NOT YET SCHEDULED FOR ORAL ARGUMENT

United States Court of Appeals for the District of Columbia Circuit

No. 26-1329

PENNALT ORGANICS, INC., d/b/a Penn Health Group,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as Administrator of the Drug Enforcement Administration; UNITED STATES DEPARTMENT OF JUSTICE; and TODD BLANCHE, in his official capacity as United States Attorney General,

Respondents.

EMERGENCY MOTION FOR STAY OF DRUG ENFORCEMENT ADMINISTRATION ACTION (TEMPORARY RESTRAINING ORDER)

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D.C. CIRCUIT RULE 28 CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

A. Parties and Amici

Petitioner is PennAlt Organics, Inc. d/b/a Penn Health Group. Respondents are the Drug Enforcement Administration, Terrance C. Cole, in his official capacity as Administrator of the Drug Enforcement Administration, Department of Justice, and Todd Blanche, in his official capacity as Attorney General (collectively "Respondents").

The ruling under review was not issued in an adjudicatory or rulemaking proceeding in which other persons participated. Counsel is not aware of any other persons or entities that participated in proceedings before DEA, and no intervenors or amici have appeared in this Court as of this filing.

B. Ruling Under Review

The ruling under review is the document titled "Timely Applicant Information for Medical Marijuana Applicants", which was issued by the DEA on October 30, 2026, and is available at: https://www.deadiversion.usdoj.gov/drugreg/Timely-Applicant-Information-for-Medical-Marijuana-Applicants.pdf. A true and correct copy of the Guidance is attached as **Exhibit A**. The document was not published in the Federal Register.

C. Related Cases

Related cases are *Standard Wellness Utah, LLC, et al., v. Drug Enforcement*

Admin., et al., Case No. 26-1324 (D.C. Cir. 2026) and *G.P.M.II, LLC, et al. v. Drug Enforcement Admin., et al.*, Case No. 26-1325 (D.C. Cir. 2026) ("Related Cases"). As of the date of this filing, the instant case has not been consolidated with the aforementioned Related Cases. Undersigned counsel is not aware of any other related cases currently pending in this Court or in any other court.

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 18

The motion complies with Federal Rule of Appellate Procedure 18 and Circuit Rule 18. On November 16, 2026, PennAlt submitted a letter request ("Letter") via FedEx, certified mail (return receipt requested), and email to the Drug Enforcement Administration ("DEA") at its 8701 Morrissette Drive, Springfield, Virginia 22152 location and at DEA.Registration.Litigation@dea.gov. PennAlt also copied: (1) Cheri Oz, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; (2) Laurie Wiesner, Diversion Enforcement Counsel, Office of the Chief Counsel, Diversion and Regulatory Litigation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; (3) Timothy Flaherty, Special Agent in Charge, Philadelphia Division, Drug Enforcement Administration, Wm. J. Green Fed. Bldg., 600 Arch Street, Room 10224, Philadelphia, Pennsylvania 19106. A true and correct copy of the Letter (without exhibits) is attached as **Exhibit B.**

In the Letter, PennAlt sought: (1) an Exception Request under 21 C.F.R. § 1307.03 and 21 U.S.C. § 822(d), seeking an exception from 21 C.F.R. § 1301.13(a), as applied through § 1301.13(k)(7), and DEA's October 30, 2026 document titled "Timely Applicant Information for Medical Marijuana Applicants" (the "Guidance"). The Letter sought, in the alternative, a stay on the Guidance as applied to PennAlt. The Letter stated, *inter alia*, "In the alternative, the Company requests

that DEA agree to stay enforcement of the penalties announced in the Guidance. Specifically, the Company asks that DEA agree to stay enforcement of paragraphs 7 and 8 of the Guidance . . . .” PennAlt requested a response from DEA by November 20, 2026. PennAlt advised that, absent a response by that date, PennAlt reserved all rights to challenge the Guidance, including that the Guidance is procedurally invalid, arbitrary and capricious, and—owing to the penalties’ lack of fair notice—a violation of due process.

DEA did not respond to PennAlt’s request. On the morning of November 23, 2026, PennAlt through undersigned counsel called the DEA Diversion Control Division and stated that absent a formal exception or stay of the Guidance, it would be filing a Petition in the D.C. Circuit today. As of the time of this filing, PennAlt has not received a response from the DEA. Due to the imminent deadline, Petitioner must treat the DEA’s lack of response as a constructive denial. Because it would be impracticable to await a decision from DEA, Petitioners have complied with Circuit Rule 18 and Federal Rule of Appellate Procedure 18.

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I. INTRODUCTION

Petitioner, PennAlt Organics, Inc. d/b/a Penn Health Group ("PennAlt") seeks a temporary restraining order ("TRO") staying the arbitrary and capricious Guidance issued by the Drug Enforcement Administration (the "DEA" or the "Agency") on October 30, 2026 titled "Timely Applicant Information for Medical Marijuana Applicants" (the "Guidance"). *See* Ex. A. PennAlt hereby challenges the Guidance and seeks an emergency stay of the DEA Guidance because it is procedurally invalid, arbitrary and capricious, and—owing to the penalties' lack of fair notice—a violation of due process. PennAlt has exhausted all available administrative remedies, including but not limited to, seeking an exception from the DEA pursuant to 21 C.F.R. § 1307.03, and therefore this issue is ripe for appellate review pursuant to 21 U.S.C. § 877, Federal Rule of Appellate Procedure 15(a), and/or Federal Rule of Appellate Procedure 18(a).

PennAlt is a Pennsylvania corporation licensed to grow, process, and dispense medical marijuana under Pennsylvania law. PennAlt's mission is to provide patients with access to high-quality medical cannabis products and to enhance the well-being of individuals facing various health challenges. PennAlt adheres to stringent standards to ensure that every step of the cultivation process is meticulously executed to ensure the potency, purity, and consistency of its products and to deliver safe and effective solutions for its patients.

PennAlt is facing an existential threat to its business and practice by the DEA's unjustified, unprecedented, and inconsistent actions regarding its issuance of the Guidance. In April 2026, the Attorney General issued an order rescheduling state-licensed medical marijuana to a Schedule III substance and creating an expedited registration process for licensees under 21 C.F.R. § 1301.13(k), which took effect on April 28, 2026. *See* 91 Fed. Reg. 22714, 22715 (Apr. 28, 2026) (the "Order"). PennAlt does not contest the Attorney General's Order rescheduling state-licensed medical marijuana to a Schedule III substance. Section 1301.13(k)(7) allows an applicant that submits a registration application within sixty (60) days of the Order's publication to continue operating under its state license while the application is pending.

After issuing its Guidance, the DEA opened a dedicated Medical Marijuana Dispensary Registration Portal that contained a detailed *dispensary*-specific application ("Form 224-M"). The DEA failed to offer a comparable portal or form to *manufacturers* or *distributors* of medical marijuana. In fact, the DEA's own website for applicants who sought to select the medical-marijuana manufacturer or distributor option on the website were routed to a notice stating that a separate Schedule III registration portal for cultivators, manufacturers, distributors, and laboratories would be available "in the coming weeks." The 60-day period following the Order ended on June 26, 2026, with no medical-marijuana-specific manufacturer

or distributor application in place. The DEA did not make a specific portal for these entities accessible until October 5, 2026, more than three months after the 60-day period ended and more than five months after DEA launched the dispensary portal, through a manufacturer-specific application ("Form 225-M"). The DEA did not communicate with PennAlt at all between June 26 and October 5, 2026, with any suggestion that it had somehow failed to comply with any DEA requirements or deadlines. After DEA released the manufacturer-specific application, PennAlt filed the necessary Form 225-M on or about November 6, 2026, which remains pending under Control No. M26172551E. A true and correct copy of PennAlt's Form 225-M manufacturer application submission confirmation is attached hereto as **Exhibit C**.

On October 30, 2026, DEA issued the Guidance[1], which for the first time announced that entities would be sanctioned for waiting for the manufacturer-specific application form. Under these sanctions, PennAlt, despite being in complete compliance with state laws, would be effectively barred from engaging in any Schedule III medical-marijuana activities. This Guidance is procedurally invalid, arbitrary and capricious, and—owing to the penalties' lack of fair notice and retroactive nature—a violation of due process. Given the DEA's arbitrary and

[1] The Guidance is available at the following DEA website: https://www.deadiversion.usdoj.gov/drugreg/Timely-Applicant-Information-for-Medical-Marijuana-Applicants.pdf (last accessed Nov. 18, 2026) (last accessed November 23, 2026).

capricious conduct with regards to its Guidance, PennAlt initiated this action to obtain relief from DEA's unlawful actions.

The Guidance will cause irreparable harm to PennAlt and the public health. PennAlt's business model revolves around being able to do business as a registered manufacturer and distributor of medical marijuana. Therefore, PennAlt will suffer severe irreparable harm to its business operations, reputation, and revenue if DEA's Guidance allows to remain.

II. FACTUAL BACKGROUND

A. PennAlt and Its Pennsylvania Operations

The Pennsylvania Department of Health ("PDOH") has issued PennAlt a medical-marijuana manufacturer permit[2] and a dispensary permit. A true and correct copy of the medical-marijuana manufacturer permit is attached as **Exhibit D**. Since it was first permitted, PennAlt has operated under Pennsylvania's Medical Marijuana Act and PDOH's implementing regulations.

PennAlt is in good standing with PDOH and, to the knowledge of PennAlt's Director of Operations, has never received a notice of violation, been the subject of an enforcement action or investigation, or been subject to any sanction by PDOH or any other state or local authority. The only communication PennAlt received from PDOH with regards to the Guidance came on November 20, 2026 when PennAlt

[2] PDOH refers to the holders of these licenses as growers/processors.

received an email from PDOH with the subject line "Important DOH, Bureau of Medical Marijuana Correspondence re: DEA Timely Applicants." PDOH quotes directly from the Guidance by stating, "Timely Applicants can continue dispensing, manufacturing, or distributing schedule III medical marijuana pursuant to their state medical marijuana permit during the pendency of their DEA application." Additionally, PDOH informed entities of the requirement that Timely Applicants will be unable to conduct business with non-registered entities. PDOH also explicitly acknowledges "the uncertainty in this evolving landscape" and that throughout this month's long process "[PDOH] has not received any formal guidance from DEA headquarters or other federal agencies regarding these changes."

PennAlt supplies medical-marijuana products wholesale to 187 third-party PDOH-licensed dispensaries, generating approximately $5 million in wholesale revenue per year. Twenty percent of PennAlt's wholesale product supplies its own dispensary. PennAlt serves approximately 3,200 patients, and PennAlt employs approximately forty-eight (48) people in Pennsylvania across its manufacturing and dispensary locations.

B. DEA's Early Application Window Provisions as Applied to Manufacturers Were Misleading.

The April 2026 order issued by the Attorney General created an expedited registration process for licensees under 21 C.F.R. § 1301.13(k). *See* 91 Fed. Reg. at 22715. Under that regulation, applicants that submit a registration application within

60 days of publication of the Order may, under Section 1301.13(k)(7), continue to operate under their state license. The Order described this applicant as an "early applicant[]". The Order thereby instructed applicants to provide proof of a state license and use "the applicable DEA form or forms" to request registration. *See* 91 Fed. Reg. at 22721–22.

The application process for state-licensed medical-marijuana *dispensaries* was immediately clear. One day after issuing the Order, on April 29, 2026, DEA opened a dedicated Medical Marijuana Dispensary Registration Portal that contained a detailed dispensary-specific application (Form 224-M). On this date, the Agency provided no such application for manufacturers or distributors. At no point during the 60-day time period did DEA provide a comparable application for manufacturers or distributors. Instead, applicants who selected the medical-marijuana manufacturer or distributor option on DEA's Diversion Control website were routed to a notice stating that a separate Schedule III registration portal for cultivators, manufacturers, distributors, and laboratories would be available "in the coming weeks."

Although this "coming soon" notice stated that "[t]hose interested in applying . . . *may* do so utilizing DEA's current Form 225 application," (emphasis added), it simultaneously promised that new medical-marijuana-specific forms —akin to Form 224-M (the dispensary application)—would soon become public. That language signaled, and could be reasonably interpreted to mean, that a dedicated manufacturer

process would soon follow and would independently govern manufacturer applications. The notice was devoid of any instructions for manufacturers to apply using the generic Form 225, which lacked the detail that Form 224-M required. The DEA, also, failed to advise manufacturers that they must use generic Form 225 in order to avail themselves of the benefits of the new Section 1301.13(k)(7). At no point did DEA inform state-licensed medical-marijuana operations that they would be sanctioned or entirely prohibited from dealing with early applicants just because the manufacturers waited for the promised medical-marijuana manufacturer-specific forms.

On June 26, 2026, when the Order's 60-day period ended, no medical-marijuana specific manufacturer or distributor application existed. DEA's notice of an impending form being available in the "coming weeks" remained on their website until October 5, 2026 when DEA finally opened its medical-marijuana manufacturer portal.. Many manufacturers understood that a similar 60-day window, akin to those who filed Form 224-M, would be afforded once the dedicated manufacturer form became available. No such grace period was given.

C. DEA Did Not Communicate Any Pending Restrictions or Any Missed Deadline to PennAlt Until Its October 30, 2026 Guidance.

PennAlt never received any communication from DEA between June 26 and October 5, 2026, suggesting that it had missed any deadline or that its ability to transact with other applicants would be restricted. Promptly after DEA released the

manufacturer-specific application, PennAlt filed its Form 225-M to ensure compliance with DEA rules. *See* Ex. C.

Nevertheless, and without any prior notice to entities who had acted with the limited knowledge provided to them from DEA, the Agency issued its Guidance which announced that entities would be *sanctioned* for choosing to wait on the manufacturer-specific application form. The Guidance stated that entities listed as "Timely Applicants" (i.e., those entities that submitted an application by June 26, 2026) or registrants "may not lawfully engage in any schedule III medical marijuana activities with entities that did not complete an application" by June 26, 2026, "until those entities become DEA registrants." *See* Guidance at ¶ 7. The Guidance further stated that such business with non-registered entities could lead to "denial of a[n] . . . application" for DEA registration "or revocation of a[n existing] certificate of registration, respectively." Guidance at ¶ 8. The Guidance, moreover, gave listed entities only until November 29, 2026 to "establish compliant supply chains." Guidance at ¶ 11. Under these provisions, listed entities would be barred from doing business with entities, such as PennAlt, who did not file within the 60-day window before DEA released the manufacturer-specific application form it promised in early May and that DEA stated would be published "in the coming weeks." In essence, the Guidance abruptly and without notice halts the business of manufacturers, such as

PennAlt, who now can no longer sell to long-time client dispensaries that appear on the "Timely Applicant" list.

D. The DEA Guidance's Sanctions Cause Immediate, Irreparable Harm to PennAlt.

The sanctions promulgated under the Guidance cause immediate and irreparable harm to PennAlt. As the affidavit of PennAlt's Director of Operations Daniel Sax ("Sax Aff."), attached hereto as **Exhibit E**, avers, the Guidance restricts the business of manufacturers which can no longer sell to long-time client dispensaries that appear on the "Timely Applicant" list—which, in PennAlt's case, comprise approximately 95% of its third-party customers. Sax Aff. ¶ 11. PennAlt is already experiencing repercussions as a result of the Guidance. Within days of the Guidance's publication, PennAlt's third-party dispensary customers began to notify PennAlt that the Guidance is preventing them from continuing to do business with PennAlt. *Id.*¶ 12. Since October 30, 2026, PennAlt has received at least two requests from customers for its DEA control number, and customers have indicated that they will no longer be doing business with suppliers devoid of Timely Applicant status. *Id.* Those two customers alone account for close to $1 million in annual revenue. *Id.* The Guidance also bars PennAlt's manufacturing operation from supplying PennAlt's own dispensary; accordingly, PennAlt must cease supplying its dispensary or risk denial of its dispensary registration application. *Id*. ¶ 13.

III. STANDING

PennAlt has standing to bring this Emergency Motion to challenge the Guidance because the Guidance penalizes PennAlt's state-licensed medical marijuana manufacturing operations, establishing a concrete and particularized injury-in-fact. *See generally Sierra Club v. EPA*, 292 F.3d 895 (D.C. Cir. 2002). Because the Guidance directly harms PennAlt's core business activities, restricts its market access, and has already caused – and will continue to cause – severe financial harm to PennAlt, there is a direct causal link between the Guidance and the financial, operational, and reputational harm PennAlt suffers. Furthermore, a judicial decision staying or enjoining the Guidance would immediately redress these injuries by removing the penalties on PennAlt's state-authorized manufacturing activities.

IV. JURISDICTION AND LEGAL STANDARDS

PennAlt seeks relief from DEA's Guidance under Section 507 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (the "Controlled Substances Act" or "CSA"), Pub. Law 91-513, 84 Stat. 1236, codified at 21 U.S.C. § 877, which grants an aggrieved party the ability to seek immediate judicial review; the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

The APA sets forth the judicial authority to review executive agency action for procedural correctness. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513

(2009). The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

The Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, authorizes federal courts to issue binding decisions declaring the rights and legal relations of interested parties in an actual controversy.

Parties seeking emergency relief must demonstrate that (1) "they are likely to succeed on the merits"; (2) "they are likely to suffer irreparable harm"; (3) "the balance of hardships tips in their favor"; and (4) "the injunction is in the public interest." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016). PennAlt's motion should be granted because it satisfies all four factors.

V. ARGUMENT

A. PennAlt Is Likely to Succeed on the Merits.

The core legal question presented in this case is whether the DEA violated its authority in issuing its October 30, 2026 Guidance without legal authority or any substantive reasoning and without providing due process to PennAlt. The DEA must operate within the scope of its delegated authority granted by Congress; however, DEA failed to do so here by taking these actions without opportunity for comment by PennAlt or transparency in its decision-making process. Because the DEA acted

arbitrarily and capriciously with respect to its Guidance the DEA has violated the APA and PennAlt is likely to prevail on the merits.

1. DEA's Guidance is Arbitrary and Capricious and in Violation of PennAlt's Due Process Rights.

The DEA's Guidance is an unlawful exercise of DEA's authority. DEA provided no legal basis for sanctioning entities that did not timely file, even though it never offered a specialized medical-marijuana manufacturer form within the 60-day period and published confusing information that the registration portal for cultivators, manufacturers, distributors, and laboratories would open "in the coming weeks." Likewise, DEA did not provide PennAlt with an opportunity to comment on DEA's Guidance, despite the Guidance being the first communication from DEA to entities such as PennAlt. Further, DEA gave no explanation for its delay in providing Form 225-M. DEA's failures are especially noteworthy considering it is now sanctioning entities who did not complete the registration. For these reasons, the Court must grant PennAlt relief from DEA's arbitrary and capricious decisions and stay the DEA Guidance to prevent more immediate, irreparable harm to PennAlt.

2. DEA Did Not Publicize the Form 225-M Until October 5, 2026.

To comply with the requirements of Section 1301.13(k)(7), DEA required parties to submit a registration application within 60 days of the Order's publication. Despite making public the Form 224-M, DEA did not make the equivalent

manufacturer-specific application, the Form 225-M, available until October 5, 2026. DEA never communicated with manufacturer-specific entities beyond posting on its website that a separate registration portal would be available "in the coming weeks." This led entities like PennAlt to reasonably infer another form would soon follow. This "coming soon" notice remained on DEA's website until October 5, 2026. From June 26 to October 5, 2026, PennAlt never heard from DEA about missing any deadlines or that it was not in compliance with the Order. In its only correspondence about the Guidance, PDOH informed entities such as PennAlt of the lack of communication with DEA. PDOH specifically stated that it "has not received any formal guidance from DEA headquarters or other federal agencies regarding these changes." Despite this lack of information from PDOH and DEA, PennAlt ensured that it remained in compliance with federal and state laws. Proof of PennAlt's diligence comes from PennAlt submitting their Form 225-M promptly after it became available on DEA's website. With this arbitrary and capricious guidance, DEA improperly and unlawfully harms PennAlt and its business. DEA is also violating PennAlt's due process rights because of the penalties' lack of fair notice.

3. DEA's Guidance Violates the Administrative Procedure Act.

Under the APA, a federal court must set aside and hold unlawful any federal agency actions, findings, or conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Courts

have held that an administrative agency action will be considered arbitrary and capricious and thus unlawful if the administrative agency fails to treat similarly situated parties in the same manner. *Bracco Diagnostics, Inc. v. Shalala*, 963 F.Supp. 20, 27–28 (D.D.C. 1997).

In the current situation, DEA's Guidance restricts PennAlt's ability to do any business without providing a clear decision on why it is taking such measures and then implementing a process that will irreparably harm PennAlt. DEA has singled out medical-marijuana manufacturers like PennAlt for unfair procedures, forcing PennAlt to justify its missing the 60-day window despite DEA's inadequate notice. DEA's notice consisted only of its website saying a portal for manufacturers and distributors would be available "in the coming weeks."

The DEA did not provide PennAlt with any reasonable notice that it was out of compliance with the DEA until the DEA issued the Guidance. The Guidance therefore retroactively punishes PennAlt. Fundamental notions of due process dictate that PennAlt at least has the right to know what violations it committed and under what legal theory DEA's sanctions can be implemented.

In the current situation, there has not even been a showing that DEA's sanctions are in the interest of public health. DEA's Guidance is arbitrary and capricious as it is clear that DEA's decisions are not being made for public safety or

access to medical-marijuana products because at no point was there a doubt that PennAlt's products were a danger to its patients.

4. DEA's Guidance Violates the Fair Notice Doctrine.

Courts consistently recognize that "[a] fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). In *Fox*, the Supreme Court held that broadcasters Fox and ABC lacked fair notice of an FCC policy under which brief nudity could be found actionably indecent. In that case, ABC had been fined for a depiction of nudity on its program NYPD Blue. *Id.* at 256. Though the Commission did not penalize Fox, the Court credited the risk of future penalties and reputational injury. *Id.* at 255-56. Over the Government's argument that ABC had notice, the Court determined that an "isolated and ambiguous statement" by the Commission did not satisfy the fair notice requirement. *Id.* at 256-57. Likewise, in *Karem v. Trump*, the D.C. Circuit applied the principle that parties must receive adequate notice. 960 F.3d 656, 664 (D.C. Cir. 2020). The D.C. Circuit held that a reporter, whose hard pass was suspended, was not provided with adequate notice because, although the White House had articulated that conduct at press-conferences could result in suspensions, it failed to have analogous rules for non-press conference events. *Id.* at 665.

This Court should likewise find DEA's Guidance did not provide PennAlt with fair notice. Similar to *Fox*, PennAlt will suffer from reputational and severe financial harm if the DEA is permitted to enforce its sanctions against PennAlt. The Guidance bars Timely Applicants from dealing with non-DEA registrants like PennAlt, so PennAlt risks losing business and consumer standing. Proof of PennAlt losing business comes from customers informing PennAlt that they will "no longer be doing business" with suppliers without Timely Applicant status. As the Supreme Court determined, the threat of harm requires that a party be given fair notice. *Fox*, 567 U.S. at 255-56.

Both the Supreme Court and the D.C. Circuit have ruled that an agency's ambiguous application of its rules is a violation of fair notice. Such is the case here as Form 224-M was made immediately available to medical-marijuana dispensaries while Form 225-M was not available until October 5, 2026. DEA's own missteps in not providing the appropriate form cannot mean that PennAlt should be under the threat of losing its entire business – such a result would be directly in violation of the fair notice doctrine. Under the precedent established by the completion of Form 224-M, PennAlt anticipated that medical-marijuana manufacturers would be given 60 days to complete Form 225-M. Instead, only 25 days passed between when Form 225-M was made available and DEA's issuance of the Guidance and its harsh penalties. The Supreme Court makes clear that inequal application of the rules for

varying parties, as exhibited by the differing Forms, does not equate to adequate notice. *See Fox*, 567 U.S. at 256-57. The only information that PennAlt received prior to the Form-225 M being made available was the "coming soon" notice. In *Karem*, the D.C. Circuit specifically noted that although there was a notice about conduct at press-conferences, no such notice was given with regards to non-press conference events. *See Karem*, 960 F. 3d at 665. This holding makes clear that just because Form 224-M was available does not mean PennAlt received adequate notice that it *must* fill out this inapplicable form in order to avoid penalties. With the "coming soon" notice alongside the availability of Form 224-M, PennAlt reasonably expected that a manufacturer specific form would be made available. The D.C. Circuit's precedent establishes that notice on one occasion does not equate to adequate notice for all future events. *See id.* Therefore, DEA's retroactive guidance where it now seeks to punish parties who simply adhere to the information that was available to them at the time does not constitute adequate notice.

B. Absent Emergency Relief, PennAlt Will Be Irreparably Harmed Without Any Adequate Remedy.

Without this Court's intervention, PennAlt will suffer immediate, irreparable harm stemming from DEA's Guidance. PennAlt faces a substantial risk of loss of significant expended resources, the ability to conduct its business, and a loss of goodwill and trust in PennAlt's reputation within the medical-marijuana industry, dispensaries, and among patients which will irreparably cause harm to PennAlt.

Under the Guidance, a Timely Applicant may not lawfully engage in business with non-applicants until they become DEA registrants. If a Timely Applicant decides to conduct business with a non-registered entity, then the Guidance promulgates that such dealings would lead to a denial of a listed entity's application for DEA registration or revocation of an existing registration. The Guidance further stated that listed entities had until November 29, 2026, to ensure their supply chains included only listed entities and registrants. This means that without Court intervention all listed entities will be barred from doing business with PennAlt. The Guidance also dictates that manufacturers cannot sell to a long-time client dispensary that appears on the Timely Applicant list. For PennAlt, this amounts to approximately 95% of its third-party customers.

Already, these sanctions are harming PennAlt. *See* Sax Aff. ¶¶ 12-13. After the Guidance's publication, third-party dispensary customers notified PennAlt that the Guidance prevented them from continuing to do business with PennAlt. *Id.* ¶ 12. At least two customers asked PennAlt for their DEA control number and other customers informed PennAlt that they will no longer continue to do business with PennAlt without Timely Applicant Status. *Id.* For PennAlt, those two customers account for almost $1 million in annual revenue. *Id.* The Guidance, additionally, bars PennAlt from supplying its own dispensary. *Id.* ¶ 13. If PennAlt continues to supply

their dispensary, then PennAlt risks denial of its dispensary registration application. *Id.*

With such harsh penalties written into the Guidance, it is unfathomable as to why DEA disregarded its obligations to provide adequate notice to parties. If relief is not granted before November 29, 2026, PennAlt will lose nearly all of its dispensary customers. If PennAlt cannot supply its own dispensary, many of its approximately 3,200 patients who rely on PennAlt's products to treat chronic pain and other debilitating medical conditions will lose access to those products and need to find other sources. *Id.* ¶ 14. Because PennAlt's dispensary serves an undeserved area, its loss would force patients to travel farther for their medication, thereby significantly limiting access to care. *Id.* ¶ 15. If the penalties announced in the Guidance take effect, PennAlt may become bankrupt and may have to lay off all forty-eight of its employees within weeks. *Id.* ¶ 16.

Based on the above, injunctive relief is appropriate because PennAlt will suffer actual and imminent irreparable harm which cannot be remedied at a later time or through monetary compensation. *See Senior Execs. Ass'n v. United States*, 891 F. Supp. 2d 745, 755 (D. Md. 2012). Irreparable harm is demonstrated where any calculation of damages is "difficult to ascertain or are inadequate" or where "the failure to grant preliminary relief creates the possibility of permanent loss of

customers to a competitor or the loss of goodwill." *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551-52 (4th Cir. 1994).

Furthermore, PennAlt will have no means to recover its losses because DEA's sovereign immunity would preclude PennAlt from recovering money damages. *See, e.g.*, *Senior Execs.*, 891 F. Supp. 2d at 755 (explaining that monetary damages are an inadequate remedy because "they are unavailable").

C. The Balance of Hardships Tips Strongly in PennAlt's Favor.

The balance of hardships here tips heavily in favor of PennAlt. PennAlt has invested significant resources in manufacturing and distribution of its medical marijuana, a necessary alternative treatment for patients with chronic pain. On the other hand, granting the limited interim relief requested will not prejudice DEA. It will only maintain the status quo while this Court reviews the Agency's actions.

In addition, PennAlt fully supports expedited proceedings on the merits of DEA's Guidance as long as PennAlt is afforded due process by the DEA, including full notice of the agency's position and the opportunity to provide PennAlt's position prior to the November 29, 2026 deadline. While PennAlt would be seriously harmed, leaving the approval of PennAlt's status unstayed would cause DEA no harm. Moreover, DEA would suffer no harm as a result of having its decision stayed pending a full hearing and decision on the merits.

D. The Public Interest Favors Granting the Limited Relief Requested.

PennAlt's request for relief is in the public interest. "The public interest is best served by ensuring [agency] compliance with [its governing] statute." *Bayer HealthCare, LLC v. FDA*, 942 F. Supp. 2d 17, 27 (D.D.C. 2013). The public interest is served by requiring DEA to comply with the law, not by allowing DEA to grant itself new powers to act outside the bounds of its authority without the notice and full public participation the APA requires for promulgating rules. *See N.C. Growers' Ass'n v. United Farm Workers*, 702 F.3d 755, 763 (4th Cir. 2012). To the contrary, allowing the DEA to arbitrarily set rules on distribution on a whim sets a dangerous precedent of extreme uncertainty to commercial interests of companies who invest significant resources in manufacturing and distribution of products, and invites gamesmanship by competitors.

PennAlt's request is also in the public interest because of the public health value of medicinal marijuana. Medical marijuana is a highly effective treatment for certain patients with chronic illness because medical marijuana is used to provide relief from chronic pain. Studies have also found medicinal marijuana to be an effective treatment as an antiemetic in the treatment of chemotherapy-induced nausea and vomiting, as a means of improving sclerosis spasticity symptoms, as a way of increasing appetite and decreasing weight loss associated with HIV/AIDS, and as a way of improving symptoms of Tourette syndrome, among other conditions.

See "Therapeutic Effects of Cannabis and Cannabinoids," THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH (2027) (available at: https://www.ncbi.nlm.nih.gov/books/NBK425767/). For these illnesses with no conventional treatment available or a treatment that is unobtainable for many patients, it is critical that patients have access to medicinal marijuana. Thousands of patients rely on PennAlt to support them in their daily lives. It would be detrimental to public health if PennAlt were unable to provide its products.

Relatedly, the entire purpose of the Order is to reinforce – not undermine – state regulations governing the lawful manufacture and dispensing of medicinal marijuana. In fact, the Order itself relies on state controls. Pennsylvania's controls continue to govern PennAlt, and PennAlt remains in good standing with the PDOH, as described *supra*. Specifically, the Order rests on the Attorney General's findings that state regimes play a critical role in achieving "*the public-interest objectives* that underlie the CSA's registration framework." 91 Fed. Reg. at 22720 (emphasis added). The Order further emphasizes how incorporating state licensing systems into federal registration provides the best way of achieving CSA's objectives. *Id.*

The federal regulation itself builds on that finding by the Attorney General. The regulation states, "In general, registration of an applicant that complies with a state-law regime that contains robust protections against diversion, requirements for

record-keeping and reporting, and safety and inspection measures *will not be inconsistent with the public interest . . . .*" *Id.* at 22722 (emphasis added). The federal regulation itself even specifies that "a state license shall constitute conclusive evidence" of state authorization. *Id.* DEA "shall accept state-required reports, records, and forms to the maximum extent permissible." *Id.* And state-law labeling, packaging, disposal, and physical-security requirements satisfy the corresponding federal requirements. *Id.* The Order also places marijuana in Schedule III specifically based on it being "subject to a state medical marijuana license." *See id.* at 22723.

None of these obligations depends on the precise date PennAlt filed its manufacturer registration application. Every control the Attorney General found sufficient in the above-mentioned finding, *see id.* at 22720, applies to PennAlt's manufacturing operation today.

VI. CONCLUSION

For the above-stated reasons, PennAlt requests that this Court enjoin application of DEA's October 30, 2026 Guidance for the duration of an inquiry that provides notice of DEA's position and a reasonable time for PennAlt to respond and be heard prior to any further decision by the DEA regarding the approval status of PennAlt's application, Control No. M26172551E.

Dated: November 23, 2026 Respectfully submitted,

PennAlt Organics, Inc.

/s/ Karima T. Thompson
Karima T. Thompson (D.C. Cir. Bar. No. 66487)
Jason W. Meuth (*pro hac vice* forthcoming)
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(202) 452 7989

Counsel for PennAlt Organics, Inc.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing motion complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because the motion contains 5,170 words. The motion complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it has been prepared using Microsoft® Word in proportionally spaced 14-point Times New Roman typeface. As permitted by Federal Rule of Appellate Procedure 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Karima T. Thompson
Karima T. Thompson (D.C. Cir. Bar. No. 66487)

CERTIFICATE OF SERVICE

I, Karima T. Thompson, hereby certify that on the 23rd day of November, 2026, I caused the foregoing Emergency Motion to be served by process server, FedEx, CM/ECF, and by e-mail (where applicable), upon:

Attorney General of the United States Todd Blanche
U.S. Department of Justice
950 Pennsylvania Avenue, NW,
Washington, DC 20530-0001

United States Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530
mckaye.l.neumeister@usdoj.gov
daniel.j.aguilar@usdoj.gov

United States Attorney's Office for D.C.
Civil Process Clerk
601 D Street, NW
Washington, DC 20530
USADC.ServiceCivil@usdoj.gov
peter.pfaffenroth@usdoj.gov

U.S. Drug Enforcement Administration
Attn: Office of the Chief Counsel
8701 Morrissette Drive
Springfield, Virginia 22152

Attn: Administrator Terrance C. Cole
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

/s/ Karima T. Thompson
Karima T. Thompson (D.C. Cir. Bar. No. 66487)

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DEA Medical Marijuana Timely Applicant Information

Title: Activities of Entities Holding State Medical Marijuana Licenses Who Applied for DEA Registration under the April 28, 2026 Final Rule between April 28, 2026, to June 26, 2026, under 21 CFR 1301.13(k)(7).

Summary: This information addresses the permissible activities that applicants for DEA registration to handle schedule III medical marijuana—who submitted complete applications to DEA between April 28, 2026, to June 26, 2026—may continue to engage in while their DEA applications remain pending. Applicants who submitted complete applications within 60 days of publication of the April 28, 2026 Final Rule can continue dispensing ("Timely Dispenser Applicants"), manufacturing ("Timely Manufacturer Applicants"), or distributing schedule III medical marijuana ("Timely Distributor Applicants" and, collectively with Timely Dispenser Applicants and Timely Manufacturer Applicants, the "Timely Applicants") pursuant to their state medical marijuana license during the pendency of their application before DEA, and may distribute schedule III medical marijuana to and obtain schedule III medical marijuana from Timely Applicants and DEA registrants.

To Whom it Applies: Entities that submitted complete applications pursuant to 21 CFR 1301.13(k) for a DEA registration to handle schedule III medical marijuana, marijuana extract, and/or naturally-derived delta-9-tetrahydrocannabinols, each as defined in 21 CFR 1308.13(g)(2)–(4) (collectively, "schedule III medical marijuana"), between April 28, 2026 to June 26, 2026—other than those applicants (a) whose application is no longer pending before DEA because the applicant has withdrawn the application or because the Administrator has issued a Final Order denying the application, or (b) who lack the requisite state medical marijuana license—and therefore have been granted special authorities by 21 CFR 1301.13(k)(7).

Question: What activities may Timely Applicants engage in while their applications before DEA are pending?

Answer:

1. Under 21 CFR 1301.13(k)(7), any applicant that submitted a complete schedule III medical marijuana registration application between April 28, 2026, to June 26, 2026, (i.e., within 60 days of the publication of the April 28, 2026 Final Rule) can dispense, manufacture, or distribute schedule III medical marijuana, marijuana extract, and naturally-derived delta-9-tetrahydrocannabinols, each as defined in 21 CFR 1308.13(g)(2)–(4), as applicable (collectively, "schedule III medical marijuana activities") pursuant to its state medical marijuana license during the pendency of the application before DEA.

2. To have submitted a complete schedule III medical marijuana application and be considered a "Timely Applicant," the applicant must have submitted payment of the applicable registration fee as well as a completed application between April 28, 2026, to June 26, 2026.

3. Sub-paragraph 21 CFR 1301.13(k)(7) allows Timely Applicants to engage in regulated activities "notwithstanding" the requirement in 21 CFR 1301.13(a), which states, "No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person."

4. Therefore, all Timely Applicants—other than those applicants (a) whose application is no longer pending before DEA because the applicant has withdrawn the application or because the Administrator has issued a Final Order denying the application, or (b) who lack the requisite state medical marijuana license—can engage in schedule III medical marijuana activities, as defined above, that otherwise would require a DEA registration.

5. Accordingly, Timely Applicants can engage in schedule III medical marijuana activities with other Timely Applicants. For example, a Timely Distributor Applicant can distribute schedule III medical marijuana to a Timely Dispenser Applicant and can obtain schedule III medical marijuana from a Timely Manufacturer Applicant.

6. Timely Applicants can also engage in schedule III medical marijuana activities with DEA registrants that hold a registration to handle schedule III medical marijuana. For example, a DEA-registered dispensary can continue receiving schedule III medical marijuana from a Timely Distributor Applicant.

7. Timely Applicants and DEA registrants may not lawfully engage in any schedule III medical marijuana activities with entities that did not complete an application for DEA registration between April 28, 2026, to June 26, 2026, or that have not applied for a DEA schedule III medical marijuana registration, until those entities become DEA registrants. As specified in 21 CFR 1301.13(k)(7), those entities remain subject to the prohibition under 21 CFR 1301.13(a).

8. If a Timely Applicant or DEA registrant engages in schedule III medical marijuana activities with someone other than a Timely Applicant or DEA registrant, such conduct could be potential grounds for denial of a Timely Applicant's application or revocation of a certificate of registration, respectively. Timely Applicants and registrants therefore should take adequate steps to confirm the status of all entities with which they will conduct schedule III medical marijuana activities. During this transitional period, adequate due diligence steps generally would include, at a minimum:

    - Obtaining from Timely Applicants (if dispensers) a copy of the "Marijuana Dispensary Information Submission" confirmation received from DEA at the time of application submission and verifying the Timely Applicant's document control number (DCN) via the DEA Diversion Control Website;

- Obtaining from Timely Applicants (if manufacturers or distributors) a copy of the submission confirmation provided by DEA at the time of application submission and verifying the Timely Applicant's DCN via the DEA Diversion Control Website;
- Obtaining from DEA registrants a copy of the registrant's DEA certificate of registration;
- Obtaining a copy of the entity's relevant state license and verifying its status is active; and
- Maintaining records of all due diligence conducted.

9. Entities that hold a DEA registration to handle schedule III medical marijuana must maintain all records required for schedule III controlled substances pursuant to 21 CFR part 1304, as the Administrator has concluded that all such records are necessary to comply with federal statutory and treaty obligations. If a DEA registrant engages in a transaction with a Timely Applicant, records maintained pursuant to 21 CFR part 1304 can include the Timely Applicant's DCN number where a DEA registration number would otherwise be required.

10. DEA recognizes that some states require entities holding state medical marijuana licenses to send *de minimis* quantities of schedule III medical marijuana to state-licensed third-party laboratories for testing. Such testing can help protect public safety and prevent unlawful products from entering the market. DEA further recognizes that, at this time, some Timely Applicants and registrants may not have access to analytical laboratories that are DEA-registered to handle schedule III medical marijuana. Therefore, to the extent such laboratories are unavailable and notwithstanding paragraph 8 above, DEA does not intend to penalize registrants and Timely Applicants for sending *de minimis* quantities of schedule III medical marijuana to a laboratory that is not DEA-registered to conduct analytical testing of schedule III medical marijuana, provided that (1) the analytical laboratory is located in the same state, and (2) the Timely Applicant/registrant retains detailed records of all such distributions.

    Because the closed system of distribution established by the Controlled Substances Act and 21 CFR 1301.13(a)[1] generally require Timely Applicants and DEA registrants to use a DEA-registered analytical laboratory, this exercise of the Administrator's discretion applies only when the use of a DEA-registered laboratory would violate state law. Specifically, it applies only to the extent that either (1) no entities anywhere in the United States are registered with DEA to conduct analytical testing of schedule III medical marijuana, or (2) state law prohibits the Timely Applicant/registrant from sending schedule III medical marijuana to an analytical laboratory in a different state, and no entities in the Timely Applicant/registrant's state are registered with DEA to conduct analytical testing of schedule III medical marijuana.

[1] Analytical laboratories are not covered by 21 CFR 1301.13(k)(7) and therefore remain subject to 21 CFR 1301.13(a).

Note that this information does not permit Timely Applicants and registrants to receive schedule III medical marijuana from non-DEA-registered analytical laboratories.

11. DEA recognizes Timely Applicants may require additional time to verify the status of their existing trading partners as Timely Applicants or registrants and to make necessary adjustments to their supply chain to comply with this information. Accordingly, Timely Applicants are expected to complete these activities and establish compliant supply chains no later than November 29, 2026.

    Timely Dispenser Applicants and Timely Distributor Applicants may continue to possess, dispense, and distribute existing inventories of schedule III medical marijuana acquired prior to the issuance of this information, including inventory previously obtained from entities that do not qualify as Timely Applicants or DEA registrants. Such inventory may continue to be used in otherwise authorized activities.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

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November 16, 2026

VIA FEDEX, CERTIFIED MAIL (RETURN RECEIPT REQUESTED), EMAIL

Drug Enforcement Administration
Attn: Diversion Control Division/DC
8701 Morrissette Drive
Springfield, VA 22152
DEA.Registration.Litigation@dea.gov

Re: Exception Request Under 21 C.F.R. § 1307.03 and 21 U.S.C. § 822(d); Alternative Request for Stay of Enforcement Pending Judicial Review—PennAlt Organics Inc. (Pennsylvania Grower/Processor Permit No. IN02-GP18-5009; DEA Application/Control No. M26172551E)

Time-Sensitive: Response Requested by November 20, 2026

Dear Diversion Control Division:

We represent PennAlt Organics Inc. (the "Company"), a Pennsylvania corporation licensed to grow, process, and dispense medical marijuana under Pennsylvania law. We submit this request pursuant to 21 C.F.R. § 1307.03, which permits "any person" to apply for an exception to "the application of any provision of this chapter" by filing a written request with the Office of Diversion Control "stating the reasons for such exception." The Company seeks an exception under 21 C.F.R. § 1307.03 from 21 C.F.R. § 1301.13(a), as applied through § 1301.13(k)(7), and DEA's October 30, 2026 document titled "Timely Applicant Information for Medical Marijuana Applicants" (the "Guidance").

The requested exception would simply maintain the status quo by allowing the Company's Pennsylvania-licensed manufacturing operation to continue supplying Pennsylvania-only medical-marijuana licensees listed as "Timely Applicants" or registrants in the Guidance, subject to the conditions described below, until DEA takes final action on the Company's pending medical-marijuana manufacturer registration application ("Form 225-M").[1] In the alternative, the Company requests that DEA agree to stay enforcement of the penalties announced in the Guidance. Specifically, the Company asks that DEA agree to stay enforcement of paragraphs 7 and 8 of the Guidance (the "counterparty restrictions"). In either case, the Company asks DEA to issue a written response by **Friday, November 20, 2026**.

[1] As used in this letter, "Form 225-M" refers to DEA's medical-marijuana-specific manufacturer registration application, as distinct from DEA's generic manufacturer registration application, Form 225. Similarly, as used in this letter, "Form 224-M" refers to DEA's medical-marijuana-specific dispensary registration application, as distinct from DEA's generic dispensary registration application, Form 224.

The penalties announced in the Guidance will devastate the Company if enforced against the Company and its business counterparts on November 30, 2026. The penalties are also procedurally invalid, arbitrary and capricious, and contrary to the fair-notice requirements of due process. The requested relief would avoid that harm without compromising DEA's diversion-control objectives: the Company would remain subject to Pennsylvania's comprehensive regulatory controls, and would accept the additional conditions described below.

A. The Company and Its Pennsylvania Operations

The Pennsylvania Department of Health ("DOH") has issued the Company a medical-marijuana manufacturer permit[2] and a dispensary permit (attached as Exhibit A).

The Company holds DOH Manufacturer Permit No. IN02-GP18-5009 for its grower/processor facility at 4020 Vision Way, Lemont Furnace, PA 15456, which is valid through July 31, 2027. It also holds Dispensary Permit No. IN12-5001-D, valid through August 12, 2027, for one location at 109 Crossroads Road, Scottdale, PA 15683. Since it was first permitted in 2018, the Company has operated under Pennsylvania's Medical Marijuana Act and DOH's implementing regulations. Under that regime, the Company is subject to seed-to-sale tracking, mandatory testing by state-approved laboratories, exacting security and surveillance requirements, and routine DOH inspection.

The Company is in good standing with DOH and, to the knowledge of its Director of Operations, has never received a notice of violation, been the subject of an enforcement action or investigation, or been subject to any sanction by DOH or any other state or local authority.

The Company supplies medical-marijuana products wholesale to 187 third-party DOH-licensed dispensaries, generating approximately $5 million in wholesale revenue per year. Twenty percent of the Company's wholesale product supplies its own dispensary. The Company serves approximately 3,200 patients, and the Company employs approximately 48 people in Pennsylvania across its manufacturing and dispensary locations. As of June 1, 2026, DOH had reported 438,727 active patient certifications in Pennsylvania.

The Company filed a Form 225-M registration application for its manufacturing operation on or about November 6, 2026, after DEA finally released that form on or about October 5, 2026.

B. Confusion Concerning the Early Application Window for Manufacturers

In April 2026, the Attorney General issued an order rescheduling state-licensed medical marijuana to Schedule III and creating an expedited registration process for licensees under 21 C.F.R. § 1301.13(k), which took effect on April 28, 2026. *See* Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements, 91 Fed. Reg. 22714, 22715 (Apr. 28, 2026) (the "Rescheduling Order" or the "Order"). Section 1301.13(k)(7) allows an applicant that submits a registration application within 60 days of the Rescheduling Order's publication—what the Order describes as an "early applicant[]"—to continue operating under its state license while the application is pending. The Order instructed that applicants must provide

[2] DOH refers to the holders of these licenses as growers/processors.

proof of a state license and use "the applicable DEA form or forms" to request registration. *See id.* at 22721–22.

DEA took a different approach for state-licensed medical-marijuana *dispensaries*. One day after promulgating the Rescheduling Order, on April 29, 2026, DEA opened a dedicated Medical Marijuana Dispensary Registration Portal that contained a detailed dispensary-specific application (Form 224-M). The agency provided no such application for manufacturers or distributors at that time. In fact, DEA provided no such application for manufacturers or distributors during the 60-day period following the agency's publication of the Rescheduling Order. Instead, applicants who selected the medical-marijuana manufacturer or distributor option on DEA's Diversion Control website were routed to a notice stating that a separate Schedule III registration portal for cultivators, manufacturers, distributors, and laboratories would be available "in the coming weeks."

Although this "coming soon" notice stated that "[t]hose interested in applying . . . *may* do so utilizing DEA's current Form 225 application" (emphasis added), it simultaneously promised that new medical-marijuana-specific forms—akin to Form 224-M (the dispensary application)—would be coming soon. That language signaled, and was reasonably understood to mean, that a dedicated manufacturer process was coming and would separately govern manufacturer applications. At a minimum, due to DEA's mixed messaging, "it was unclear if a separate registration portal would open for other medical cannabis license types, such as manufacturers, or if they were expected to use the DEA's standard 225 Form to complete the process."[3] The notice nowhere instructed manufacturers to apply using generic Form 225, which seeks only basic business and contact information, not the detailed operational, security, and personnel information that Form 224-M required. Nor did DEA advise that manufacturers *must* use generic Form 225 in order to avail themselves of the benefits of the new § 1301.13(k)(7). And DEA never—*in that notice or anywhere else*—warned that state-licensed medical-marijuana operators would be sanctioned, let alone wholly *barred* from doing business with early applicants, if they waited for the promised medical-marijuana-specific forms.

The 60-day period following the Rescheduling Order ended on June 26, 2026, with no medical-marijuana-specific manufacturer or distributor application in place. The "coming soon" notice remained on DEA's website until *October 5, 2026*. DEA did not open the medical-marijuana manufacturer portal until that date, more than three (3) months after the 60-day period ended and more than five (5) months after DEA launched the dispensary portal. Because Form 224-M was announced and launched at the start of the 60-day period, many manufacturers understood that a similar 60-day window would be afforded once the dedicated manufacturer form became available.

The Company received no communication from DEA between June 26 and October 5, 2026, suggesting that it had missed any deadline or that its ability to transact with other applicants would be restricted. Promptly after DEA released the manufacturer-specific application, the

[3] Tony Lange, *DEA's Schedule III Cannabis Registration 'Coming Soon' For Cultivators, Manufacturers, Distributors, Labs*, Cannabis Business Times (May 11, 2026), https://www.cannabisbusinesstimes.com/cannabis-rescheduling/news/15824820/deas-schedule-iii-cannabis-registration-coming-soon-for-cultivators-manufacturers-distributors-labs.

Company filed its Form 225-M, which remains pending under Control No. M26172551E. *See* Exhibit B (manufacturer application submission confirmation).

On October 30, 2026, DEA issued the Guidance, which for the first time announced that entities would be sanctioned for waiting for the manufacturer-specific application form. The Guidance stated that entities listed as "Timely Applicants" (i.e., those referred to as "early applicants" in the Rescheduling Order, meaning entities that submitted an application by June 26, 2026) or registrants "may not lawfully engage in any schedule III medical marijuana activities with entities that did not complete an application" by June 26, 2026, "until those entities become DEA registrants." It warned that such dealings could mean denial of a listed entity's application for DEA registration or revocation of an existing registration. The Guidance further advised listed entities that they had only until November 29, 2026—less than a month—to "establish compliant supply chains," i.e., to ensure that their supply chains included only listed entities and registrants. The effect of these provisions is to bar all listed entities from doing business with medical-marijuana manufacturers, like the Company, that did not file within the 60-day window, before DEA released the manufacturer-specific application form it promised in early May would be published "in the coming weeks." By the same token, the Guidance abruptly halts the business of manufacturers like the Company, for they can no longer sell to long-time client dispensaries that appear on the "Timely Applicant" list—which, in the Company's case, comprise approximately 95% of its third-party customers.

These sanctions caused immediate harm. Within days of the Guidance's publication, the Company's third-party dispensary customers began to notify the Company that the Guidance prevents them from doing business with the Company. Since October 30, 2026, at least two customers have indicated that they will "no longer be doing business" with suppliers without Timely Applicant status. Those two customers alone account for close to $1 million in annual revenue.

If relief is not granted promptly—before the November 29, 2026 deadline for "compliant" supply chains—the Company could lose nearly all of its dispensary customers, at least temporarily and possibly for good. Many of the approximately 3,200 patients who rely on the Company's products to treat chronic pain and other debilitating medical conditions would lose access to those products and need to find other sources. If the penalties announced in the Guidance take effect, the Company could be bankrupt and have to lay off all 48 of its employees within weeks.

C. Legal Basis for the Exception

Under 21 C.F.R. § 1307.03, the Administrator may, in his discretion, grant an exception to any provision of Chapter II of Title 21 of the Code of Federal Regulations, including §§ 1301.13(a) and 1301.13(k)(7). *See Visels Drug Store, Inc. v. DEA*, 593 F. App'x 12, 14 (2d Cir. 2014). DEA promulgated § 1307.03 under, among other authorities, 21 U.S.C. § 822(d), which authorizes the Attorney General to "waive the requirement for registration" of manufacturers, distributors, or dispensers where "consistent with the public health and safety." The Company asks DEA to exercise that authority here, to authorize a temporary exception until DEA takes final action on the Company's medical-marijuana manufacturer application (Form 225-M).

An exception is warranted because it would create no additional risk of diversion, align with the objectives of the April 2026 Rescheduling Order, and serve the public interest. The

Company is subject to the same comprehensive DOH controls as every Pennsylvania manufacturer listed as a "Timely Applicant" in the Guidance. It differs only in the timing of its federal application, which DEA had not made available in manufacturer-specific form during the 60-day window. The Attorney General expressly found that existing state medical-marijuana regimes, including Pennsylvania's, "fulfill the objectives of federal registration and recordkeeping requirements." 91 Fed. Reg. at 22720. Indeed, the Rescheduling Order states that, absent evidence of harm to the public interest, DEA "*must* grant registration" to state-licensed medical-marijuana applicants. *Id.* (emphasis added). The Attorney General incorporated state regimes into the federal framework with the aim of creating "the least disruption for patients and existing state systems." *Id.* Denying the relief requested here would undercut each of these principles.

D. The Rescheduling Order Relies on State Controls, and Pennsylvania's Controls Continue to Govern the Company

The Rescheduling Order rests on the Attorney General's finding that state regimes "have developed robust infrastructure for preventing diversion, ensuring product safety, maintaining records, and conducting facility inspections—functions that fulfill the objectives of federal registration and recordkeeping requirements." 91 Fed. Reg. at 22720. The Attorney General found that, "taken as a whole," these regimes "demonstrate a sustained capacity to achieve the public-interest objectives that underlie the CSA's registration framework, including . . . preventing the diversion of controlled substances into illicit channels." *Id.*

The regulation itself builds on that finding. Registration of an applicant that complies with a state regime containing "robust protections against diversion, requirements for record-keeping and reporting, and safety and inspection measures will not be inconsistent with the public interest." *Id.* at 22722. A state license is "conclusive evidence" of state authorization. *Id.* (21 C.F.R. § 1301.13(k)(2)). DEA must accept state-required reports, records, and forms "to the maximum extent permissible." *Id.* (§ 1301.13(k)(4)). And state-law labeling, packaging, disposal, and physical-security requirements satisfy the corresponding federal requirements. *Id.* (§ 1301.13(k)(8)–(10)). The Order also places marijuana in Schedule III *based on* it being "subject to a state medical marijuana license," without reference to DEA registration status. *Id.* (§ 1308.13(g)(2)–(3)).

Pennsylvania's regulatory scheme is one of the regimes on which the Attorney General relied, and its many controls map directly onto the requirements § 1301.13(k) imposes on medical-marijuana registrants. Among others, those requirements include:

- **Medical use only (§ 1301.13(k)(1)(iv)).** Pennsylvania issues no adult-use licenses. Product may be dispensed only to certified patients and registered caregivers, 35 P.S. § 10231.303(b)(1), and a manufacturer may deliver only to Pennsylvania medical-marijuana organizations and approved laboratories, 28 Pa. Code § 1151a.35(a).

- **Registration tracks the state license (§ 1301.13(k)(2)–(3)).** A federal registration may not exceed the scope of the state license and is automatically suspended if that license is suspended, revoked, or expires. The Company's activities are bounded by its DOH permits, which DOH may inspect, investigate, suspend, or revoke. 28 Pa. Code §§ 1141a.45, 1141a.47.

- **Reports and records (§ 1301.13(k)(4)).** Every manufacturer must use DOH's real-time seed-to-sale tracking system, which DOH can access at any time "to inhibit diversion." 35 P.S. §§ 10231.301(a)(4), 10231.701; 28 Pa. Code § 1151a.39. Manufacturers must also conduct regular inventories and retain records for at least four years. 28 Pa. Code § 1151a.30; 35 P.S. § 10231.301(a)(13).

- **Storage, access, and cultivation restrictions (§ 1301.13(k)(6)).** Manufacturers may grow, store, and process only in an indoor, secure, DOH-inspected facility with clearly marked growing and processing areas, which DOH, law enforcement, and "other Federal, State or local government officials" may enter. 28 Pa. Code §§ 1151a.23(a)–(b), 1151a.25(g).

- **Labeling, packaging, and disposal (§ 1301.13(k)(8)–(9)).** DOH must pre-approve all packaging and labels, which must be child-resistant and tamper-evident and carry a criminal-penalty warning. All medical-marijuana waste must be rendered unusable before disposal. 28 Pa. Code §§ 1151a.34, 1151a.40.

- **Physical security (§ 1301.13(k)(10)).** Manufacturers must maintain commercial-grade security and surveillance, locked limited-access storage, and secured, manifested transport. They must also promptly report losses to DOH and law enforcement. 35 P.S. §§ 10231.702–.703; 28 Pa. Code §§ 1141a.29, 1151a.26, 1151a.31, 1151a.35, 1151a.36, 1151a.38.

- **Safety and inspection measures (§ 1301.13(k)).** All product must be tested by DOH-approved laboratories, and DOH conducts announced and unannounced inspections. 35 P.S. §§ 10231.301(a)(8), 10231.704. Principals and employees must complete diversion training. 35 P.S. § 10231.301(a)(7); 28 Pa. Code § 1141a.48.

None of these obligations depends on the date the Company filed its manufacturer registration application. Every control the Attorney General found sufficient applies to the Company's manufacturing operation today, exactly as it applies to the entities listed in the Guidance. The 60-day window in § 1301.13(k)(7) is a mechanism designed to facilitate the swift and smooth transition to federal regulation. Yet DEA's implementation of that provision directly undercuts those goals. It also threatens to put the Company out of business, jeopardizes the livelihoods of the Company's employees, and risks patient welfare. An exception is warranted.

E. Proposed Conditions to the Issuance of an Exception

The Company proposes the following conditions on any exception, which track the obligations that apply to Timely Applicants and DEA registrants:

- It will maintain records consistent with 21 C.F.R. Part 1304, in addition to its state records, including the DEA registration number or DCN of each counterparty and records of all due diligence conducted, and make them available to DEA on request.
- It will consent to DEA inspection of its facility.
- It will make no interstate transfers.
- It will submit any and all required reports to the Philadelphia Field Division.

- It will handle marijuana only for medical purposes and only within the scope of its DOH permit, and will notify DEA in writing within one business day of any suspension, revocation, or expiration of that permit. *See* 21 C.F.R. § 1301.13(k)(1)(iv), (k)(3).
- It will participate in DEA's nominal-price purchase-and-resale mechanism for its crops, store crops in a facility to which DEA has access and may inspect on demand, and identify its permitted cultivation areas. *See* 21 C.F.R. § 1301.13(k)(6).
- It will label all products with the warning required by 21 U.S.C. § 825(c), in addition to DOH-required labeling. *See* 21 C.F.R. § 1301.13(k)(8).
- It will take an initial inventory of all marijuana on hand as of the date the exception is granted and biennial inventories thereafter, consistent with 21 C.F.R. § 1304.11.
- It will report any theft or significant loss to the Philadelphia Field Division in writing within one business day of discovery and file DEA Form 106 within 45 days, consistent with 21 C.F.R. § 1301.74(c), and will not permit access to marijuana by any person disqualified under 21 C.F.R. § 1301.76(a).
- It will send product to non-DEA-registered laboratories only in *de minimis* quantities, only to in-state DOH-approved laboratories, and only where a DEA-registered laboratory is unavailable, and will keep detailed records of each such distribution.
- It will provide DEA, on request, its supplier and customer lists, list of employees with access to marijuana, standard operating procedures, and DOH inspection reports, and will notify DEA of any DOH enforcement action.

The exception will expire automatically when DEA takes final action on the Company's medical-marijuana manufacturer application (Form 225-M).

F. Reservation of Rights

Nothing in this letter withdraws, waives, or modifies any right associated with the Company's pending registration applications, including its Form 225-M application. The Company reserves all rights to challenge the Guidance, including that the Guidance is procedurally invalid, arbitrary and capricious, and—owing to the penalties' lack of fair notice—a violation of due process. In the event the agency denies the Company's request for an exception, this letter also constitutes the Company's request that the agency agree to stay enforcement of the counterparty restrictions as described above.

Conclusion

We respectfully ask DEA to grant the requested exception or, in the alternative, to consent to the requested stay, and to issue a written response as soon as possible, and in any event by November 20, 2026, given the November 29, 2026 deadline. The Company will respond promptly to any request for additional information. Please direct any questions to the undersigned.

Respectfully submitted,



Jesse H. Alderman

cc: Attn: Cheri Oz, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152

Attn: Laurie Wiesner, Diversion Enforcement Counsel, Office of the Chief Counsel, Diversion and Regulatory Litigation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152

Attn: Timothy Flaherty, Special Agent in Charge, Philadelphia Division, Drug Enforcement Administration, Wm. J. Green Fed. Bldg., 600 Arch Street, Room 10224, Philadelphia, PA 19106

Enclosures:

Exhibit A: DOH permits
Exhibit B: Form 225-M submission confirmation

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Completed Internet Form - NOT FOR SUBMISSION **DEA/Control Number**: M26172551E **Submission Date**: Fri Nov 06 10:54:10 EST 2026	**APPLICATION FOR REGISTRATIONUNDER CONTROLLED SUBSTANCES ACT OF 1970**	**Form** DEA 225 Completed Internet Receipt. NOT FOR SUBMISSION
NAME: Applicant or Business (LAST) PENNALT ORGANICS INC.	**(First, MI)**	Application Complete. Tracking Number: 15712262 Fee Paid: 3699
TAX IDENTIFYING NUMBER and/or XX-XXXXX19	**SOCIAL SECURITY NUMBER**	For more information regarding SSN/TIN, See Note 3 under ADDITIONAL INFORMATION below
PROPOSED BUSINESS ADDRESS. (When entering a P.O. box, you are required to enter a street address)		
4020 VISION WAY		
PENN HEALTH GROUP		
CITY LEMONT FURNACE	**STATE** PA **ZIP CODE** 15456	
APPLICANT'S BUSINESS PHONE NUMBER 4124172128	**POC CELL PHONE NUMBER** 4125267433	
POC NAME DANIEL SAX	**POC EMAIL ADDRESS** ACCOUNTING@PENNHGROUP.COM	
REGISTRATION CLASSIFICATION		
BUSINESS ACTIVITY: MEDICAL MARIJUANA MANUFACTURER	**INDICATE HERE IF YOU REQUIRE ORDER FORMS.** N	
Drug Schedules: 3N	Will your firm be handling medical marijuana?: YES Will your firm be handling recreational marijuana?: NO	

State License/Liability Information

You must be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate.
Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn **WITHOUT refund.**

State License No. IN02-GP18-5009 State: PA Expire Date: 07-31-2027

State Controlled License No. Expire Date:

1. Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or any such action pending?	N
2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?	N
3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?	N
4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?	N

Registration Fee: Registration Fee Paid: 3699

Certification for Fee Exemption (if applicable)			
Certifying Official's Name		**Certifying Official's Title**	
Certifying Official's Phone		**Certifying Official's Email**	
Name of Fee Exempt Institution			

Practitioner Information (if applicable)			
National Provider ID		**Professional Degree**	
Date of Birth		**Graduation Year (Medical/Professional School)**	
Medical/Professional School			

Manufacturer Details (if applicable)

Category/Schedule	1	2	2N	3	3N	4	5	L1
Bulk Growing					X			
Extraction					X			
Processing					X			
Repackager					X			

SELECTED DRUG CODES:

DRUG CODES:
7353 7362 7386

BULK DRUG CODES:
7353 7362 7386

Application Certification:

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.

By typing my full name in the space below, I hereby certify that the foregoing information furnished on this electronic DEA application is true and correct and understand that this constitutes an electronic signature for purposes of this electronic DEA application only.

* Name of Applicant (For individual registrants, the registrant themselves MUST complete this E-Signature) or name of Officer of the Corporation/Company

e-Signature: RIKKILEE ROSE

This electronic DEA application must be certified by the applicant/registrant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust, or other entity. See 21 C.F.R § 1301.13(j) for more information on who can certify this application

ADDITIONAL INFORMATION

Form 225 Form 225 ApprovedOMB Form No. 1117-0012 Expires: 07/31/2028(15 minutes)

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is (See Above). Public reporting burden for this collection of information is estimated to average (See Above) per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.
3. The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.
4. **PRIVACY ACT NOTICE:**
   Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are §§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§ 822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and person registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

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Commonwealth of Pennsylvania
Department of Health
Bureau of Medical Marijuana
625 Forster St. Harrisburg, PA 17120

PERMIT

PERMIT #: IN02-GP18-5009

TO OPERATE A MEDICAL MARIJUANA GROWER/PROCESSOR FACILITY

This is to certify that
PennAlt Organics Inc

has been granted this permit to operate a medical marijuana facility located at
4020 Vision Way, Lemont Furnace, PA 15456.
This permit shall be effective from 7/31/2026 until 7/31/2027 in accordance with law.

Laura Mentch

Laura Mentch, RPh, MBA
Director

pennsylvania
DEPARTMENT OF HEALTH

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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PENNALT ORGANICS, INC.,	)	
	)	
Petitioner,	)	
	)	
v.	)	Case No.
	)	
DRUG ENFORCEMENT ADMINISTRATION,	)	
	)	
Respondent.	)	

AFFIDAVIT OF DANIEL SAX

I, Daniel Sax, declare as follows under penalty of perjury:

1. I am the Authorized Representative of PennAlt Organics, Inc. ("PennAlt") d/b/a Penn Health Group. I am more than eighteen years of age and am competent to make this Affidavit.

2. I am currently the Director of Operations at PennAlt where I regularly oversee the obtaining of permits and licenses for PennAlt.

3. PennAlt is a Pennsylvania corporation, with its principal place of business at 4020 Vision Way, Lemont Furnace, Pennsylvania 15456.

4. In the ordinary and regular course of business and as a regular business practice, PennAlt routinely reviews developments in the medical marijuana field in accordance with the law.

5. Based on the foregoing, I am authorized to make this Affidavit. I make this Affidavit based on my personal knowledge described above, and based on my knowledge of the severe harms PennAlt shall experience if the Drug Enforcement Agency ("DEA") enforces its guidance document.

6. In April 2026, the Attorney General issued an order rescheduling state-licensed

medical marijuana to a Schedule III substance and creating an expedited registration processes for licensees under 21 C.F.R. § 1301.13(k) (the "Order"). To be in compliance with the law, companies such as PennAlt were required to submit a registration application within sixty days of the Order's publication to continue operating under its state license while the application is pending. The DEA immediately opened Form 224-M for completion by medical-marijuana dispensaries. At this time, a similar form was not made available to manufacturers or distributors of medical marijuana.

7. In fact, applicants who selected the medical marijuana or distributor option on DEA's Diversion Control website were routed to a notice stating that a separate portal for manufacturers and distributors would be available in the coming weeks. At no point in a review of the DEA website would we have seen any instructions for manufacturers to apply using generic Form 225, which seeks only basic business and contact information, not the detailed operational, security, and personnel information that the Form 224-M required.

8. DEA opened the manufacturer portal on October 5, 2026 and with it Form 225-M. After the release of the manufacturer-specific application, on or about November 6, 2026, my colleagues and I filed PennAlt's Form 225-M which remains pending under Control No. M26172551E. Between June 26 and October 5, 2026, PennAlt received no communication from DEA suggesting that it had missed any deadline or that it was not in compliance with the Order or other federal laws.

9. On October 30, 2026, DEA issued its guidance document titled "Timely Applicant Information for Medical Marijuana Applicants" (the "Guidance"). This was the first time PennAlt had ever heard from DEA about PennAlt possibly being in noncompliance with the Order.

10. Under the Guidance, a Timely Applicant "may not lawfully engage in any schedule

III medical marijuana activities with entities that did not complete an application" by June 26, 2026, "until those entities become DEA registrants." My understanding is that, under the new Guidance, if a Timely Applicant decides to conduct business with a non-registered entity, then such dealings would lead to a denial of a listed entity's application for DEA registration or revocation of an existing registration. My understanding is that the Guidance also states that listed entities have until November 29, 2026, to ensure their supply chains include only listed entities and registrants. I understand this to mean that, absent any halting of the Guidance, all listed entities will be barred from doing business with PennAlt.

11. The implications of the Guidance on PennAlt are severe. The sanctions from the Guidance will cripple PennAlt, and will pose an existential threat to the survival of PennAlt. The Guidance restricts the business of manufacturers which can no longer sell to long-time client dispensaries that appear on the "Timely Applicant" list. In PennAlt's case this comprises approximately 95% of its third-party customers.

12. In fact, within days of the Guidance's publication my team received messages from third-party dispensary customers notifying us that the Guidance prevents them from continuing to do business with PennAlt. Since the Guidance's issuance, at least two customers have asked PennAlt for their DEA control number. Other customers informed PennAlt that they will no longer continue to do business with PennAlt without Timely Applicant Status. Those two customers account for close to $1 million in annual revenue.

13. The Guidance also bars PennAlt's manufacturing operation from supplying PennAlt's own dispensary. Therefore, PennAlt must cease supplying its dispensary or it risks denial of its dispensary registration application.

14. Without Court intervention before November 29, 2026, PennAlt will lose nearly all

of its dispensary customers. Currently, through its dispensary, PennAlt supplies approximately 3,200 patients. If PennAlt is unable to supply its own dispensary many of these patients who rely on PennAlt's products for treatment will lose access to those products and need to find other sources.

15. PennAlt prides itself in the fact that PennAlt's dispensary serves an undeserved area, and so patients would be forced to travel a greater distance to receive their medication. Such a loss of supply would significantly limit patient access to care.

16. If this Guidance is allowed to go into effect, it is likely PennAlt will become bankrupt and PennAlt may have to lay off all forty-eight of its employees within weeks.

17. With assistance of counsel, PennAlt submitted a request to the DEA under 21 C.F.R. § 1307.03, seeking an exception from the sanctions under the Guidance. As of this date, PennAlt has not received any response from DEA regarding PennAlt's request.

Further the affiant sayeth not.

Name: Daniel Sax
Title: Director of Operations/Authorized Representative, PennAlt Organics, Inc. d/b/a Penn Health Group
Date: November 20, 2026

SWORN TO AND SUBSCRIBED before me

this 20th day of November, 2026.

Commonwealth of Pennsylvania - Notary Seal
DAPHNE DEINER - Notary Public
Allegheny County
My Commission Expires February 24, 2027
Commission Number 1432888

Notary Public