

- whether the information will have practical utility;
- Evaluate the accuracy of the agencies 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.

Overview of This Information Collection

(1) Type of Information Collection: Extension of a currently approved collection.

(2) Title of the Form/Collection: ATF F 5630.5R, NFA Special Tax Renewal Registration and Return, ATF F 5630.5RC, NFA Special Tax Location Registration Listing, ATF F 5630.7, NFA Special Tax Registration and Return National Firearms Act.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number: ATF F 5630.5R, ATF F 5630.5RC, ATF F 5630.7. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Other: None. ATF F 5630.7, NFA Special Tax Registration and Return National Firearms Act is completed and returned by businesses that are subject to Special Occupation Taxes under the National Firearms Act for either initial tax payment or business information changes. This form serves as both a return and a business registration. ATF F 5630.5R, NFA Special Tax Renewal Registration and Return and ATF F 5630.5RC, NFA Special Tax Location Registration Listing are preprinted forms sent to taxpayers who Special Occupational Taxes under the National Firearms Act. Taxpayers validate/correct the information and send the forms back with payment for the applicable tax year.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 2,800 taxpayers will complete forms ATF F 5630.5R and ATF F 5630.5RC in approximately 20 minutes (10 minutes for each form). It is also estimated that

200 new taxpayers will complete ATF F 5630.7 in its entirety in approximately 15 minutes. The total number of respondents for this information collection is 3,000.

(6) An estimate of the total public burden (in hours) associated with the collection: The total burden for ATF F 5630.5R and ATF F 5630.5RC is 933 hours. The total burden for ATF F 5630.7 is 50 hours. The estimated total public burden associated with this information collection is 983 hours.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: August 22, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, Department of Justice.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 20, 2007, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78664, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Aminorex (1585)	I
4-Methylaminorex (cis isomer) (1590)	I
Gamma Hydroxybutyric acid (2010)	I
Methaqualone (2565)	I
Alpha-Ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
3,4,5-Trimethoxyamphetamine (7390)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I

Drug	Schedule
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
Alpha-methyltryptamine (7432)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Acetyldihydrocodeine (9051)	I
Benzylmorphine (9052)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Heroin (9200)	I
Hydromorfinol (9301)	I
Methyldihydromorphine (9304)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Pholcodine (9314)	I
Acetylmethadol (9601)	I
Allylprodine (9602)	I
Alphacetylmethadol except levopropylisomer (9603)	I
Alphameprodine (9604)	I
Alphamethadol (9605)	I
Betacetylmethadol (9607)	I
Betameprodine (9608)	I
Betamethadol (9609)	I
Betaprodine (9611)	I
Hydroxypethidine (9627)	I
Noracetylmethadol (9633)	I
Norlevorphanol (9634)	I
Normethadone (9635)	I
Trimeperidine (9646)	I
Phenomorphan (9647)	I
Para-Fluorofentanyl (9812)	I
3-Methylfentanyl (9813)	I
Alpha-Methylfentanyl (9814)	I
Acetyl-alpha-methylfentanyl (9815)	I
Beta-hydroxyfentanyl (9830)	I
Beta-hydroxy-3-methylfentanyl (9831)	I
Alpha-Methylthiofentanyl (9832)	I
3-Methylthiofentanyl (9833)	I
Thiofentanyl (9835)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Ambobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II

Drug	Schedule
1-Piperidinocyclohexane carbonitrile (8603)	II
Alphaprodine (9010)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylcegonine (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-alphaacetylmethadol (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.

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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 non-traditional (or gray-market) retailers, which include such entities as gas stations, convenience stores, mini-marts, 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 widely-advertised and are distributed to 'non-traditional' 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).¹ In

¹ In 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).