. Fed. Aviation Admin.*, 86 F.3d 880, 882 (9th Cir. 1996) (stating that "it is a common rule of judicial economy that we will not require a party to exhaust administrative procedures when exhaustion would be futile . . . . Accordingly, we will treat [the agency's position] as final agency action.").

Second, several courts have held that "federal courts may legitimately decline to require exhaustion" where a plaintiff may suffer irreparable harm if unable to secure immediate judicial consideration of its claim. *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30 (D.D.C. 1997); *see also Bowen v. City of New York*, 476 U.S. 467, 483, 106 S.Ct. 2022, 90 L.Ed.2d 462 (1986) (disability-benefit claimants "would be irreparably injured were the exhaustion requirement now enforced against them"); *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 773, 67 S.Ct. 1493, 91 L.Ed. 1796 (1947) ("impending irreparable injury flowing from delay incident to following the prescribed procedure" may contribute to finding that exhaustion is not required). Here, without ruling on the validity of Plaintiff's assertion, the Court does note that Plaintiff contends that it faces irreparable economic injury flowing from the DEA's May 5, 2006 determination, as its efforts to secure an ANDA and be the first generic version of Marinol® to market have been thwarted/significantly set back by the DEA's decision. Such a contention, if valid, could certainly affect Plaintiff's exhaustion requirement and possibly impact the ultimate "finality" of the DEA's May 5, 2006 denial for the purposes of APA review.

4. Conclusion

When the review sought is not pursuant to specific authorization in a substantive statute but only under the general review provisions of the APA, the "agency action" in question must be "final agency action." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 881-84, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990). Here, the Court faces two disparate possibilities. First, given the existing, remaining administrative process as set forth in 21 C.F.R. § 1312.44 and § 1312.47, which may well reverse the DEA's May 5, 2006 determination, the agency action at the center of this dispute might not be "final agency action" for the purposes of the APA. Because APA requires "finality" in order for a court to have jurisdiction and to undertake judicial review, dismissal without prejudice of Plaintiff's

Complaint and denial without prejudice of Plaintiff's Motion for a Preliminary Injunction may well be warranted at this point because this Court lacks subject-matter jurisdiction over Plaintiff's unripe, non-final claims.

Second, in contrast, given the fact that both the DEA and Plaintiff believe that the May 5, 2006 decision was "final," and it is uncontested that the decision is sufficiently direct and immediate and has a direct effect on Plaintiff's day-to-day business, *see DRG Funding*, 814 F.2d at 1214, it may well be the case that the DEA's May 5, 2006 determination is "final" for the purposes of APA review. So, rather than dismissing Plaintiff's claims without prejudice due to finality concerns, the Court could begin a more extended consideration of Plaintiff's allegations. However, as discussed *infra*, Section II(B), the Court concludes that even *assuming arguendo* that federal jurisdiction over Plaintiff's claims is not barred under the APA's "finality" mandate, it is clear that this Court lacks jurisdiction over Plaintiff's action. As such, the Court shall dismiss without prejudice both Plaintiff's Complaint and its Motion for a Preliminary Injunction.

B. The Impact of 21 U.S.C. § 877 on This Court's Jurisdiction

Assuming *arguendo* that jurisdiction over Plaintiff's action would not be generally barred by finality concerns arising under the APA, this Court – prior to delving into the merits of Plaintiff's Motion for a Preliminary Injunction – still must check to see if its exercise of jurisdiction under 28 U.S.C. § 1331 is proper, as Plaintiff asserts. *See* Compl. ¶ 6 ("This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331, as the claims arise under 21 U.S.C. §§ 952 and 958, 5 U.S.C. §§ 701-06 and the Fifth Amendment of the United States Consitution.").

In this case, it is clear that Plaintiff's claims arise under the Controlled Substances Act ("CSA"), *see, e.g.*, Pl.'s Reply at 11, 12, 13, 15, as Plaintiff is challenging the DEA's decision that the product it seeks to import is properly classified as a Schedule I – rather than Schedule III –

controlled substance. Importantly, the CSA contains a specific jurisdictional provision, 21 U.S.C. § 877, which provides:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

Id.; *see also* 21 C.F.R. § 1316.68 ("Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Administrator in quintuplicate. The Administrator shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals."); Pub. L. No. 91-513, Title II, § 507, 84 Stat. 1273 (Oct. 27, 1970).[6]

A plain reading of Section 877 indicates that jurisdiction over challenges to the DEA's determinations under the CSA rests exclusively with the Court of Appeals; indeed, the statute itself provides no other explicit avenue for judicial review and relief. A review of numerous cases from a variety of jurisdictions supports this position, revealing that challengers to DEA determinations under the CSA (in circumstances often similar to the present dispute) almost exclusively bypass the federal district court level, and instead directly petition the applicable court of appeals. *See Noramco of Del., Inc. v. Drug Enforcement Admin.*, 375 F.3d 1148, 1152-53 (D.C. Cir. 2004) (drug company challenged the DEA's conditional grant of another drug company's application for registration as an importer of controlled substances by directly petitioning the D.C. Circuit); *Reckitt*

[6] As noted previously, the Attorney General has delegated his authority under the CSA to the Administrator of the DEA. *See* 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b).

& Colman, Ltd. v. Adm'r, Drug Enforcement Admin., 788 F.2d 22, 23 (D.C. Cir. 1986) (distributor of buprenorphine brought petition directly to the D.C. Circuit for review of DEA order that maintained the classification of buprenorphine as a narcotic under the CSA); *see also Fry v. Drug. Enforcement Admin.*, 353 F.3d 1041, 1043-44 (9th Cir. 2003) (physician petitioned court of appeals for review of the DEA's revocation of registration to dispense controlled substances); *Humphreys v. Drug Enforcement Admin.*, 96 F.3d 658, 659-60 (3d Cir. 1996) (physician sought review of license registration by DEA directly with court of appeals); *ALRA Labs., Inc. v. Drug Enforcement Admin.*, 54 F.3d 450, 451-52 (7th Cir. 1995) (drug manufacturer petitioned court of appeals for review of the DEA's denial of license to manufacturer controlled substances); *Nutt v. Drug Enforcement Admin.*, 916 F.2d 202, 203 (5th Cir. 1990) (doctor petitioned court of appeals for review of the DEA's denial of registration renewal for certificate to handle controlled substances); *Steckman v. Drug Enforcement Admin.*, No. Civ. A. H-97-1334, 1997 WL 588871, at *1-*2 (S.D. Tex. Sept. 16, 1997) (holding that it, as a district court, lacked jurisdiction over the plaintiff's CSA-related claim "because the only forum for review of her claim is the court of appeals for the District of Columbia Circuit or the court of appeals of the circuit in which [plaintiff] has her principal place of business").

Despite the seemingly clear language and intent of Section 877, district courts have occasionally struggled with actions that do not necessarily appear to be "final determinations, findings, and conclusions" of the DEA. For example, in *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24 (D.D.C. 2001), Judge Henry Kennedy rejected the DEA's argument that the district court did not have jurisdiction over the action, which was brought by a pharmaceutical manufacturer (PDK) challenging the DEA's decision to deny a third-party importer's letter-of-non-objection for

importation of a listed chemical. *See id.* at 29. Judge Kennedy concluded that the jurisdiction before him was proper "as a federal question under 28 U.S.C. § 1331" because "[a]t best, DEA's letter is considered its final interpretation of § 971(c), as opposed to a final action under the CDTA [Chemical Diversion and Trafficking Act] as contemplated by § 877." *Id.* As such, Judge Kennedy found that the DEA's letter at issue was insufficient to "constitute a final determination, finding, or conclusion within the meaning of § 877," meaning that the district court – rather than the Court of Appeals – could exercise jurisdiction because the case fell outside of the parameters of Section 877. *See also Novelty, Inc. v. Tandy*, No. 104 CV 1502 (DFH/TAB), 2005 WL 2253599, at *3 (S.D.Ind. Sept. 1, 2005) (magistrate judge, in reviewing a discovery dispute, was faced with a jurisdictional challenge by the DEA, and concluded that the matter was best left for a motion to dismiss, but mentioned "that the challenged action does not appear to be a final agency action such that 21 U.S.C. § 877 would deprive the Court of subject matter jurisdiction") (citing Judge Kennedy's decision in *PDK Labs*). The Court of Appeals for the D.C. Circuit eventually reviewed a later phase of the *PDK Labs* litigation, *see* 362 F.3d 786 (D.C. Cir. 2004), but offered no commentary as to whether Judge Kennedy's prior assertion of jurisdiction was proper.

In *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D.Or. 2002), another district court judge, the Honorable Robert E. Jones of the United States District Court for the District of Oregon, struggled with a similar issue. In that case, the DEA had challenged the district court's subject-matter jurisdiction over a matter involving a directive by the Attorney General indicating that physicians who assist the suicide of terminally ill patients pursuant to Oregon's Death with Dignity Act would be violating the federal CSA. *See id.* at 1083-85. Throwing up his hands to a certain degree, Judge Jones concluded that the district court could exercise jurisdiction because the so-called "Ashcroft directive" at issue, "however it is characterized, is not a final determination, finding, or conclusion

within the meaning of section 877." *Id.* at 1085. However, Judge Jones also, in the alternative, ordered the petitions for review before him transferred to the United States Court of Appeals for the Ninth Circuit pursuant to 28 U.S.C. § 1631, which provides:

> Whenever a civil action is filed in a court . . . including a petition for review of administrative action . . . and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or notice[.]

Id.; *see Oregon*, 192 F. Supp. 2d at 1086-87 (entering alternative jurisdictional ruling).

Upon appeal, the Ninth Circuit ruled that the district court lacked jurisdiction under the CSA, and accepted the alternative transfer order. *See* 368 F.3d 1118, 1120 (9th Cir. 2004), *aff'd on other grounds*, *Gonzales v. Oregon*, --- U.S. ----, 126 St. 904, 163 L.Ed.2d 748 (2006). The Ninth Circuit, in finding that district court was without subject-matter jurisdiction, emphasized:

> Because the Attorney General maintains that his interpretive rule is a "final determination" and because the Directive orders sanctions for violations of its provisions, we have original jurisdiction pursuant to § 877. *See Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003) (holding that an interpretive rule issued by the Attorney General pursuant to the CSA is a "final determination" for jurisdictional purposes because the rule "impos[es] obligations and sanctions in the event of violation [of its provisions]"); *see also City of Auburn v. Quest*, 260 F.3d 1160, 1171-73 (9th Cir. 2001).

368 F.3d at 1120 & n.1 ("Although we conclude that the district court did not have jurisdiction, Judge Jones' opinion on the merits is well reasoned, and we ultimately adopt many of his conclusions.").

Stepping into this vacuum of confusion, Plaintiff claims that subject-matter jurisdiction over this case properly rests with this Court because the DEA's decision denying its April 18, 2006 import permit application is not a "final determination" as contemplated by Section 877. *See* Pl.'s Surrebuttal at 2. Plaintiff contends:

> Like the DEA's action against PDK, the informal telephone conference denial followed by the recent letter denial of [Plaintiff]'s permit application does not constitute a final determination, finding, or conclusion within the meaning of 21 U.S.C. § 877. *See PDK*, 134 F. Supp. 2d at 29. Indeed, the DEA's recent letter [i.e., the June 12, 2006 Rannazzisi Letter] advises [Plaintiff] of its right to request an administrative hearing on the denial, *see* Administrative Record at 117-18, making it clear that the "final determination" contemplated by § 877 has not occurred.

Id. at 4. Plaintiff attempts to differentiate *ALRA*, *Fry*, *Oregon v. Ashcroft*, and *Nutt* by suggesting that judicial review in each of those cases was triggered "either after some assertion of rulemaking by an executive branch official; after a full adjudicatory hearing, final agency action based thereon, and an appeal of such agency action; or after the failure of a party to request an adjudicatory hearing followed by subsequent agency action once the time for such requests expired." *Id.* at 5.

The Court finds Plaintiff's jurisdiction argument to be unpersuasive for four reasons. First, Plaintiff's contention appears to be logically untenable. Simply, if the DEA's May 5, 2006 determination meets the standards necessary to satisfy the "final agency action" requirement under the APA, 5 U.S.C. § 704, thereby triggering federal jurisdiction for the purposes of judicial review, it seems certain to meet the "final determinations, findings, and conclusions" criteria of 21 U.S.C. § 877, thereby triggering the United States Court of Appeals for the District of Columbia's exclusive jurisdiction over Plaintiff's CSA-based claims. While the two statutes are not necessarily *in pari materia*, nor – because they are distinct statutes – do they trigger the traditional canon of statutory construction that identical terms with an Act bear the same meaning, *see Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 478, 112 S.Ct. 2589, 120 L.Ed.2d 379 (1992), such a conclusion appears most in line with the clear intent arising out of Section 877's language. Indeed, the CSA, pursuant to Section 877, provides one explicit avenue for judicial review – i.e., via petition to the applicable court of appeals – and nowhere does it contemplate that district courts should involve themselves in adjudicating CSA-based determinations by the DEA. The traditional canon of

statutory construction *expressio unius est exclusio alterius* ("express mention of one thing implies the exclusion of another") supports this reading in this situation, i.e., where the courts of appeals are vested with explicit, apparently exclusive jurisdiction via a statute apparently enacted to avoid the usual 28 U.S.C. § 1331 process.

Second, the Ninth Circuit in *Oregon v. Ashcroft* perhaps spoke most directly to this conclusion. There, as noted above, the Ninth Circuit reversed the district court's finding of jurisdiction and concluded that it properly had "original jurisdiction pursuant to § 877" because (1) the Attorney General maintained that his CSA-based "interpretive rule" is a "final determination" and (2) "the Directive orders sanctions for violations of its provisions." *Oregon*, 368 F.3d at 1120. Here, assuming *arguendo* that the agency action was sufficiently final to trigger APA jurisdiction, the Court encounters a similar situation; that is, (1) the DEA maintains that its CSA-based May 5, 2006 import permit denial is "final agency action" and (2) Plaintiff faces severe consequences if it chooses to violate such a determination in the future. As such, the somewhat analogous situation faced in *Oregon v. Ashcroft* supports the idea that the Court of Appeals, rather than this Court, is the proper locus of Plaintiff's suit.

Third, the Court notes that in similar situations under other statutory schemes, courts have traditionally refused to allow litigants to circumvent clear statutory directives requiring direct petition to the courts of appeals. *See, e.g.*, *Fed. Commc'ns Comm'n v. ITT World Commc'ns, Inc.*, 466 U.S. 463, 468-69, 104 S.Ct. 1936, 80 L.Ed.2d 480 (1984) (overturning the decision by a district court to enjoin FCC action as *ultra vires* because review of "final FCC orders" lies exclusively with the courts of appeals pursuant to 28 U.S.C. § 2342; stressing that "[l]itigants may not evade these provisions by requesting the District Court to enjoin action that is the outcome of the agency's order"); *Greenwood v. Fed. Aviation Admin.*, 28 F.3d 971, 975 (9th Cir. 1994) (where

challenge was inescapably intertwined with a review of the procedures and merits surrounding the actions undertaken by the Secretary of the Department of Transportation, that challenge, pursuant to 49 U.S.C. § 46110(a), properly resides before the court of appeals, not the district court); *Connors v. Amax Coal Co.,* 858 F.2d 1226, 1231 (7th Cir. 1988) ("when jurisdiction to review administrative decisions is vested in the courts of appeals[,] these specific, exclusive jurisdiction provisions preempt district court jurisdiction over related issues under other statutes"); *Gen. Fin. Corp. v. Fed. Trade Comm'n*, 700 F.2d 366, 368 (7th Cir. 1983) (litigant "may not bypass the specific method Congress has provided for reviewing adverse agency action simply by suing the agency in federal district court under [section] 1331 or 1337; the specific statutory method, if adequate, is exclusive"). Here, Section 877 is clear in its mandate that "[a]ll final determinations, findings, and conclusions" of the DEA pursuant to the CSA are to be reviewed upon a challenge by the applicable court of appeals. Given (1) the plain statutory directive of Section 877, (2) the absence of explicit, contrary language indicating that district courts may exercise jurisdiction over certain CSA-related challenges, and (3) the general trend to subsume similar agency actions in cases before the courts of appeals, Plaintiff's jurisdictional argument appears misplaced.

Fourth, and finally, important public policy considerations undermine Plaintiff's jurisdictional argument. Plaintiff's analysis would support a loophole around the common Section 877 jurisdiction held by the courts of appeals; rather, pursuant to Plaintiff's theory, district courts could exercise jurisdiction over CSA-related claims as long as the petitioner "jumped the gun" and failed to go through the administrative process that would have otherwise produced a "final determination." Such a loophole would allow selective forum shopping by essentially letting the petitioner choose the court (either district or court of appeals) where it believes it has the greatest chance of early success – an especially important consideration in the context of a motion for a

preliminary injunction. Moreover, such a loophole would undermine what appears to be the basic intent behind Congress' enactment of Section 877 – that is, to allow for expedient, efficient adjudication of claims relating to the DEA's regulation of controlled substances. By vesting exclusive jurisdiction with the courts of appeals, Congress ensured that litigation could be resolved more quickly (eliminating the need for petitioners or the DEA to appeal a district court's determination), thereby allowing important determinations regarding critical issues vital to the public – i.e., the regulation of controlled substances and the development of pharmaceutical drugs – to be reviewed in the first instance by the courts of appeals. Plaintiff's position, by (1) promoting forum shopping and (2) ultimately delaying litigation on critical issues, would countermine crucial policy considerations in a manner not contemplated by Congress.

Two points, however, do give the Court slight pause before making this determination. First, in virtually all of CSA-based cases described above involving direct petition to the court of appeals or assertion of jurisdiction by the court of appeals, the petitioners were much further advanced in their administrative process than Plaintiff in this case. These petitioners were most commonly affected by (1) rules issued after notice-and-comment rule-making, or (2) lengthy final decisions following an administrative hearing. It is uncontested that Plaintiff has not reached such a stage, having failed to exhaust its administrative remedies. Rather than suggesting to this Court that these cases are somehow not persuasive in this context or allow for some form of loophole for district court jurisdiction, the Court concludes that the fact that Plaintiff in this case is not as far along in the administrative process intimates that – as described in Section II(A) – the DEA's action might not be sufficiently "final" to merit federal jurisdiction over Plaintiff's APA-based claims; the fact that Plaintiff is not as advanced in the administrative process does not suggest that *this Court* should involve itself in the action.

Second, Plaintiff continually emphasizes the United States Supreme Court's holding in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 111 S.Ct. 888, 112 L.Ed.2d 1005 (1991), as supporting this Court's intervention in this situation. *See* Pl.'s Surrebuttal at 5-6. The *McNary* Court held that Section 210(e) of the Immigration and Nationality Act ("INA") did not preclude a federal district court from exercising general federal-question jurisdiction over an action alleging a pattern or practice of procedural due process violations by the Immigration and Naturalization Service ("INS") in its administration of the Special Agricultural Worker ("SAW") program. *See McNary*, 498 U.S. at 483, 111 S.Ct. 888. According to the Supreme Court:

> We hold that given the absence of clear congressional language mandating preclusion of federal jurisdiction and the nature of respondents' requested relief, the District Court had jurisdiction to hear respondents' constitutional and statutory challenges to INS procedures.

Id. at 483-84, 111 S.Ct. 888. Plaintiff seizes upon this language, and suggests that Section 877 allows for some form of "dormant" district court jurisdiction over CSA-based determinations.

Judge Jones in his district court opinion in *Oregon v. Ashcroft* relied upon *McNary* as the keystone rationale supporting his assertion of jurisdiction, *see* 192 F. Supp. 2d at 1086 – reasoning that the Ninth Circuit clearly found to be misplaced, *see* 368 F.3d at 1120 & n.1. Such a rejection of *McNary* as applicable precedent appears to be correct, given the vast differences in Plaintiff's situation and the position faced by respondents in *McNary*. In *McNary*, the Supreme Court emphasized that "[w]ere we to hold otherwise and instead require respondents to avail themselves of the limited judicial review procedures set forth in Section 210(e) of the INA, meaningful judicial review of their statutory and constitutional claims would be foreclosed." 498 U.S. at 484, 111 S.Ct. 888. The *McNary* Court concluded that because Section 210(e) of the INA only denied the district court jurisdiction over the denial of individual SAW applications, and because the petitioners did not

seek review on the merits of a denial of a particular SAW application, the district court could maintain general jurisdiction of respondents' constitutional challenge under § 1331. *Id.* at 494, 111 S.Ct. 888. Here, (1) the language of Section 877 is much broader in its language, as it seems to explicitly vest exclusive jurisdiction in the courts of appeals over any CSA-based agency determination that could properly be before a federal court; and (2) unlike respondents apparent situation in *McNary*, Plaintiff here does have an avenue to seek meaningful judicial review of its claims – the Court of Appeals.

Ultimately, the Court concludes that it lacks subject-matter jurisdiction over Plaintiff's action. If the DEA's May 5, 2006 determination was not a "final agency action" for the purposes of the APA, federal jurisdiction and judicial review is inappropriate. If the DEA's May 5, 2006 import permit denial was a "final agency action" for the purposes of the APA, the explicit language of 21 U.S.C. § 877 and other considerations support a finding that federal jurisdiction vests, but judicial review over Plaintiff's APA claim – and its related 5th Amendment and statutory authority claims, both of which are also inextricably linked to an agency determination under the CSA – may only take place before the Court of Appeals. In either situation, *this Court* lacks jurisdiction to hear Plaintiff's contentions, rule on the merits of Plaintiff's claim, or issue the requested mandatory injunctive relief. Finding that it lacks subject-matter jurisdiction over this case, the Court shall dismiss without prejudice Plaintiff's Complaint and Motion for Preliminary Injunctive Relief in order to allow Plaintiff to either (1) fully pursue its administrative remedies and then re-file in the Court of Appeals or (2) immediately re-file and seek appropriate relief before the Court of Appeals. *Cf. Emily's List v. Fed. Election Comm'n*, 362 F. Supp. 2d 43, 53 (D.D.C. 2005) ("Although a motion for a preliminary injunction against an agency is not always inappropriate, the better course is to rule on the merits of the substantive issues at a later date, particularly where allegations of

irreparable injury are lacking at this stage.") (citing *Am. Bioscience*, 243 F.3d at 1083-84 & nn. 7-8).

III: CONCLUSION

For the reasons set forth above, the Court finds that it lacks subject-matter jurisdiction over this dispute. As such, the Court shall dismiss without prejudice Plaintiff's Complaint and Motion for Mandatory Injunctive Relief. An appropriate Order accompanies this Memorandum Opinion.

Date: June 29, 2006

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge