



**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**Allied Medical Products, Inc.;
Decision and Order**

I. INTRODUCTION

On April 21, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Allied Medical Products, Inc., of Santa Ana, California (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 6. The OSC proposed the revocation of Registrant's DEA Certificate of Registration, number RA0235146, alleging that its registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(f)).

On June 2, 2025, the Government submitted a RFAA to the Administrator requesting that the Agency¹ issue a default final order revoking Registrant's registration. RFAA, at 1, 4-5. After carefully reviewing the entire record and conducting the analysis as set forth in detail below, the Agency grants the Government's request for final agency action and revokes Registrant's registration. As a preliminary matter, this Decision addresses whether Registrant is in default and finds that it is. Thereafter, this Decision makes specific factual findings on the alleged violations as set forth in the OSC, including Registrant's failure to perform due diligence on a customer before distributing controlled substances to that customer and allowing a customer to purchase controlled substances using Registrant's account information. Next, this Decision considers whether Registrant's registration is inconsistent with the public interest and finds that it is. Lastly, this Decision determines that the appropriate sanction is revocation of Registrant's registration.

II. DEFAULT DETERMINATION

¹ The Controlled Substances Act (CSA) delegates authority to the Attorney General, who has delegated it to the Administrator of DEA (the Agency). 28 CFR 0.100.

The Government’s RFAA included a declaration by a DEA Diversion Investigator (DI), in which DI declared under penalty of perjury that on April 24, 2025, he traveled to Registrant’s registered location and “personally served a copy of the OSC upon an authorized representative” of Registrant. RFAAX 2, at 1. The declaration states that the authorized representative signed a Form DEA-12 confirming receipt of the OSC. *Id.* at 2-3. A copy of the Form DEA-12 is attached to DI’s declaration. *Id.* at 3. Accordingly, due to personal service of the OSC upon a representative of Registrant, who, according to DI’s declaration was authorized to be served the OSC on Registrant’s behalf, the Agency finds that due process notice requirements have been satisfied.²

Under 21 CFR 1301.43, a registrant or applicant entitled to a hearing who fails to file a timely hearing request “within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default” unless “good cause” is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a demonstration of good cause, a registrant or applicant who fails to timely file an answer also is “deemed to have waived their right to a hearing and to be in default.” 21 CFR 1301.43(c)(2).

The OSC notified Registrant of its right to file a written request for a hearing and an answer, and that if it failed to file such a request and answer, it would be deemed to have waived its right to a hearing and be in default. RFAAX 1, at 5 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, file an answer, or respond to the OSC in any way. RFAA, at 1-2. Accordingly, Registrant is in default. 21 CFR 1301.43(c)(1).

“A default, unless excused, shall be deemed to constitute a waiver of [Registrant’s] right to a hearing and an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

² The declaration omits the statutory language: “. . . the foregoing is true and correct.” 28 U.S.C. 1746(2). Nevertheless, the declaration begins with the statement, “I, [DI], under penalty of perjury, declare and state the following . . .,” and DI’s claim of personally serving a representative of Registrant, and that the representative was authorized to receive service of the OSC on Registrant’s behalf, is uncontroverted. RFAAX 2, at 1; *see also David Payne, M.D.*, 90 Fed. Reg. 46,925, 46,925 n.2 (2025); *Immacula Michel, M.D.*, 90 Fed. Reg. 45,813, 45,813 n.3 (2025).

Because Registrant is in default and has not moved to excuse the default, the Agency finds that Registrant has admitted to the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

Further, “[i]n the event that [a registrant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.” 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant’s default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1, 5; *see also* 21 CFR 1316.67.

III. PUBLIC INTEREST DETERMINATION

A. Overview of Law

Congress enacted the Controlled Substances Act (CSA) “to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). A particular concern of Congress was “the need to prevent the diversion of drugs from legitimate to illicit channels,” and it “devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Id.* at 12-13.

The CSA’s requirements under this closed regulatory system include that “[e]very person who . . . distributes any controlled substance . . . , or who proposes to engage in the . . . distribution of any controlled substance . . . , shall obtain annually a registration issued by [DEA].” 21 U.S.C. 822(a)(1); *see also Gonzales v. Raich*, 545 U.S. at 27-28. To protect the American people and ensure compliance with the CSA, Congress empowered the Agency to deny, suspend, or revoke a registration if it would be inconsistent with the public interest.³ 21 U.S.C. 823(f); 21 U.S.C. 824(a)(4); *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006).

³ A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing “otherwise would mean that all applications would have to be granted only to be revoked the next day” *Robert Wayne Locklear, M.D.*, 86 Fed. Reg. 33,738, 33,744-45 (2021) (collecting cases).

In determining whether Registrant's registration is inconsistent with the public interest, the Agency analyzes five statutorily established public interest factors. *Gonzales v. Oregon*, 546 U.S. at 251; 21 U.S.C. 823(f)(1)-(5). The five factors for distributors are:

- (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) past experience in the distribution of controlled substances; and
- (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(f).

These five public interest factors are considered in the disjunctive. *Morris & Dickson Co., LLC*, 88 Fed. Reg. 34,523, 34,533 (2023); *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418, 55,472-73 (2015); *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,497 (2007); *Holloway Distrib.*, 72 Fed. Reg. 42,118, 42,122 (2007). Any one factor, or combination of factors, may be decisive, and the Agency "may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied." *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 Fed. Reg. 33,207, 33,208 (2007)); see also *Penick Corp. v. Drug Enf't Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007); *Morris & Dickson*, 88 Fed. Reg. at 34,533; *Masters*, 80 Fed. Reg. at 55,472-73; *Southwood*, 72 Fed. Reg. at 36,497-98; *Holloway*, 72 Fed. Reg. at 42,122.

Moreover, while the Agency is required to consider each of the factors, it "need not make explicit findings as to each one." *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U. S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Morris & Dickson*, 88 Fed. Reg. at 34,533; *Masters*, 80 Fed. Reg. at 55,473; *Southwood*, 72 Fed. Reg. at 36,497-98; *Holloway*, 72 Fed. Reg. at 42,122. "In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how

many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009). Accordingly, as the Eleventh Circuit has recognized, Agency decisions have explained that findings under a single factor can support a sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Pharmacy Doctor Enters., Inc. v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 729 (11th Cir. 2019).

In this matter, the Government's evidence is confined to factor one. RFAAX 1, at 2. Evidence is considered under factor one when it concerns the maintenance of effective controls against diversion of controlled substances into other than legitimate channels. 21 U.S.C. 823(f)(1). To determine whether Registrant's registration is in the public interest, the Agency has evaluated the Government's allegations of Registrant's failure to maintain effective controls against diversion, including failure to conduct due diligence on a customer and allowing a customer to purchase controlled substances using Registrant's account.

The Government has the burden of proof in this proceeding, *Morris & Dickson*, 88 Fed. Reg. at 34,533 (citing 21 CFR 1301.44(e)), and the Agency must make its findings based on "substantial [record] evidence." 5 U.S.C. 556(d); *see also* 5 U.S.C. 706(2)(E); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that revoking Registrant's registration is in the public interest, then the burden shifts to Registrant to rebut the Government's case. *Morris & Dickson*, 88 Fed. Reg. at 34,538; *Masters*, 80 Fed. Reg. at 55,473; *Southwood*, 72 Fed. Reg. at 36,498.

B. Public Interest Factor One: Effective Controls Against Diversion

In determining whether a distributor's registration is inconsistent with the public interest, the CSA requires the Agency to consider the distributor's "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. 823(f)(1); RFAAX 1, at 2. Likewise, DEA rules require all

registrants, including distributors, to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 CFR 1301.71(a); RFAAX 1, at 2.

Part of the requirement to maintain effective controls against diversion is the “duty to perform due diligence on [the distributor’s] customers.” *Masters*, 80 Fed. Reg. at 55,477 (citing 21 U.S.C. 823 and 21 CFR 1301.71(a)); RFAAX 1, at 2. A distributor “has an affirmative duty to protect against diversion by knowing its customers and the nature of their . . . sales.” *Holloway*, 72 Fed. Reg. at 42,124; RFAAX 1, at 2. A distributor’s duty to know its customers includes “conduct[ing] a reasonable investigation ‘to determine the nature of a potential customer’s business before it’ sells to the customer, and the distributor cannot ignore ‘information which raise[s] serious doubt as to the legality of [a potential or existing customer’s] business practices.’” *Masters*, 80 Fed. Reg. at 55,477 (quoting *Southwood*, 72 Fed. Reg. at 36,498); RFAAX 1, at 2. “Moreover, the obligation to perform due diligence is ongoing throughout the course of a distributor’s relationship with its customer.” *Id.* (citing *Southwood*, 72 Fed. Reg. at 36,498-500); RFAAX 1, at 2.

Here, the Agency finds that, in light of Registrant’s default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted to each of the following facts.⁴

On August 3, 2023, DEA requested Registrant’s due diligence files for Salus Medical, LLC (Salus), a mid-level distributor located in Phoenix, Arizona, that was registered with DEA. RFAAX 1, at 4. Although Registrant had been distributing controlled substances to Salus since approximately June 2021, Registrant failed to maintain or conduct any meaningful due diligence prior to establishing Salus as a customer or distributing controlled substances to Salus. *Id.*

⁴ According to the CSA, “[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.” 21 U.S.C. 877. Here, where Registrant is found to be in default, all the factual allegations in the OSC are deemed to be admitted. These uncontested and deemed admitted facts constitute evidence that exceeds the “substantial evidence” standard of 21 U.S.C. 877; it is unrebutted evidence.

On September 7, 2023, Registrant provided DEA with limited documentation purporting to constitute Registrant's due diligence regarding Salus. *Id.* The documentation provided showed a signature/creation date of August 30, 2023—approximately one month after DEA requested information from Registrant and over two years after Registrant established Salus as a customer. *Id.*

Additionally, from at least June 2021 until at least October 2022, Registrant knowingly provided its account information and password to employees of Salus, allowing Salus to obtain direct access to Registrant's purchasing authority. RFAAX 1, at 4. This conduct allowed Salus to directly purchase controlled substances through Registrant's account, misleading suppliers with respect to the actual purchasing entity. *Id.* By providing the account and password information, and without conducting adequate due diligence, Registrant facilitated the unlawful distribution of approximately 3,221 437-ml bottles of promethazine with codeine⁵ 6.25 mg.⁶ *Id.*

Therefore, the Agency finds substantial record evidence that Registrant failed to maintain effective controls against diversion by: failing to conduct any due diligence (i.e., failing to know its customer) prior to distributing controlled substances to Salus; failing to conduct any ongoing due diligence on Salus while it was distributing controlled substances to Salus from approximately June 2021 to August 2023; and allowing Salus to purchase controlled substances using Registrant's account information. RFAAX 1, at 4; 21 U.S.C. 823(f)(1); 21 CFR 1301.71(a); *Morris & Dickson*, 88 Fed. Reg. at 34,526; *Masters*, 80 Fed. Reg. at 55,477; *Holloway*, 72 Fed. Reg. at 42,124; *Southwood*, 72 Fed. Reg. at 36,498-500.

C. Public Interest Conclusion

While the Agency considered all the public interest factors of 21 U.S.C. 823(f),⁷ its

⁵ This combination of promethazine with codeine falls into Schedule V. 21 CFR 1308.15(c); RFAA, at 4.

⁶ In October 2024, the owners of Salus pleaded guilty in the Southern District of Texas to one count of conspiracy to unlawfully distribute and dispense controlled substances in connection with a scheme to distribute over 18.6 million dosage units of commonly diverted controlled substances. RFAAX 1, at 5. Following its conviction, on October 16, 2024, Salus surrendered for cause its DEA registration. *Id.*

⁷ The lack of evidence regarding the other public interest factors is not dispositive, and weighs neither for nor against a finding that Registrant's registration is inconsistent with the public interest. *See, e.g., Tracy Amerson-Rivers, A.P.R.N.*, 90 Fed. Reg. 48,884, 48,886 n.10 (2025).

findings are relevant to factor one (maintenance of effective controls against diversion of controlled substances into other than legitimate channels). 21 U.S.C. 823(f)(1); 21 CFR 1301.71(a); *Masters*, 80 Fed. Reg. at 55,473, 55,477; *Southwood*, 72 Fed. Reg. at 36,498-500. Here, the Agency found substantial record evidence that Registrant failed to conduct due diligence on a customer prior to and while it was distributing controlled substances to that customer for over two years. *See supra* Section III.B. The Agency further found substantial record evidence that Registrant allowed another entity to purchase controlled substances using Registrant's account information. *Id.* Registrant's proven misconduct, therefore, establishes that it failed to maintain effective controls against diversion of controlled substances. 21 U.S.C. 823(f)(1); 21 CFR 1301.71(a); *Southwood*, 72 Fed. Reg. at 36,502; *Holloway*, 72 Fed. Reg. at 42,123-24.

Accordingly, the Agency finds that after considering the factors of 21 U.S.C. 823(f), the Government satisfied its *prima facie* burden showing that Registrant's registration is "inconsistent with the public interest."⁸ 21 U.S.C. 824(a)(4); *see also* 21 U.S.C. 823(f)(1). The Agency further finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. *See supra* Section II. Thus, the only remaining issue is whether revocation of Registrant's registration is the appropriate sanction.

IV. SANCTION

When the Agency concludes that a registrant's registration is inconsistent with the public interest, the Agency then determines the appropriate sanction, which may include revocation of the registration. 21 U.S.C. 824(a)(4); *see also Pharmacy Doctors*, 789 Fed. Appx. at 734 (the Agency is entitled to choose a sanction); *Scott Hansen, A.R.N.P.*, 90 Fed. Reg. 27,338, 27,341 (2025); *Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,972-73 (2019). At this stage, the burden is on registrants to show why they can be trusted to maintain their registration. *Morall*, 412 F.3d at

⁸ Given the violations of law proven by unrebutted record evidence as discussed herein, the Agency need not reach the remaining allegations related to the failure to report suspicious orders of controlled substances. RFAAX 1, at 4. Registrant's failure to maintain effective controls against diversion of controlled substances are sufficient to revoke.

174; *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Stein*, 84 Fed. Reg. at 46,972; *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833.

As past performance is the best predictor of future performance, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that they will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). Moreover, the Agency requires a registrant's unequivocal acceptance of responsibility. *Morris & Dickson*, 88 Fed. Reg. at 34,537; *Janet S. Pettyjohn, D.O.*, 89 Fed. Reg. 82,639, 82,641 (2024); *Mohammed Asgar, M.D.*, 83 Fed. Reg. 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830-31.

In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 830-31; *Hoxie*, 419 F.3d at 483-84. The Agency also considers the need to deter similar acts by Registrant and by the community of registrants. *Stein*, 84 Fed. Reg. at 46,972-73.

Here, Registrant failed to answer the allegations contained in the OSC and did not otherwise avail itself of the opportunity to prove to the Agency that it can be trusted to maintain its registration. *See supra* Section II. Thus, there is no record evidence that Registrant takes responsibility, let alone unequivocal responsibility, for the misconduct. Accordingly, it has not convinced the Agency that its future controlled-substance-related actions will comply with the CSA such that it can be entrusted with the responsibilities of a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Registrant's misconduct in this matter concerns the CSA's "strict requirements regarding registration" and, therefore, goes to the heart of the CSA's "closed regulatory system"

specifically designed “to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Raich*, 545 U.S. at 12-14. If the Agency were to allow Registrant to maintain its registration under these circumstances, it would send a dangerous message that compliance with the law is not essential to maintaining a registration.

In sum, Registrant has not offered any evidence on the record that rebuts the Government’s case for revocation of its registration, and Registrant has not demonstrated that it can be entrusted with the responsibility of registration. Accordingly, the Agency will order the revocation of Registrant’s registration.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. RA0235146 issued to Allied Medical Products, Inc. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby deny any pending applications of Allied Medical Products, Inc., to renew or modify this registration, as well as any other pending application of Allied Medical Products, Inc., for additional registration in California. This Order is effective **[INSERT DATE THIRTY DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on January 16, 2026, by Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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