

permitted establishment during the inspection.” *Id.* r.64F–12.012(6)(b).

As the forgoing demonstrates, Respondent failed to comply with a variety of federal and state controlled substance laws and regulations as well as state pharmacy laws and rules. As for the latter, while these laws and rules are applicable to all prescription drugs and not just controlled substances, these violations are properly considered under factor five as other conduct which may threaten public health and safety for two reasons. First, the violations involved the dispensing of controlled substances. Second, violations of state pharmacy rules and food and drug safety provisions are relevant (even if the conduct did not involve controlled substances) in assessing the likelihood of an applicant’s future compliance with the CSA. *See Paul Weir Battershell*, 76 FR 44359, 44368 (2011); *Wonderyears, Inc.*, 74 FR 457, 458 n.2 (2009).

On the other hand, the record in this matter establishes that Respondent’s record of non-compliance with the CSA was limited to a seventeen-day period. While it may be that this conduct would have continued but for the DOH inspection, Respondent stated in her letter that following the inspection she terminated her relationship at the clinic and there is no evidence disputing this.¹⁰

It is also acknowledged that Respondent’s letter demonstrated some degree of contrition. However, I do not find credible Respondent’s numerous assertions that she believed that JF was a licensed pharmacist. In addition, while Respondent emphasizes that her employment at Mercy “was the first time in [her] professional career that [she] had been a dispensing practitioner,” and that she “was completely unaware that [she] had run afoul of the laws governing dispensing practitioners,” GX 6, at 1, ignorance of the law is no excuse. *See Patrick W. Stodola*, 74 FR 20727, 20735 (2009) (quoting *Hageseth v. Superior Ct.*, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007) (a “licensed health care provider cannot ‘reasonably claim ignorance’ of state provisions regulating medical practice”). Indeed, in her statement, Respondent explained that at the time she took her position, she “was doing

due diligence” on two internal medicine groups. One must wonder why she did not make a similar effort to familiarize herself with the various requirements applicable to the dispensing of controlled substances under both the CSA and state laws, as well as the manner in which Mercy’s business was operated.

DEA can, of course, consider deterrence interests in determining whether to grant or deny an application. *See Joseph Gaudio*, 74 FR 10083, 10094 (2009) (citing *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007)). As I have previously explained, “even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.” *Gaudio*, 74 FR at 10094 (quoting *Southwood*, 72 FR at 36504 (citing *Butz v. Glover Livestock Commission Co., Inc.*, 411 U.S. 182, 187–88 (1973)). “The ‘[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA’s purpose of protecting the public interest,” which is manifested in both 21 U.S.C. 823(f) and 824(a)(4). *Gaudio*, 74 FR at 10094 (quoting 72 FR at 36504).

All registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules. Moreover, those registrants who contemplate employment in circumstances in which their registrations are used to operate clinics owned by non-registrants need to recognize that there are serious consequences for failing to comply with the Act and that they remain strictly liable for all activities which occur under the authority of their registrations. *See, e.g., Robert Raymond Reppy*, 76 FR 61154, 61157–58 (2011); *Paul Weir Battershell*, 76 FR 44359, 44368 (2011); *Paul Volkman*, 73 FR 30630, 30643–44 (2008), *pet. for rev. denied* 567 F.3d 215 (6th Cir. 2009). It is no excuse that the practitioner is not the employer of those persons who perform controlled substance activities and lacks the power to hire or fire the employee.

Accordingly, having considered the record as a whole, I conclude that Respondent has not sufficiently demonstrated why she should be entrusted with a new registration. I therefore hold that granting Respondent’s application would, at this time, be “inconsistent with the public interest.” 21 U.S.C. 823(f). However, given that the violations proved on this record were limited in both their scope and duration, a new application should be given favorable consideration if submitted no earlier than one year from

the date of this Order, provided that Respondent meets the following conditions: (1) That she does not engage in any further misconduct, and (2) that she takes a certified Continuing Medical Education course on controlled substance handling and dispensing.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Sigrid Sanchez, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This order is effective July 31, 2013

Dated: June 20, 2013.

Michele M. Leonhart,
Administrator.

[FR Doc. 2013–15706 Filed 6–28–13; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

**Importer of Controlled Substances;
Notice of Application; Mylan
Pharmaceuticals, Inc.**

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on March 8, 2013, Mylan Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Remifentanyl (9739)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company’s own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled

¹⁰ Hanging over this matter is the dark cloud of evidence that Mercy was a pain clinic and that Respondent was seeing some 60 to 65 patients a day to whom she was prescribing such drugs as oxycodone 30mg and 15mg, muscle relaxants such as carisoprodol, and Xanax (alprazolam). However, evidence which creates only a suspicion of wrongdoing does not constitute substantial evidence. *See NLRB v. Columbian Enameling & Stamping Co., Inc.*, 306 U.S. 292, 299–300 (1939). I therefore do not rely on it.

substances listed in schedule II, which falls 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 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than July 31, 2013.

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 substances 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: June 18, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–15587 Filed 6–28–13; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Akorn, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 9, 2013, Akorn, Inc., 1222 W. Grand Avenue, Decatur, Illinois 62522, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Remifentanyl (9739), a basic class of controlled substance listed in schedule II.

The company plans to import Remifentanyl in bulk for use in dosage-form manufacturing.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture

such basic class of controlled substance 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 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than July 31, 2013.

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: June 18, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–15600 Filed 6–28–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Application, Boehringer Ingelheim Chemicals

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 31, 2013, Boehringer Ingelheim Chemicals, 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to bulk manufacture amphetamine.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedule II, which falls 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 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than July 31, 2013.

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 substances in schedule 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: June 18, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–15602 Filed 6–28–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice Of Registration; Mallinckrodt, LLC.

By Notice dated February 8, 2013, and published in the **Federal Register** on February 21, 2013, 78 FR 12101, Mallinckrodt, LLC., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances: