**NOT SCHEDULED FOR ORAL ARGUMENT**

**Nos. 26-1324, 26-1325 (consol.)**

---

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

---

STANDARD WELLNESS UTAH, LLC, VERDE AMERICANO, LLC, and NW CONFECTIONS OK 241AA LLC
*Petitioners,*

v.

DRUG ENFORCEMENT ADMINISTRATION and TERRANCE C. COLE, ADMINISTRATOR
*Respondents.*

---

Petition for Review from
a Decision of the Drug Enforcement Administration

---

# REPLY IN SUPPORT OF EMERGENCY MOTION FOR ADMINISTRATIVE STAY AND FOR STAY PENDING REVIEW

---

Shane Pennington
(DC Circ: 55524)
Blank Rome LLP
717 Texas Avenue, Suite 1400
Houston, TX 77002
713-632-8607
Shane.pennington@blankrome.com

Christina Manfredi McKinley
(DC Circ: 53419)
Blank Rome, LLP
501 Grant Street, Suite 850
Pittsburgh, PA 15219
412-932-2733
Christina.mckinley@blankrome.com

*Counsel for Petitioners*

## TABLE OF CONTENTS

INTRODUCTION....1
ARGUMENT....1
I. Petitioners are likely to succeed because the Information changed the law without notice, comment, or rationale....1
A. The Information's text shows it changed the law in both directions....1
B. Section 1301.13(k)(7) measures applicants' authority by state licenses, not registrant rules....4
C. The Information gave no reasons, and *Chenery* and *Regents* bar the reasons counsel now supplies....5
D. The Information is final, and Verde and NW Confections have redressable standing....8
II. Petitioners face irreparable harm....9
A. The Information forces Verde and NW Confections to choose between their customers and their applications....9
B. DEA's 7,100-application figure does not show a workable supply chain....10
C. The disruption is immediate and market-wide....11
D. The harm is not self-inflicted....11
III. The equities favor a stay, which will restore DEA's own regulation....12
CONCLUSION....12
CERTIFICATE OF COMPLIANCE....14
CERTIFICATE OF SERVICE....15

## TABLE OF AUTHORITIES

**Cases** **Page(s)**

*Adya LLC v. DEA*,
826 F. Supp. 3d 115 (D.D.C. 2026).....9

*Am. Wild Horse Pres. Campaign v. Perdue*,
873 F.3d 914 (D.C. Cir. 2017).....3

*Appalachian Power Co. v. EPA*,
208 F.3d 1015 (D.C. Cir. 2000).....3

*Bennett v. Spear*,
520 U.S. 154 (1997).....8

*Coal. for Humane Immigrant Rts. v. Mullin*,
185 F.4th 1275 (D.C. Cir. 2026).....8

*Dep't of Educ. v. California*,
604 U.S. 650 (2025).....11

*DHS v. Regents of the Univ. of Cal.*,
591 U.S. 1 (2020).....5, 6, 7

*FCC v. Fox Television Stations, Inc.*,
556 U.S. 502 (2009).....5

*Gonzales v. Raich*,
545 U.S. 1 (2005).....5

*Holistic Candlers & Consumers Ass'n v. FDA*,
664 F.3d 940 (D.C. Cir. 2012).....8

*Ipsen Biopharmaceuticals, Inc. v. Azar*,
943 F.3d 953 (D.C. Cir. 2019).....8

*Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*,
463 U.S. 29 (1983).....5

*Ohio v. EPA*,
603 U.S. 279 (2024).....7

*Perez v. Mortg. Bankers Ass'n*,
575 U.S. 92 (2015).....3

*Rumsfeld v. FAIR*,
547 U.S. 47 (2006).....8

*SEC v. Chenery Corp.*,
332 U.S. 194 (1947).....5

*Sierra Club v. EPA*,
292 F.3d 895 (D.C. Cir. 2002).....8

*Sugar Cane Growers Coop. of Fla. v. Veneman*,
289 F.3d 89 (D.C. Cir. 2002).....3

*Trump v. CASA, Inc.*,
606 U.S. 831 (2025).....12

**Statutes**

5 U.S.C.
§553(b)(B).....3
§553(b)-(c).....3
§702.....9
§706(2)(D).....3

21 U.S.C.
§822(d).....7

**Other Authorities**

21 C.F.R.§1301.13(k)(1).....1, 2, 4

21 C.F.R.§1301.13(k)(6).....4

21 C.F.R.§1301.13(k)(7).....*passim*

91 Fed. Reg. 22,714 (Apr. 28, 2026).....7, 8, 12

## GLOSSARY OF ABBREVIATIONS

| Abbreviation | Definition |
|---|---|
| APA | Administrative Procedure Act |
| CSA or Act | Controlled Substances Act |
| DEA | Drug Enforcement Administration |
| DCN | Document control number assigned to a DEA application |
| Final Order | AG Order No. 6754-2026, 91 Fed. Reg. 22,714 (Apr. 28, 2026) (Mot. Ex. 1) |
| Information | DEA Medical Marijuana Timely Applicant Information, emailed Oct. 30, 2026 (Mot. Ex. 2) |
| Mot. | Petitioners' Emergency Motion to Stay (Nov. 18, 2026) |
| Opp. | Respondents' Combined Opposition to Petitioners' Motions for Stay Pending Review (Nov. 23, 2026) |
| OBNDD | Oklahoma State Bureau of Narcotics and Dangerous Drugs Control |

## INTRODUCTION

DEA's opposition rests on one claim: the October 30 Information "changed nothing." Opp.3–4. The Information's text belies that claim. The Information sets a November 29 compliance date found in no statute or regulation, renders dealing with non-timely state licensees grounds for denial, protects inventory acquired before its own issuance, and supplies a rule for registrants' dealings with pending applicants that no regulation contained. *See* Ex.2¶¶6–11. A document that narrows one regulatory provision, adds to another, and creates new compliance dates is a rule. DEA issued it without notice and comment, good cause, or stated reasons.

Petitioners relied on the Final Order and its implementing regulation. On November 29, the Information will split each State's medical marijuana market into two, forcing timely applicants to cut off longtime state-licensed partners or risk denial of their own applications. The Court should stay the deadline before then.

## ARGUMENT

### I. Petitioners are likely to succeed because the Information changed the law without notice, comment, or rationale.

#### A. The Information's text shows it changed the law in both directions.

To begin, §1301.13(k)(1) governs *registrants*: a registered manufacturer or distributor may transfer only to, and receive only from, other registrants. 21 C.F.R. §1301.13(k)(1). Section (k)(7), by contrast, governs *applicants*: "[n]otwithstanding paragraph (a)," a timely applicant "may engage in the manufacture, distribution,

and/or dispensing of marijuana … in conformity with a state-issued license during the pendency of the application." *Id.*(k)(7). The Information changed both.

First, it narrowed (k)(7). It now bars timely applicants from dealing with anyone who did not apply between April 28 and June 26, replacing (k)(7)'s state-license measure with the filing date of someone else's application. Ex.2¶ 7.

Second, it expanded (k)(1). Paragraph 6 now permits timely *applicants* to "engage in schedule III medical marijuana activities with DEA *registrants*," and paragraph 9 lets *registrants* record an *applicant's* document control number "where a DEA registration number would otherwise be required." *Id.*¶¶6, 9. No prior regulation addressed a registrant's dealings with a pending applicant. While DEA says the Information "merely recounts preexisting requirements," its cited passage says only that early applicants "may lawfully operate under their state-issued licenses during the pendency of review"—nothing about a registrant's counterparties. Opp.14 (internal quotations omitted); 21 C.F.R. §1301.13(k)(7). Supplying a missing rule is not restating one.

Third, it added a new consequence: paragraph 8 makes dealing with "non-timely" applicants "potential grounds for denial of a Timely Applicant's application." Ex.2¶8. No rule says that.

Fourth, it dated obligations to its own issuance. Paragraph 11 sets a November 29 deadline and lets timely dispensers and distributors keep selling inventory

"acquired prior to the issuance of this information," including from non-timely entities. *Id.*¶11. If this prohibition previously existed, those purchases were unlawful; a "restatement" could not excuse them. Only a new rule needs a grandfather clause.

This Court rejected DEA's nothing-has-changed argument in *American Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 924 (D.C. Cir. 2017). A disclaimer is "boilerplate" when the document "commands,… requires, … orders, [and] dictates." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). Here, the Information says applicants "may not lawfully engage" in these dealings and "are expected to" comply, Ex.2¶¶7, 11; DEA's disclaimers are veneer.

The Information is a legislative rule requiring notice and comment. 5 U.S.C. §553(b)–(c); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). "[A]n agency may not escape the notice and comment requirements … by labeling a major substantive legal addition to a rule a mere interpretation." *Appalachian Power*, 208 F.3d at 1024. DEA invoked no §553(b)(B) good cause, and counsel cannot supply it now. The error was prejudicial: "an utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002). That failure alone warrants relief under 5 U.S.C. §706(2)(D).

### B. Section 1301.13(k)(7) measures applicants' authority by state licenses, not registrant rules.

DEA offers a syllogism: (k)(7) lets applicants operate as though registered, Opp.2; registrants deal only with registrants, Opp.3; so applicants "cannot claim a greater right now … than they could as fully registered" entities. Opp.25 (emphasis removed). The first step is DEA's gloss. Section 1301.13(k)(7) removes paragraph (a)'s limits without importing registrant rules: it provides that applicants may operate "[n]otwithstanding paragraph (a)" and "in conformity with a state-issued license during the pendency of the application." 21 C.F.R. §1301.13(k)(7). The measure is the state license. Section (k)(7) exists precisely because timely applicants could not immediately satisfy registrant requirements, such as Single Convention quota and crop-sale obligations, *see* 91 Fed. Reg. at 22,718; 21 C.F.R. §1301.13(k)(6); the regulation allows them to operate under state licenses until they can.

Petitioners do not challenge (k)(1), which will govern each applicant once DEA grants its application. But DEA identifies no granted registration and concedes it missed its own October 28 target. Opp.8–9; Almendinger Decl.¶3. The Final Order contemplates a gradual transition, with each applicant moving to (k)(1) when its application is granted. The Information replaces that measured transition with a single, haphazard date while Petitioners' applications remain pending. That substitution is a rule change requiring notice and comment.

DEA's "closed system," Opp.12–13, is irrelevant. That system bars handling controlled substances "except in a manner authorized by" the Act. *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). Section (k)(7) *is* such an authorization, one DEA defends. Opp.17. The Information's grandfather clause confirms it: timely entities may keep distributing inventory "previously obtained from entities that do not qualify as Timely Applicants or DEA registrants." Ex.2¶11. Those purchases were lawful only because of (k)(7). The ban is *new*, and it comes from the Information.

### C. The Information gave no reasons, and *Chenery* and *Regents* bar the reasons counsel now supplies.

***First.*** To the extent the Information did not "change" the existing rule as DEA asserts, DEA's newfound explanations cannot justify it. A court must judge agency action "solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). The problem with a later rationale "is the timing, not the speaker." *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 20, 23 (2020). The Information states a legal premise, Ex.2¶7, and a purpose—"clarity … regarding existing requirements," *id.* at Conclusion—but no reasons for its choices. It does not explain why November 29, why thirty days, why manufacturers get no inventory protection, why it imposed a registrant restriction mid-pendency, or how applicants can comply if no registration has been granted in a state. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *FCC v. Fox*

*Television Stations, Inc.*, 556 U.S. 502, 515 (2009). DEA's opposition supplies reasons the agency never gave.

It argues that had DEA finished every review by October 28, all registrants would be confined to dealing with registrants. Opp.17–18. Then the limit would attach because each application was decided, not because a date passed. But (k)(7) runs "during the pendency of the application"; the Final Order directs only that DEA "make every effort" to finish within six months. 91 Fed. Reg. at 22,722. DEA concedes "the only difference here is that [its] review still requires additional time." Opp.18. That difference is dispositive; treating a processing target as a cutoff would be a new rule.

DEA also recasts November 29 as unreviewable nonenforcement. Opp.18. But paragraph 7 declares what applicants "may not lawfully" do, and paragraph 8 makes doing it grounds for denial. Ex.2¶¶7–8. DEA invoked discretion only in paragraph 10. *Id.*¶10. A directive to every timely applicant, with a deadline and a basis for denial, is not a decision not to prosecute. *Cf. Regents*, 591 U.S. at 18.

DEA next claims 7,100 timely applications make compliance workable. Opp.16, 25. This ignores the markets' intrastate reality. The Information makes no feasibility finding. Rather, DEA relies on a declaration executed November 20, three weeks later, that counts applications, not registrations, on "a preliminary

assessment" and aggregates four States "collectively" although the markets are *intra*state. Almendinger Decl.¶¶3–4; *see* Part II.B.

Finally, DEA now invokes a "time-limited registration waiver" under 21 U.S.C. §822(d) to treat applicants "as if they had a DEA registration." Opp.8. But the Final Order never cites §822(d) or uses either phrase. *See* 91 Fed. Reg. at 22,719 n.40, 22,721. The construct is new, and the Final Order refutes it.

***Second.*** To the extent the Information changed the existing rule (it did), it required proper process. DEA knew how to address a supply-chain gap: recognizing that some applicants "may not have access to analytical laboratories that are DEA-registered," it excused transfers to unregistered labs. Ex.2¶10. Yet it never considered parallel relief where no growers or distributors are registered. Failing to consider an alternative "within the ambit of the existing policy" and to weigh reliance is arbitrary. *Regents*, 591 U.S. at 30–33 (internal quotations omitted). DEA's awareness that applicants needed time, Ex.2¶11, is no solace: "awareness is not itself an explanation." *Ohio v. EPA*, 603 U.S. 279, 295 (2024). Nor does petitioners' reliance come from violating federal law, Opp.16; it comes from (k)(7)—which *is* federal law. The Information cannot change that regulation without notice and comment.

### D. The Information is final, and Verde and NW Confections have redressable standing.

The Information reflects DEA's settled position, and bears legal consequences: a new ground for denial, a deadline, and an inventory limitation tied to its issuance. Ex.2¶¶7–8, 11; Ex.4¶19; *see Bennett v. Spear*, 520 U.S. 154, 178 (1997); *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 956–958 (D.C. Cir. 2019). Unlike FDA letters that "compel[led] action by neither the recipient nor the agency," Opp.19–20 (quoting *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012)), the Information compels restructuring by a fixed date. Verde and NW Confections are direct objects of the Information and have standing. *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002). The Court need not reach Standard Wellness's standing, Mot.6. *See Rumsfeld v. FAIR*, 547 U.S. 47, 52 n.2 (2006).

And their claims are redressable. A merits decision vacating the Information would allow Petitioners to proceed with the orderly and timely transition process the Attorney General envisioned, *see* 91 Fed. Reg. at 22,720, and would allow the market to adjust gradually to the supply/demand changes brought about by federal registration. By contrast, the Information swiftly disrupts the market, sowing chaos without rationale.

DEA's reliance on *Coalition for Humane Immigrant Rights v. Mullin*, Opp.23, omits why a stay was unhelpful there: the plaintiffs left unchallenged a regulation

independently authorizing the same removals. 185 F.4th 1275, 1282–1283 (D.C. Cir. 2026). Here, by contrast, the remaining regulation—(k)(7)—would preserve the authority the Information withdraws, and remove the threat that exists only in paragraph 8.

## II. Petitioners face irreparable harm.

### A. The Information forces Verde and NW Confections to choose between their customers and their applications.

On November 29, each timely petitioner must sever longtime state-licensed partners or risk denial of the application on which its federal authority—and in Oklahoma, its state authority—depends. *See* Ex.3¶22; Ex.4¶¶20, 28; Mot.18–21. Verde, a timely manufacturer and dispenser, has ~$600,000 in monthly sales to non-timely customers, some 40–50% of its revenue; it therefore expects to lay off ~70% of its 136 employees. Ex.3¶¶8, 21–22, 31. NW Confections, a timely manufacturer, will lose fifteen non-timely customers and warns of insolvency; lost sales and new transport costs consume ~40–80% of its monthly margin. Ex.4¶¶22–26. These losses are not recoverable, and they extend well beyond monetary harm. *See* 5 U.S.C. §702 (waiving immunity only for relief "other than money damages"); *Adya LLC v. DEA*, 826 F. Supp. 3d 115, 133–134 (D.D.C. 2026) (lost customers and goodwill are irreparable; unrecoverable losses "buttress[]" that harm).

### B. DEA's 7,100-application figure does not show a workable supply chain.

DEA's only counter is that "more than 7,000" entities filed timely applications, "including thousands in petitioners' home states." Opp.25. That number does nothing to establish an available replacement supply chain in Utah, Arizona, or Oklahoma (Petitioners' states). DEA provides only national totals and pooled four-state figures—not state-specific capacity, product availability, or evidence that those businesses can absorb Petitioners' lost volume by November 29.

First, DEA aggregates *intra*state markets. The four-state figures are reported only "collectively." Almendinger Decl.¶4. All of NW Confections' sales, for example, are in Oklahoma. Ex.4¶6. DEA's pooled totals do not identify replacement counterparties available within each Petitioner's state-licensed market.

Second, it ignores commercial realities. Authorized counterparties do not account for the lack of commercially available replacements. In Utah, five timely producers may sell only to fourteen timely pharmacies, and four of the seven timely pharmacy operators will be unable to stock even their own products. Ex.5¶¶13–14. No oil source exists in the State capable of replacing the lost supply. *Id.*¶21. In Arizona, some 100 of roughly 175 dispensaries are timely, and others already supply them, meaning there is no replacement for lost demand. Ex.3¶¶21, 30.

Third, DEA's scattershot process compounded the transition problems. Its distributor form offered no medical marijuana drug code, and it opened no dedicated

manufacturer or distributor application until October 5, over three months after the window closed. Ex.4¶¶15–16. But a viable supply chain requires timely manufacturers, distributors, *and* dispensers—not just one class of the above—something the Information ignores. The existing supply chain cannot support these markets on November 29, and replacing lost partners could take up to a year. Ex.3¶30.

**C. The disruption is immediate and market-wide.**

The disruption to Standard Wellness Utah illustrates this market-wide effect. It expects to lose twelve timely pharmacy locations (~$275,900 in monthly sales, 38% of its pharmacy sales) and two timely processors supplying ~16% of its oil. Ex.5¶¶17, 20; *see* Mot.21–22. One operator will quarantine all its inventory, including ~$80,000 already delivered; another operator and three processors will deal only with timely applicants. Ex.5¶18(a)–(b), (d). Its affiliated pharmacy, The Forest Murray, will lose ~38% of its products. *Id.*¶24.

**D. The harm is not self-inflicted.**

DEA says Petitioners' harms are "of their own making" because they failed "to ensure that their suppliers and customers would all file early applications." Opp.24 (quoting *Dep't of Educ. v. California*, 604 U.S. 650, 652 (2025)). Verde and NW Confections applied within the window. Ex.3¶¶10–12; Ex.4¶13. Neither could *make* counterparties file. Further, DEA's portals left some licensees without a

workable way *to* file. Ex.4¶¶11–16. Nothing in the Final Order warned that a counterparty's filing date could cost an applicant *its* application—that consequence first appeared October 30, four months after the window closed. Ex.2¶¶7–8. Nor was Standard Wellness told that its timely partners would be barred from dealing with it; the Utah Entities applied within days of learning so. Ex.5¶¶8–9. A harm first imposed after the chance to comply passes is not self-inflicted.

### III. The equities favor a stay, which will restore DEA's own regulation.

DEA invokes the harm of being "enjoined by a court from effectuating statutes." Opp.26 (quoting *Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025)). A stay enjoins no statute. It restores §1301.13(k)(7), premised on the Order's findings that state systems "demonstrate a sustained capacity" to prevent diversion and the rule should cause "the least disruption for patients and existing state systems." 91 Fed. Reg. at 22,720.

## CONCLUSION

The Court should stay the Information's November 29 deadline pending review, or enter an administrative stay, by November 25, 2026.

Dated: November 24, 2026

Respectfully submitted,

*/s/ Christina Manfredi McKinley*
Christina Manfredi McKinley (DC Circ: 53419)
Blank Rome, LLP
501 Grant Street, Suite 850
Pittsburgh, PA 15219
Counsel for Petitioners
412-932-2733
Christina.mckinley@blankrome.com

Shane Pennington (DC Circ: 55524)
Blank Rome, LLP
717 Texas Avenue, Suite 1400
Houston, TX 77002
713-632-8607
Shane.pennington@blankrome.com

*Counsel for Petitioners*

## CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This reply complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(C) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), it contains 2,599 words.

2. This reply complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 27(d)(1)(E), 32(a)(5), and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 in 14-point Times New Roman font.

November 24, 2026

*/s/ Christina Manfredi McKinley*
Christina Manfredi McKinley

**CERTIFICATE OF SERVICE**

I certify that on November 24, 2026, I electronically filed the foregoing reply with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system. All participants in the case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

November 24, 2026

*/s/ Christina Manfredi McKinley*
Christina Manfredi McKinley