community, without linkage to specific conduct by a proposed registrant, is also at odds with analogous Agency precedent. For example, in *East Main Street Pharmacy,* 75 FR 66,149 (DEA 2010), the Agency rejected as irrelevant evidence that the respondent was located in a high crime area to include the fact that the owner-pharmacist carried a gun. The ''principle issue * * * was whether [the r]espondent was dispensing controlled-substance prescriptions which it either knew or had reason to know lacked a legitimate medical purpose and were issued outside the usual course of professional practice.'' *Id.* at 66,155. In other contexts, the Agency has also rejected an expansive reading of the public interest factors, focusing instead on specific conduct or acts by the registrant. ''The public interest standard of 21 U.S.C. [§] 823(f) is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider * * * which focus primarily on the acts committed by a practitioner.'' *Gregory D. Owens, D.D.S.* 74 FR 36,751, 36,757 (DEA 2009).

In the instant case, the Government's evidence of a serious diversion problem in Ohio was credibly established through the testimony of DI Kresnak, but there is simply no credible evidence of record establishing that Respondent will be a contributing source of drug diversion through any acts or omissions by any owner-member or employee of Respondent. As the record evidence reveals, Respondent's Ohio-licensed pharmacist-in-charge has over thirty years of unblemished experience and expects to adhere to standards of dispensing above those required by existing law and regulation.

The Government's further argument that the size of the ''walk-in vault'' alone supports a finding by a preponderance of the evidence ''that the pharmacy intends to do a large business in controlled substances and this, coupled with the diversion problem that exists in southern Ohio, would not be in the public interest'' [32] is equally unpersuasive. The credible testimony at hearing from Respondent's pharmacist, Mr. James, established that he did not know the volume of controlled substances that would be kept at the pharmacy, since there was no way to know that until the pharmacy was operational. (Tr. 50.) Similarly, Mr. Hillman testified that he did not know the volume of expected sales of controlled substances until the business was operational. (Tr. 100.) He credibly explained that he believed there was enough business in the area for the pharmacy to be successful, noting that if ''there's not enough business, I'll go broke.'' (Tr. 122.)

Although Respondent did not establish a specific quantity of controlled substances expected to be sold once operational, it had no burden to do so. 21 CFR 1301.44(d). The Government's argument that a walk-in vault constitutes de facto evidence of the volume of controlled substances Respondent will handle, and further proof that this will contribute to the diversion problem in southern Ohio is at best speculative. ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith* v. *Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt* v. *Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)). More importantly, the Government did not prove by a preponderance of evidence at hearing that Respondent's handling of controlled substances, whether in a large volume or small, would be contrary to applicable state and federal law. In fact, testimony from DI Kresnak pertaining to various precautions Respondent's pharmacist intended to take to prevent the diversion of controlled substances were ''above what DEA requires.'' (Tr. 148.) DI Kresnak also testified that there was nothing wrong with the kind of security measures taken by Respondent to protect against diversion. (Tr. 147.)

After careful consideration of the entire record, I find that the Government has failed to establish by a preponderance of the evidence any acts or demonstrable conduct by any member or employee of Respondent, that would support a finding by substantial evidence that Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). I therefore find that Respondent's registration under Factors Two, Four, and Five would not be inconsistent with the public interest.

V. Conclusion and Recommendation

I find that the Government has not established by substantial evidence a prima facie case in support of denying Respondent's application for a DEA COR as a retail pharmacy. The Government has failed to demonstrate by a preponderance of the evidence that such registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f). Accordingly, I recommend approval of Respondent's application for a DEA COR as a retail pharmacy pursuant to 21 U.S.C. 823(f).

Dated: December 15, 2011.

Timothy D. Wing,
Administrative Law Judge.

[FR Doc. 2012–19221 Filed 8–6–12; 8:45 am]

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[32] Gov't Br. at 5.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; SA INTL GMBH C/O., Sigma Aldrich Co. LLC

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on May 2, 2012, SA INTL GMBH C/O., Sigma Aldrich Co. LLC., 3500 Dekalb Street, St. Louis, Missouri 63118, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
Ethylamphetamine (1475)	I
Aminorex (1585)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4–Bromo-2,5-dimethoxyamphetamine (7391)	I
4–Bromo-2,5-dimethoxyphenethylamine (7392)	I
4–Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5–Dimethoxyamphetamine (7396)	I
3,4–Methylenedioxyamphetamine (7400)	I
N–Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4–Methylenedioxy-N-ethylamphetamine (7404)	I
3,4–Methylenedioxymethamphetamine (MDMA) (7405)	I
4–Methoxyamphetamine (7411)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
1-[1-(2–Thienyl)cyclohexyl]piperidine (7470)	I
N–Benzylpiperazine (BZP) (7493)	I
Heroin (9200)	I
Normorphine (9313)	I
Etonitazene (9624)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium, powdered (9639)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis.

In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for this drug code is authorized for this registration.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

In regard to the non-narcotic raw material, any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 6, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic classes of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: July 30, 2012.

Joseph T. Rannazzisi,

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

[FR Doc. 2012–19191 Filed 8–6–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Lipomed

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on June 13, 2012, Lipomed, One Broadway, Cambridge, Massachusetts 02142, made application by letter to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
1-Piperidinocyclohexanecarbonitrile (8603)	II

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 U.S.C. 952(a)(2)(B) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 6, 2012

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: July 30, 2012.

Joseph T. Rannazzisi,

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

[FR Doc. 2012–19196 Filed 8–6–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Cerilliant Corporation

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on July 6, 2012, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
4-Methyl-N-methylcathinone (1248)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Fenethylline (1503)	I
Gamma Hydroxybutyric Acid (2010)	I
JWH–018 (7118)	I
JWH–073 (7173)	I
JWH–200 (7200)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
CP–47497 (7297)	I
CP–47497 C8 Homologue (7298)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348)	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
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxyamphetamine (7400)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N-N-dimethyltryptamine (7431)	I
Alpha-methyltryptamine (7432)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I