

applicable state board had taken action which rendered the practitioner without state authority. *See, e.g., Morgan*, 78 FR at 61973–74 (upholding ALJ’s granting of government motion for summary disposition based on physician’s loss of state authority which occurred post-hearing and holding that due process did not require amending the show cause order; motion for summary disposition provided adequate notice); *Roy E. Berkowitz*, 74 FR 36758, 36759–60 (2009) (rejecting argument that revocation based on loss of state authority was improper based on board action not alleged in the Show Cause Order; “The rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence. The Government’s failure to file an amended Show Cause Order alleging that Respondent’s state CDS license had expired does not render the proceeding fundamentally unfair.”). *See also Kamal Tiwari, et al.*, 76 FR 71604 (2011); *Silviu Ziscovici*, 76 FR 71370 (2011); *Deanwood Pharmacy*, 68 FR 41662 (2003); *Michael D. Jackson*, 68 FR 24760; *Robert P. Doughton*, 65 FR 30614 (2000); *Michael G. Dolin*, 65 FR 5661 (2000).

Here, by virtue of my order directing the parties to address the issues of: (1) Whether Respondent currently possesses authority to dispense controlled substances, and (2) if Respondent does not possess such authority, what consequence attaches for this proceeding, Respondent was provided with a meaningful opportunity to show that he retains his state authority. Of consequence, Respondent does not dispute that he no longer holds authority to dispense controlled substances under Michigan law, this being the only material fact that must be adjudicated in determining whether Respondent’s registrations can be revoked and his applications denied under 21 U.S.C. 823(f) and 824(a)(3) as well as the Agency’s precedent. That there are no dispositive legal arguments to preclude my reliance on this basis as an additional ground to revoke Respondent’s registrations and to deny his applications is not the result of constitutionally inadequate notice. Rather, it is the result of the statute itself, which makes the possession of state authority mandatory for obtaining and maintaining a registration and renders irrelevant the issues of acceptance of responsibility and the adequacy of remedial measures. Accordingly, I will order that Respondent’s registrations be revoked and that his pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 28 CFR 0.100(b), I order that DEA Certificates of Registration BA7776353 and FA2278201 issued to Hatem M. Ataya, M.D., be, and they hereby are, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that all pending applications submitted by Hatem M. Ataya, M.D. be, and they hereby are, denied. This Order is effective immediately.⁵⁶

Dated: February 10, 2016.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Mallinckrodt, LLC

ACTION: Notice of registration.

SUMMARY: Mallinckrodt, LLC applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mallinckrodt, LLC registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated September 16, 2015, and published in the **Federal Register** on September 23, 2015, 80 FR 57388, Mallinckrodt, LLC, 3600 North Second Street, Saint Louis, Missouri 63147 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, LLC to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the

⁵⁶ Based on the extensive findings of egregious misconduct by Respondent, I conclude that the public interest necessitates that this Order be effective immediately.

company’s compliance with state and local laws, and reviewing the company’s background and history.

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 following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) (9821).	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333).	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254) ...	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture bulk active pharmaceutical ingredients (API) for distribution to its customers.

Dated: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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