Drug	Schedule
1-Piperidinocyclohexane carbonitrile (8603).	II
Alphaprodine (9010)	П
Cocaine (9041)	ii
Codeine (9050)	ii
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Racemethorphan (9732)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537; or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than October 29, 2007.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16937 Filed 8–27–07; 8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 07–36]

Spirit Pharmaceuticals, L.L.C., c/o Novelty, Inc; Denial of Request for Hearing

On June 22, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Suspend Shipment to Spirit Pharmaceuticals, L.L.C., of Fairless Hills, Pennsylvania. See 21 U.S.C. 971(c). The Order suspended Spirit's proposed importation of 2,000 kilograms of Ephedrine Hydrochloride to be purchased from Emmellen Biotech Pharmaceuticals, LTD., of Mumbai, India. Order at 1.

The factual basis of the Order was that Spirit, a registered importer, had identified AAA Pharmaceuticals, Inc. (AAA), as the customer, on the Import Declaration (DEA Form 486) that it filed. Id. at 2. DEA personnel subsequently contacted AAA and determined that the ephedrine was to be used to manufacture tablets that would be sold to Novelty, Inc. Id. at 2.

The Order related that ephedrine is a list I chemical, which while having a legitimate use as a bronchodilator, is also a precursor chemical which is used in the illicit manufacture of methamphetamine, a schedule II controlled substance. Id. The Order also related that DEA has found that nontraditional (or gray-market) retailers, which include such entities as gas stations, convenience stores, minimarts, and liquor stores, "purchase and sell ephedrine * * * OTC products in quantities that exceed what would be necessary to meet legitimate demand" at these establishments, and that the products "are often sold to persons for use in the illicit manufacture of methamphetamine." Id. Finally, the Order related that "AAA manufactures and Novelty distributes" ephedrine products which are "not widelyadvertised and are distributed to 'nontraditional' retail outlets * * * such as convenience stores and gas stations." Id. at 3. Based on DEA's experience with similar ephedrine products which were distributed to non-traditional retailers. I found that "the proposed importation of ephedrine may be diverted to the clandestine manufacture of controlled substances." Id.

The Order notified Spirit that it could request a hearing by filing a written request within thirty days of its receipt of the Order, and that if it failed to do so, it would be deemed to have waived its right to a hearing. *Id.* Spirit did not,

however, request a hearing. Nor did AAA.

Instead, on July 5, 2007, Novelty filed a request for a hearing asserting that it is "a regulated person to whom an order applies" under 21 U.S.C. 971(c)(2). ALJ Memorandum at 1; see also Ltr. of Novelty's Counsel (June 28, 2007), at 1. Novelty also contended that it "is directly harmed, both in its property and liberty interests," and that it "has an independent due process right to a hearing under the Fifth Amendment * * * regardless of whether Spirit also requests a hearing on the order of suspension." Ltr. of Novelty's Counsel at 1. Id.

Upon receipt of Novelty's letter, the matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who initiated pre-hearing procedures. Shortly thereafter, the Government filed a motion to deny Novelty a hearing on various grounds including that it is a downstream distributor and thus not entitled to a hearing under the statute. See Mot. to Deny Novelty, Inc. an Adjudicatory Hearing Under 21 U.S.C. 971(c)(2) (hereinafter, Mot. to Deny).

Upon review of the Government's motion, the ALJ concluded "that the usual manner of handling an administrative hearing is not appropriate here." ALJ Memorandum at 2. Noting that "[t]he entity asking for a hearing, Novelty, is not the entity addressed in the Order to Suspend Shipment, Spirit Pharmaceuticals," and that the Government had objected to granting Novelty a hearing on the validity of the suspension order, the ALJ concluded that "the designation of this matter for a hearing is not clear." Id. The ALJ thus transmitted the issue to me for resolution. Id. at 2-3.

For the reasons set forth below, I conclude that Novelty is not "a regulated person to whom an order applies under [21 U.S.C. 971(c)(1)]." 21 U.S.C. 971(c)(2). Accordingly, I deny Novelty's request for a hearing to challenge the suspension order. I further order that the proceedings currently pending before the ALJ be terminated.

Discussion

Under 21 U.S.C. 971(a), "[e]ach regulated person who imports * * * a listed chemical shall notify the Attorney General of the importation * * * not later than 15 days before the transaction is to take place." (emphasis added). In

¹In subsection (b), Congress directed that the Attorney General issue regulations "for circumstances in which the requirement of subsection (a) * * * does not apply to a transaction between a regulated person and a regular customer or to an importation by a regular importer." 21 U.S.C. 971(b)(1).

addition, in subsection (c)(1), Congress granted the Attorney General the authority to "order the suspension of any importation * * * of a listed chemical * * * on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance." *Id.* § 971(c)(1). Subsection (c)(1) further provides that "[f]rom and after the time when the Attorney General provides written notice of the order * * * to the regulated person, the regulated person may not carry out the transaction." *Id.*

In the event that the Agency orders the suspension of an importation, Congress provided that "[u]pon written request to the Attorney General, a regulated person to whom an order applies under paragraph(1) is entitled to an agency hearing on the record in accordance with" subchapter II of the Administrative Procedure Act. Id. § 971(c)(2) (emphasis added). It is this provision which is at issue in this proceeding

Relying on PDK Labs. v. Reno, 134 F. Supp.2d 24 (D.D.C. 2001), Novelty contends that as a wholesale distributor, it "is a 'regulated person' within the meaning of 21 U.S.C. 802(38) and, as such, is entitled to a hearing under' subsection (c)(2). Novelty's Resp. to Mot. to Deny at 7. Novelty also maintains that it "is a party within the 'zone of interests' designedly protected by" the hearing provision and thus entitled to a hearing on this alternative ground. Id. Relatedly, Novelty contends that to deny it a hearing would violate the rule of law because PDK Labs. v. Reno "remain[s] the law governing this agency's construction of the hearing provision," id. at 5, and that "DEA possesses no lawful power to act against the holding of the District Court in" that

In *PDK Labs.* v. *Reno*, the district court addressed the question of whether a manufacturer (PDK) was entitled to a hearing to challenge this Agency's refusal to issue a Letter of No Objection (LONO) to Indace, Inc., an importer which had notified the Agency of its intent to import bulk ephedrine on behalf of PDK. 134 F.Supp.2d at 28. When the Agency refused to grant the LONO, PDK filed suit raising various claims including that the Agency had violated the Administrative Procedure Act and had "failed to perform its statutory duties." ² *Id.* at 27.

In the course of discussing whether PDK had standing to bring its APA claims, the district court addressed the Government's arguments that PDK was "not an intended beneficiary of § 971's procedures," and that "the interests underlying [its] claims [were] not within the 'zone of interests' protected by" the statute. *Id.* at 29–30. In rejecting these arguments, the court began by noting that under 21 U.S.C. 802(38), "regulated persons' included manufactures [sic], distributors, importers, and exporters of listed chemicals," and that "as both a manufacturer and distributor PDK is a regulated person within the meaning of § 802." Id. at 30. Observing that '[s]ection 971 uses both the terms 'importers' and 'regulated persons,'" the court reasoned that "Congress easily could have limited the right to a hearing in § 971(c)(2) exclusively to 'importers to whom an order applies,' but chose not to do so—instead extending this right to 'regulated persons.'" Id. The court then concluded that "[t]he specific use of the term 'regulated persons' in § 971(c)(2) at least suggests that Congress intended to permit a regulated entity to whom an order appliesincluding a manufacturer like PDK—to obtain judicial review." Id. (emphasis added)

The court buttressed its reasoning asserting that this Agency "itself previously adopted a similar reading in Yi Heng Enterprises Dev. Co., 64 FR 2234, 2235 (1999)." Id. While noting that "Yi Heng arose in a different context * * * because it involved the interests of two importers rather than an importer and a manufacture [sic]," the court noted that the "decision recognized that 'the statute provides the opportunity for a hearing to "a regulated person to whom an order (suspending shipment) applies," not necessarily the person to whom the order was issued." Īd.

After discussing the zone of interests test for review under the APA—a separate inquiry from that of who is entitled to an agency hearing under the statute—the court further concluded that "the phrase 'regulated person to whom any [sic] order applies' is evidence that a manufacturer affected by a suspension order is protected under § 971's review provision." *Id.* at 31. The court also noted that because PDK was specifically listed on the DEA Form 486 as "the intended recipient of" the proposed importation and that the suspension order "hinge[d] largely on

the identity of the eventual purchaser," PDK was "entitled to a hearing." *Id.*

Most of the district court's analysis of the hearing provision occurred in the course of its discussion of whether PDK had standing under the APA. The court nonetheless clearly incorporated this reasoning in granting PDK's motions for injunctive and declaratory relief. See id. at 36 ("PDK is a 'regulated person to whom an order applies' within the meaning of § 971. As such, it is entitled to an expedited hearing of formal suspension orders that apply to it."). See also id. at 38. DEA did not appeal the court's decision, which ordered the Agency to either issue a LONO or a suspension order. Id. Instead, the Agency complied with the court's order by issuing orders suspending the importations. See Indace, Inc., c/o Seegott, Inc., 67 FR 77805 (2002). Thereafter, PDK requested a hearing and "DEA complied with the court's ruling" by granting PDK a hearing. Id.

The Government disagrees with Novelty as to the precedential weight of PDK Labs. v. Reno. First, the Government argues that Yi Heng, upon which the district court relied, does not support granting Novelty a hearing because there, both entities were deemed to be importers and thus the case did not address "the question of whether someone other than an importer could obtain a hearing." Motion to Deny at 9. The Government further argues that "Novelty is a step further removed from the importation than the plaintiff in PDK Labs.," and that to grant a hearing "to any downstream regulated person affected by a suspension order is a considerable expansion of the flawed reasoning in PDK Labs. v. Reno." Mot. to Deny at 10. Relatedly, the Government contends that "under Novelty's reasoning, any one of [its] thousands of customers, which are also "regulated persons" under the statute, "could receive [a hearing] regardless of whether Spirit, AAA, or even Novelty was interested in pursuing the importation." *Id.* at 11.

Having considered the parties arguments, I agree with the Government that *PDK Labs* v. *Reno* is not controlling authority in this matter. The statutory scheme, reasonably read, grants a hearing only to those who are properly deemed to be importers. While in some circumstances, a manufacturer may also be deemed to be an importer because it is the real party in interest in an import transaction, Novelty is neither an importer nor a manufacturer. Rather, it is the purchaser and distributor of a new and different product combining the ephedrine with guaifenesin, which has been manufactured in the United States.

² At the time PDK filed suit, Indace had indicated that it planned to pursue the matter by having DEA issue a suspension order. 134 F.Supp.2d at 28. The day after PDK filed suit, Indace notified the Agency that it considered the matter as being "solely between" DEA and PDK and that it no longer intended to pursue the matter. *Id.* DEA then

notified Indace that it considered the request for importation to have been withdrawn. *Id.*

To be sure, a distributor such as Novelty falls within the definition of a "regulated person." 21 U.S.C. 802(38). In subsection (c)(2), however, Congress did not extend the hearing right to all "regulated persons." Rather, it limited the right to only "a regulated person to whom an order applies under paragraph(1)." Id. § 971(c)(2) (emphasis added). And as paragraph (1) (subsection (c)(1)) makes plain, the "regulated person to whom an order applies" is the regulated person that is seeking to "carry out the transaction" of the importation and which is the same regulated person that has previously notified the Agency of the proposed transaction. Id. § 971(c)(1) (emphasis added). See also id. § 971(a) ("Each regulated person who imports * * * a listed chemical shall notify the Attorney General of the importation * * * not later than 15 days before the transaction is to take place.") (emphasis added). As section 971's text and structure demonstrate, an entity's entitlement to a hearing is not based solely on its status as a "regulated person," but rather, as a "regulated person" seeking to carry out an import transaction.

As explained above, the transaction which is the subject of the suspension order is the importation of bulk ephedrine by Spirit Pharmaceuticals from Emmellen Biotech Pharmaceuticals of Mumbai, India. Novelty is not a party to this transaction.

My predecessor's decision in Yi Heng (which the district court relied on in PDK) provides no comfort to Novelty. In Yi Heng, my predecessor apparently adopted the ALJ's interpretation that "the statute does not specify that only one party in a transaction is entitled to a hearing. * * * [T]he statute provides the opportunity for a hearing to 'a regulated person to whom an order (suspending shipment) applies,' not necessarily the person to whom the order was issued." 64 FR at 2235 (int. quotations omitted).

In the decision, my predecessor relied on the Agency's regulation which defines a "chemical importer" as "a regulated person who, as "the principal party in interest in the import transaction", has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States." Id. (quoting 21 CFR 1300.02(b)(8)). Because title to the chemical had passed to Yi Heng's customer "before the chemical entered the United States," the customer was also "a regulated person to whom the suspension order applies." Id.

Unlike Yi Heng's customer, Novelty is not "the principal party in interest in the import transaction." 21 CFR 1300.02(b)(8). Indeed, as explained above, it is not even a party to the import transaction. Novelty thus stands on a different footing than a manufacturer (such as PDK did) which lacks an import registration and which must therefore import by entering into an agency relationship with a registered importer.3 Novelty does not have "the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States." Id. As the Government points out, even were Novelty to prevail at a hearing, it cannot "compel Spirit to import the ephedrine." Mot. to Deny at 8. Nor does Novelty identify any consequence that would attach to it were Spirit to violate the suspension order. See 21 U.S.C. 960(d).

Furthermore, here, in contrast to the PDK case, not even the manufacturer (AAA) filed a request for a hearing. Moreover, under Novelty's construction of the statute, any one of a manufacturer's wholesale-distributor customers (and some manufacturers have numerous wholesaler customers) would be entitled to a hearing even if the manufacturer had decided that it no longer desired to pursue the importation and manufacture the product. I will not adopt a construction of the statute that would lead to such an absurd result.4 Cf. Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 575 (1982).

The text and structure of section 971 thus provide ample evidence that Congress intended to grant a hearing only to those regulated persons who are principal parties to a proposed import transaction. Because Novelty is not such a party but rather the purchaser of a new and different product, which has been manufactured in the United States, it is not "a regulated person to whom an

order applies." 21 U.S.C. 971(c)(2). It is therefore not entitled to a hearing.⁵

Novelty further argues that to deny it a hearing would deprive it of liberty and property interests in violation of the Due Process Clause. Novelty's Resp. at 16–17. Relatedly, Novelty argues that under the avoidance doctrine, DEA must construe the statute to provide it with a hearing.

Novelty has not established that the suspension order has deprived it of either a liberty or property interest. Novelty maintains that it "has a liberty interest in avoiding damage to its reputation * * * that will result from the stigmatizing suspension DEA creates by its effective import ban." Novelty Resp. at 17. This contention is easily dismissed because in *Paul* v. *Davis*, 424 U.S. 693, 712 (1976), the Supreme Court held that one's "interest in reputation" is "neither 'liberty' nor 'property'" under the Due Process Clause.

Novelty further asserts that "the stigmatizing effects" of the suspension order will "preclude[it] from obtaining 10–15% of its revenue." Novelty Resp. at 17. The Suspension Order does not, however, prevent Novelty from obtaining product from any one of the numerous other manufacturers of these products and thus does not preclude Novelty "from pursuing its core business." PDK Labs. v. Reno, 134 F.Supp.2d at 33. As for Novelty's claimed property interest, the PDK court held that "[n]othing in the overall scheme of the [Chemical Diversion and Trafficking Act] justifies the finding that [a manufacturer] has an entitlement to import List I chemicals." Id. at 33. The same is equally true with respect to a distributor. I therefore conclude that construing the statute to deny Novelty a hearing—as Congress intended—does not raise any constitutional question.6

Order

Pursuant to the authority vested in me by 28 CFR 0.100(b) & 0.104, I hereby order that the request of Novelty, Inc., for a hearing to challenge the Order to Suspend Shipment issued to Spirit Pharmaceuticals, Inc., be, and it hereby is, denied. I further order that the proceedings in this matter be, and they

³ As our regulation makes clear, a manufacturer is an importer only when the registered importer acts as the manufacturer's agent in importing the chemical and the manufacturer is the principal party in interest in the transaction. When an importer proposes to import a listed chemical for its own account, its future customers are not importers.

⁴Novelty also argues that importers "have little interest or incentive to do battle in a hearing with DEA," and that "the importer has no way of discerning the intricacies of its client's business." Novelty's Resp. at 8 n.3. Novelty ignores, however, that in an agency relationship, the "principal has the right to control the conduct of the agent with respect to matters entrusted to him." 1 American Law Institute, Restatement (Second) of Agency § 14, at 60 (1958). Presumably, the principal's right to control its agent should be sufficient to induce the agent to request a hearing, at which the manufacturer would intervene and litigate the basis for the order.

⁵ For the same reasons, I also reject Novelty's contention that it is entitled to a hearing because it is within the zone of interests protected by section 971

⁶ Novelty also argues that "DEA's refusal to grant [it] a hearing violates the DEA Administrator's oath of office to uphold the Constitution and the laws of the United States," Novelty Resp. at 19, and kindly reminds me that "[v]iolation of the oath is an offense punishable by judicial action." *Id.* at 20. Novelty can be assured that both I and the Administrator fully appreciate our obligation to faithfully discharge the duties of our offices.

hereby are, terminated. This Order is effectively immediately.

Dated: August 17, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7-16936 Filed 8-27-07; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

August 22, 2007.

The Department of Labor has submitted the following public information collection requests (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). Copies of each ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at http://www.reginfo.gov/ public/do/PRAMain or by contacting Darrin King on 202-693-4129 (this is not a toll-free number)/e-mail: king.darrin@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: Carolyn Lovett, OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202-395-7316/Fax: 202-395-6974 (these are not a toll-free numbers), Email: OIRA_submission@omb.eop.gov within 30 days from the date of this publication in the Federal Register. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Âgency: Employment Standards Administration.

Type of Review: Revision and Extension of currently approved collection.

Title: Employer's First Report of Injury or Occupational Disease; Physician's Report on Impairment of Vision; and Employer's Supplementary Report of Accident or Occupational Illness.

OMB Control Number: 1215–0031. Estimated Number of Respondents: 26,381.

Estimated Total Burden Hours: 6,595. Affected Public: Private Sector: Business or other for-profits.

Description: The Forms LS–202 and LS–210 are used to report injuries, periods of disability, and medical treatment under the Longshore and Harbor Workers' Compensation Act.

Agency: Employment Standards Administration.

Type of Review: Revision and Extension of currently approved collection.

Title: Operator Controversion, Operator Response, Operator Response to Schedule for Submission of Additional Evidence, and Operator Response to Notice of Claim.

OMB Control Number: 1215–0058. Estimated Number of Respondents: 8.000.

Estimated Total Burden Hours: 2,333. Affected Public: Private Sector: Business or other for-profits.

Description: The Forms CM-2790 & CM-2970a are used for claims filed after January 19, 2001 and indicate that the coal mine operator will submit additional evidence or respond to the notice of claim.

Darrin A. King,

Acting Departmental Clearance Officer. [FR Doc. E7–16961 Filed 8–27–07; 8:45 am] BILLING CODE 4510–CF–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Renewal of Advisory Committee on Electronic Records Archives

This notice is published in accordance with the provisions of section 9(a)(2) of the Federal Advisory

Committee Act (Pub. L. 92–463, 5 U.S.C., App.) and advises of the renewal of the National Archives and Records Administration's (NARA) Advisory Committee on Electronic Records Archives. In accordance with Office of Management and Budget (OMB) Circular A–135, OMB approved the inclusion of the Advisory Committee on Electronic Records Archives in NARA's ceiling of discretionary advisory committees.

NARA has determined that the renewal of the Advisory Committee on Electronic Records Archives is in the public interest due to the expertise and valuable advice the Committee members provide on technical, mission, and service issues related to the Electronic Records Archives (ERA). NARA will use the Committee's recommendations on issues related to the development, implementation, and use of the ERA system. NARA's Committee Management Officer is Mary Ann Hadyka. She can be reached at 301–837–1782.

Dated: August 21, 2007.

Mary Ann Hadyka,

Committee Management Officer. [FR Doc. E7–16991 Filed 8–27–07; 8:45 am] BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation. **ACTION:** Notice of permit modification received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of a requested permit modification.

DATES: Interested parties are invited to

submit written data, comments, or views with respect to this permit application by September 27, 2007. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.