

Therefore, pursuant to 21 U.S.C. § 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: July 19, 2011.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 11, 2011, and published in the **Federal Register** on April 19, 2011, 76 FR 21916, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 4-Anilino-N-Phenethyl-4-Piperidine (8333), a basic class of controlled substance listed in schedule II.

The company plans to use this controlled substance in the manufacture of another controlled substance.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Mallinckrodt, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: July 19, 2011.

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. 09-51]

Paul Weir Battershell, N.P.; Suspension Of Registration

On May 8, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Paul Weir Battershell, N.P. ("Respondent"), of Caldwell and Meridian, Idaho. The Show Cause Order proposed the revocation of Respondent's DEA Certificates of Registration MB1090670 (for his Caldwell registered location) and MB1294711 (for his Meridian registered location), and the denial of any pending applications to renew or modify either registration, on the ground that his "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that from "July 2005 through at least August 2006," Respondent "prescribed and dispensed Human Growth Hormone and controlled substances, including anabolic steroids, to individuals for no legitimate medical purpose and outside the course of professional practice" in violation of 21 U.S.C. §§ 333(e) and 841(a)(1), as well as 21 CFR 1306.04(a). *Id.* at 1.

The Order further alleged that from September 2005 through August 2006, Respondent "failed to maintain proper security over [his] controlled substances by not maintaining a proper key control system, failing to maintain adequate supervision over fellow employees who handle[d] [his] controlled substances and failing to monitor the distribution of [his] controlled substances in violation of 21 CFR 1301.71." *Id.* The Order also alleged that "[i]n August 2005," Respondent "failed to record the transfer of another practitioner's controlled substances into [his] inventory, when that practitioner left the clinic where [Respondent] was employed," *id.* at 2 (citing 21 U.S.C. § 827(a)(3) and 21 CFR 1304.21); that "[i]n November and December 2005," he "failed to keep records of controlled substances [he] received, specifically Phentermine 30 mg"; and that "during calendar year 2005," Respondent further "failed to properly record the date on [his] dispensing records." *Id.* (citing 21 U.S.C. § 827(a)(3) and 21 CFR 1304.21 & 1304.22).

Finally, the Show Cause Order alleged that "[d]uring 2005 and 2006," Respondent "accepted controlled

substances from non-DEA registered sources (patients) in violation of 21 U.S.C. § 844(a) and redistributed those illicitly obtained controlled substances to other patients in violation of 21 U.S.C. § 841(a)(1)." *Id.*

On June 5, 2009, counsel for Respondent timely requested a hearing, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). ALJ Ex. 2. Following pre-hearing procedures, an ALJ conducted a hearing in Boise, Idaho on December 1-2, 2009. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted post-hearing briefs.

On April 9, 2010, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ, after considering the five public interest factors, *see* 21 U.S.C. § 823(f), recommended that Respondent be granted a restricted registration and be admonished.

As to the first factor—the recommendation of the appropriate state licensing board—the ALJ found that while the Idaho Board of Pharmacy (Board) had previously placed Respondent on probation, there was "no pending action[] against" him and "the Board has made no recommendations with regards to his registration." ALJ at 34. As to the second factor—Respondent's experience in dispensing controlled substances—the ALJ found that "Respondent's actions as well as his own statements suggest that at the time of these infractions in 2006, [Respondent] was inexperienced, or at least unaware of numerous regulations relating to the security and inventory requirements for controlled substances under the [Controlled Substances Act]." *Id.* at 34-35. She further found that while Respondent claimed that he had "sought guidance but did not receive it * * * in some instances, when [he] did receive such guidance, he was still unable to follow it." *Id.* at 35. The ALJ thus concluded that "the record demonstrates that [Respondent's] past practices demonstrate a lack of knowledgeable experience in handling controlled substances." *Id.*

As to factor three—Respondent's conviction record for offenses related to the distribution or dispensing of controlled substances—the ALJ found that the "record contains no evidence of any convictions related to the handling of controlled substances." *Id.* The ALJ thus concluded that "this factor does not fall in favor of revocation." *Id.*

With respect to the fourth factor—Respondent's compliance with applicable State, Federal or local laws related to controlled substances—the