

[ORAL ARGUMENT HELD APRIL 19, 2022]

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

HEMP INDUSTRIES ASSOCIATION and
RE BOTANICALS, INC.,

Petitioners,

v.

No. 20-1376

DRUG ENFORCEMENT
ADMINISTRATION and
ANNE MILGRAM, ADMINISTRATOR, DRUG
ENFORCEMENT ADMINISTRATION

Respondents.

**PETITIONERS' OPPOSED MOTION FOR LEAVE TO FILE
ADDITIONAL EVIDENCE OF STANDING**

At oral argument, the Court questioned Petitioners' Article III standing to challenge the United States Drug Enforcement Administration's Interim Final Rule entitled "Implementation of the Agriculture Improvement Act of 2018." *See* JAO01; 85 Fed. Reg. 51639 (Aug. 21, 2020). To assist the Court in its "obligation to assure [itself] that jurisdiction is proper before proceeding to the merits," *Plains Commerce Bank v. Long Family Land and Cattle Co.*, 554 U.S. 316, 324 (2008), Petitioners request leave to supplement the record with additional evidence "to ensure that

standing can be confirmed,” *Am. Library Ass’n v. FCC*, 406 F.3d 689, 696-97 (D.C. Cir. 2005). The undersigned has contacted counsel for Respondents, and they have stated that they oppose this motion.

GROUND FOR MOTION AND RELIEF SOUGHT

Petitioners bear the burden of proof with respect to standing. *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). They must “show a ‘substantial probability’ that [they] have been injured, that the [Respondents] caused [their] injury, and that the court could redress that injury.” *Id.* (quoting *Am. Petroleum Inst. v. EPA*, 216 F.3d 50, 63 (D.C. Cir. 2000) (per curiam)). “[T]here is ordinarily little question,” however, “that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated.” *State Nat’l Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992)). Indeed, a “petitioner’s standing to seek review of administrative action is [usually] self-evident ... if the complainant is ‘an object of the action (or forgone action) at issue’” *Sierra Club*, 292 F.3d at 899-900 (quoting *Lujan*, 504 U.S. at 561); *see also Nat’l Ass’n of Home Builders v. EPA*, 786 F.3d 34, 43 (D.C. Cir. 2015) (“[R]egulated entities’ standing to challenge the rules that govern them is normally not an issue.”) (cleaned up).

In the unusual case where the petitioner is the object of the challenged agency rule and yet the “petitioner’s standing is not apparent from the administrative record,” Circuit Rule 28(a)(7) provides that “the [petitioner’s] brief must include arguments and evidence establishing the claim of standing.” D.C. Cir. R. 28(a)(7) (citing *Sierra Club*, 292 F.3d at 900-01). Yet, this Court has acknowledged that the language of Circuit Rule 28(a)(7) “is hardly free from ambiguity.” *Ams. for Safe Access v. Drug Enforcement Administration*, 706 F.3d 438, 445 (D.C. Cir. 2013) (internal quotation marks and citations omitted). Therefore, to avoid turning *Sierra Club* and Circuit Rule 28(a)(7) into “a ‘gotcha’ trap,” this Court permits petitioners to supplement the record with additional evidence of standing when they “reasonably, but mistakenly, believed” that they “sufficiently demonstrated standing” or when they “reasonably assumed that their standing was self-evident.” *Twin Rivers Paper Co. LLC v. SEC*, 934 F.3d 607, 614 (D.C. Cir. 2019) (cleaned up). The Court has allowed petitioners to do so “through additional briefing or affidavits submitted to the court ... after oral argument.” *Nat’l Council for Adoption v. Blinken*, 4 F.4th 106, 111 (D.C. Cir. 2021) (cleaned up).

Petitioners reasonably assumed that their standing to challenge the Interim Final Rule was self-evident. Good cause therefore exists to permit

them to file “additional briefing [and] affidavits” in support of their standing. *Id.* That supplemental evidence, which is included with this Motion and which Petitioners discuss in Part II *infra*, “ma[kes] [Petitioners’] standing ‘patently obvious’ and ‘irrefutable.’” *Twin Rivers Paper Co. LLC*, 394 F.3d at 615 (quoting *Communities Against Runway Expansion, Inc. v. F.A.A.*, 355 F.3d 678, 685 (D.C. Cir. 2004)). For these reasons, which are discussed in greater detail below, Petitioners request that the Court grant their request for leave to file additional evidence of standing and hold that Petitioners have standing to challenge the Interim Final Rule.

I. Petitioners Reasonably Assumed That Standing Was Self-Evident Because They Are “Objects of” the Interim Final Rule.

Standing is self-evident when the petitioner is the “object of” the challenged regulation. *Lujan*, 504 U.S. at 561-62. Where that is so, “no evidence outside the administrative record is necessary” for the Court “to be sure of [standing].” *Sierra Club*, 292 F.3d at 899-900. When assessing standing, this Court “must ... assume that on the merits the [Petitioners] would be successful in their claims,” *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003), and that their “allegations are accurate,” *In re Navy Chaplaincy*, 534 F.3d 756, 761 (D.C. Cir. 2008).

A. Petitioners' assumption was reasonable because the Interim Final Rule applies to hemp and hemp derivatives.

The Interim Final Rule purports to implement amendments to the Controlled Substances Act that all agree removed hemp and hemp derivatives from DEA control. *See, e.g.*, Govt. Br. 28 (“[T]he [Interim Final Rule] acknowledges that the Farm Bill narrowed DEA’s authority over cannabis-derived materials”). Its applicability to every hemp company, including Petitioner RE Botanicals, Inc., and other members of Petitioner Hemp Industries Association is therefore manifest.¹

Where, as here, Petitioners challenge a regulation that plainly applies to their businesses or products, this Court has consistently held that standing is self-evident, and “no evidence outside the administrative record is necessary.” *Sierra Club*, 292 F.3d at 899-900; *see also Bonacci v. TSA*, 909 F.3d 1155, 1160 (D.C. Cir. 2018 (pilot “plainly” had standing to challenge a regulation “of pilots and flight attendants”). In *American Trucking Associations, Inc. v. Federal Motor Carrier Safety Administration*, for example, the Court held that a trade association had

¹ *See Hemp Industries Association v. Drug Enforcement Admin.* (“*Hemp II*”), 357 F.3d 1012, 1019 (9th Cir. 2004) (DEA’s promulgation of regulation defining schedule I “Tetrahydrocannabinols” to include natural tetrahydrocannabinols was an unlawful “scheduling action[.]”); *Tozzi v. Dep’t of Health and Human Servs.*, 271 F.3d 301, 308-10 (D.C. Cir. 2001) (PVC manufacturer had standing to challenge an agency’s listing of a *byproduct* of the incineration of PVC as a known carcinogen).

“obvious” standing to challenge a regulation limiting its members’ hours-in-service. 724 F.3d 243, 247 (D.C. Cir. 2013). That was so despite the fact that the association failed to submit affidavits on behalf of its members or other additional evidence supporting standing. *See* Brief for Pet’r 15-16, No. 12-1092 (D.C. Cir. Nov. 21, 2012); Reply Brief for Pet’r 2-3 & n.2 (D.C. Cir. Nov. 21, 2012) (arguing that association’s standing was self-evident but offering to “file a supplemental submission including declarations in support of standing if the Court so requests”).

Likewise, in *State National Bank of Big Spring v. Lew*, the Court held that a bank had standing to challenge the creation of the Consumer Financial Protection Bureau because the bank’s products fell within the Bureau’s jurisdiction. 795 F.3d 48, 53-54 (D.C. Cir. 2015). It did not require additional evidence demonstrating that the Bureau had prohibited any of the bank’s current practices. Because the bank fell within the broad sweep of the Bureau’s jurisdiction, there was “no doubt” that the Bureau’s regulations applied to the bank. *Id.*; *see also Sabre, Inc. v. Dep’t of Transp.*, 429 F.3d 1113, 1115-16 (D.C. Cir. 2005) (independent reservation system had standing to challenge an agency rule that subjected such companies to regulation as ticket agents even though “no regulations promulgated by the Department currently constrain[ed] [its] business activity”).

These cases demonstrate the reasonableness of Petitioners' assumption that their standing was self-evident because the Interim Final Rule indisputably applies to their products. As Petitioners explain next, however, three additional considerations put the question beyond debate.

B. This Court's recognition that schedule I classification is "inherently pejorative" underscores the reasonableness of Petitioners' assumption.

Petitioners allege² that by classifying natural tetrahydrocannabinols as schedule I "Tetrahydrocannabinols," the Interim Final Rule has saddled every hemp company with what this Court called the "inherently pejorative" distinction of creating or selling products laced with a schedule I substance. *Ams. for Safe Access*, 706 F.3d at 448. And because that "inherently pejorative" designation emanates from DEA, it constitutes "the federal government's 'authoritative statement' on the legitimacy of particular narcotics and dangerous drugs." *Id.* (quoting *Tozzi*, 271 F.3d at 309).

² See Opening Br. for Pet'rs 32, 45, 48-50; Br. for Respondents 2 (listing "[w]hether the [Interim Final Rule] unlawfully ... purports to control previously unscheduled substances" and "[w]hether DEA was required to engage in notice and comment or conduct a scheduling action under the Controlled Substances Act before promulgating the rule" as "questions presented"); *id.* at 26 (noting, in an argument heading, "Petitioners' Claim That The Rule Purports To Schedule Naturally Occurring THC"); *id.* at 39 (acknowledging that "petitioners assert that DEA independently ... added natural THC to Schedule I"). Petitioners focus on this claim because it was the focus of most of the Court's questions during oral argument. Of course, if Petitioners have standing to bring this claim, they have standing to raise their procedural challenges to the Interim Final Rule and their Federal Vacancies Reform Act claim as well.

“When the DEA classifie[s] [a substance] as a Schedule I drug ... it announce[s] an authoritative value judgment that [is] surely ... meant to affect the policies of third-party federal agencies.” *Id.*

This Court has held that far less-damaging classifications to a petitioner’s companies, businesses, or products supported standing. In *Tozzi*, for example, a PVC manufacturer had standing to challenge an agency’s listing of dioxin—a chemical released when PVC is incinerated—as a known carcinogen. 271 F.3d at 308-10.³ The listing, this Court explained, was “authoritative,” “widely disseminated[,] and highly influential.” *Id.* at 308. And because the classification of a chemical associated with PVC as a “carcinogen” was “inherently pejorative and damaging,” the Court held that the plaintiff had standing to challenge it. *Id.* at 309.

Petitioners’ standing in this case is even more obvious. In *Tozzi*, the inherently pejorative designation applied to a mere *byproduct* of the *incineration* of plaintiff’s PVC products. *Id.* at 308. DEA’s “inherently

³ See also, e.g., *Mead v. Browner*, 100 F.3d 152, 155 (D.C. Cir. 1996) (EPA’s listing of a company’s property on the agency’s “National Priorities List” of hazardous-waste sites supported standing because it increased property owner’s exposure to liability for cleanup costs, provided EPA with additional leverage over the property owner, and damaged the company’s business reputation); *CTS Corp. v. EPA*, 759 F.3d 52, 58 (D.C. Cir. 2014) (EPA’s listing of site that the company previously owned on the “National Priorities List” supported standing even though company had already been publicly associated with environmental concerns at former property because “the List’s inclusion of a larger site ... link[ed] CTS to a new and expanded threat to human health and the environment”) (cleaned up).

pejorative” designation of natural tetrahydrocannabinols as schedule I “Tetrahydrocannabinols,” by contrast, targets a component of hemp *itself*.

Moreover, as this Court emphasized in *Americans for Safe Access*, DEA’s listing of a substance in schedule I “announces an authoritative value judgment that surely ... affect[s] the policies of third-party federal agencies.” 706 F.3d at 447. In their Reply Brief, Petitioners detailed several examples of how DEA’s unlawful scheduling of natural tetrahydrocannabinols has influenced law enforcement and third-party regulators. *See* Reply Br. for Pet’rs 18-20 (discussing cases); *see also id.* at 13 (explaining that misclassifying a substance as schedule I tetrahydrocannabinols instead of “marihuana” results in significantly harsher criminal penalties under 21 U.S.C. § 841). Petitioners cited statutes, regulations, and cases that prove that it already has. *Id.* at 13, 18-20 (discussing various authorities). These harms are real, concrete, and evident from this Court’s own opinions discussing the effects of schedule I classification and other materials subject to judicial notice. *Ams. for Safe Access*, 706 F.3d at 447; *Tozzi*, 271 F.3d at 308-10; *see also Kareem v. Haspel*, 986 F.3d 859, 866 n.7 (D.C. Cir. 2021) (Court may take judicial notice of facts “generally known and [that] can be readily determined from reliable sources” when assessing Article III standing). As a result,

Petitioners' assumption that their standing to challenge the Interim Final Rule was self-evident was, at the very least, reasonable.

C. The Ninth Circuit's affirmance of Hemp Industries Association's standing in *Hemp I* underscores the reasonableness of Petitioners' assumption.

The Ninth Circuit upheld Petitioner Hemp Industries Association's standing to challenge a near-identical—and equally unlawful—DEA attempt to impose schedule I controls on natural tetrahydrocannabinols almost twenty years ago. *See Hemp Industries Ass'n v. Drug Enforcement Admin.* (“*Hemp I*”), 333 F.3d 1082, 1086-87 (9th Cir. 2003); *Hemp Industries Ass'n v. Drug Enforcement Admin.* (“*Hemp II*”), 357 F.3d at 1012, 1019. If Petitioners had standing to challenge this unlawful agency action *before* the Agriculture Improvement Act of 2018 (“2018 Farm Bill”) reduced DEA's authority over hemp and hemp derivatives, then *a fortiori*, they have it now.

Because Petitioners reasonably assumed that standing was self-evident, this Court may consider the additional evidence supporting standing that Petitioners have submitted with this motion. *See, e.g., Council for Adoption*, 4 F. 4th at 112 (accepting supplemental declarations in part because they did not “raise an entirely new theory of standing”).

II. Petitioners Have Article III Standing.

To the extent that Petitioners' assumption that standing was self-evident was mistaken, the additional affidavit and declaration included

with this motion make standing “patently obvious” and “irrefutable.” *Id.* at 111 (quoting *Communities Against Runway Expansion, Inc.*, 355 F.3d at 685). “And because standing was so apparent, [Petitioners’] delay does not prejudice [Respondents].” *Id.* (citations omitted).

Petitioners earlier briefing in this case explained that DEA’s unlawful attempt to define schedule I “Tetrahydrocannabinols” to include natural tetrahydrocannabinols caused them reputational harm and increased their exposure to civil and criminal penalties. Reply Br. of Pet’rs 20-23. The affidavit and declaration of Hemp Industries Association members have included with this motion and discussed below demonstrate that those harms exist and will continue unless and until DEA’s Interim Final Rule is declared unlawful and set aside.

The Affidavit of Janel Ralph, CEO of Hemp Industries Association member RE Botanicals, Inc., attests to the reputational harms hemp companies have faced in the wake of the Interim Final Rule. Shortly after the 2018 Farm Bill became law, RE Botanicals, Inc. “saw an increase in revenue and investment” that Ms. Ralph “attributes ... to the 2018 Farm Bill’s legitimizing effect on the hemp industry.” Ralph Affidavit ¶ 2. In the wake of the Interim Final Rule, however, RE Botanicals, Inc.’s “revenues decreased substantially”:

For example, comparing the seven-month period immediately preceding the [Interim Final Rule] with the seven-month period immediately following it [RE Botanicals, Inc.’s] gross revenue fell by approximately 19% during the seven-month period of time following the [Interim Final Rule]. This trend continued.

Id. Ms. Ralph also explains that wholesalers that had been willing to carry RE Botanicals, Inc.’s products when the 2018 Farm Bill was published “refused to carry them because of the [Interim Final Rule].” *Id.*

When DEA promulgated the Interim Final Rule, RE Botanicals, Inc. “felt compelled to change its business practices in light of the increased risk of civil and criminal liability associated with handling natural tetrahydrocannabinols during hemp manufacturing and processing.” *Id.*

¶ 3. The removal of hemp and “tetrahydrocannabinols in hemp” from DEA control with the enactment of the 2018 Farm Bill prompted RE Botanicals, Inc. to “expand its hemp-processing operations and thus its involvement with natural tetrahydrocannabinols.” *Id.* Ms. Ralph explains that “[a] significant factor in [RE Botanicals Inc.]’s decision to do so was [its] reliance on the 2018 Farm Bill’s amendment of the Controlled Substances Act’s listing of ‘Tetrahydrocannabinols’ in schedule I to exclude ‘tetrahydrocannabinols in hemp.’” *Id.* (quoting 21 U.S.C. § 812(c) (Schedule I (c)(17))). “When DEA promulgated the [Interim Final Rule], however, [RE Botanicals, Inc.] feared that third-party regulators at the state and federal

levels as well as local law enforcement officers would view DEA's assertion of authority to enforce its regulatory definition of "Tetrahydrocannabinols" against natural tetrahydrocannabinols—*i.e.* 'tetrahydrocannabinols in hemp'—as undermining the legitimacy of RE [Botanicals Inc.]'s hemp-processing operations." *Id.*

The Interim Final Rule's unlawful scheduling of natural tetrahydrocannabinols also "made it more difficult for [RE Botanicals, Inc.] to obtain banking services." *Id.* ¶ 4. Shortly after the enactment of the 2018 Farm Bill, "[RE Botanicals Inc.] found banking services more accessible for [its] hemp business"—a change that RE Botanicals, Inc. "attributes ... to the 2018 Farm Bill's legitimizing effect on hemp businesses generally." *Id.* In particular, Ms. Ralph "believes that the 2018 Farm Bill's amendment of the Controlled Substances Act's listing of 'Tetrahydrocannabinols' in schedule I to exclude 'tetrahydrocannabinols in hemp' was an important factor in bringing about this change in the way banks perceived and interacted with hemp companies generally and [RE Botanical]'s business in particular." *Id.* (quoting 21 U.S.C. § 812(c) (Schedule I (c)(17)). "Shortly after DEA promulgated the [Interim Final Rule], however, [RE Botanicals, Inc.] found it more difficult to access banking services." *Id.*

Finally, RE Botanicals, Inc. “has lost a significant number of its employees due to the [Interim Final Rule].” *Id.* ¶ 5. Just before “publication of the [Interim Final Rule],” RE Botanicals, Inc. “had 31 employees.” Today, “it only has 15.” *Id.*

The Declaration of John Mitchell, Vice President for Product Development for NuSachi Inc., a Hemp Industries Association member based in Nashville, Tennessee, demonstrates that hemp companies felt compelled to make detrimental changes to their business activities due to DEA’s unlawful treatment of natural tetrahydrocannabinols in the Interim Final Rule. Before DEA promulgated the Interim Final Rule, Nusachi Inc. “was developing a proprietary hemp extract refinement process that would allow the company to produce more compelling hemp extracts for its customers.” Mitchell Declaration ¶ 4. According to Mr. Mitchell, “[t]his proprietary process was a key part of NuSachi’s business and growth strategy.” *Id.*

DEA’s Interim Final Rule “alarmed the company” and “forced [it] to halt development of th[is] proprietary process.” *Id.* ¶ 5. As a “contract manufacturer,” Mr. Mitchell explains, NuSachi faces “increased financial and business risk due to the Interim Final Rule and DEA’s position on its authority to regulate hemp production.” *Id.*

These are precisely the sorts of harms that Petitioners described in their Reply Brief. Reply Br. of Pet'rs 20-23. They also mirror the harms this Court has often associated with “inherently pejorative” regulatory designations like DEA’s designation of natural tetrahydrocannabinols within the regulatory definition of schedule I “Tetrahydrocannabinols” in the Interim Final Rule. *See* Part I.B. *supra* (discussing *Ams. for Safe Access*, 706 F.3d at 438; *Tozzi*, 271 F.3d at 308-10; *Mead*, 100 F.3d at 155 *CTS Corp.*, 759 F.3d at 58). These harms are attributable to DEA’s unlawful regulatory definition of “Tetrahydrocannabinols” in the Interim Final Rule, *see* 21 C.F.R. § 1308.11(d)(31), and an order from this Court declaring the Interim Final Rule promulgating that regulation unlawful and setting it aside would redress the harms petitioners have experienced and continue to experience in the form of reputational injury and increased liability risk stemming from DEA’s promulgation of the Interim Final Rule.⁴

⁴ Respondents’ recent Opposition to Appellants’ Motion for Leave to File a Supplemental Brief in Related Case No. 21-5111 lends further support to Petitioners’ standing to challenge the Interim Final Rule in this case. There, Respondents argue that Appellants allege harm arising from the Interim Final Rule. *See, e.g.*, Opposition 2 (“The district court correctly concluded that section 877 applies because plaintiffs challenge DEA’s rule”); *id.* (“Plaintiffs’ suit plainly challenges the DEA rule.”). If Respondents are to be believed, then Petitioners not only have standing in this case, but the Interim Final Rule is an inherently “legislative” rule, does not “merely conform[] DEA’s regulations to the statutory amendments to the CSA,” JAO01, and is plainly unlawful. *See, e.g., Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (“We have repeatedly made clear that the good

CONCLUSION

For these reasons, Petitioners urge the Court to grant their motion for leave to supplement the record with additional evidence of standing and hold that Petitioners have standing to challenge the Interim Final Rule.

cause exception is to be narrowly construed and only reluctantly countenanced.” (quotation marks omitted)); *Nat’l Fam. Plan. & Reprod. Health Ass’n, Inc. v. Sullivan*, 979 F.2d 227, 236 (D.C. Cir. 1992) (“Obviously, HHS may for good cause, change the regulation and even its interpretation of the statute through notice and comment rulemaking, but it may not constructively rewrite the regulation.”).

Dated: May 9, 2022

Respectfully submitted,

/s/ Shane Pennington

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CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(A). This document contains 3,376 words. I further certify that this motion complies with the type-style requirements of Federal Rule of Appellate Procedure 27(d)(1)(E) because it has been prepared in 14-point Georgia, a proportionally spaced font.

Date: May 9, 2022

/s/ Shane Pennington
Shane Pennington

CERTIFICATE OF SERVICE

I certify that this document was filed with the Court via the Court's electronic filing system, on the 9th of May, 2022, and an electronic copy of this document was served on all counsel of record, as listed below, via the Court's electronic filing system on the same date:

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Shane Pennington

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No. 20-1376

DRUG ENFORCEMENT
ADMINISTRATION and
ANNE MILGRAM, ADMINISTRATOR, DRUG
ENFORCEMENT ADMINISTRATION

Respondents.

**AFFIDAVIT OF JANEL RALPH AND DECLARATION OF JOHN
MITCHELL IN SUPPORT OF PETITIONERS' STANDING**

STATE OF SOUTH CAROLINA)
) AFFIDAVIT OF JANEL
RALPH
COUNTY OF HORRY)

I, Janel Ralph, the undersigned Affiant, after first being duly sworn, do testify and state the following:

1. I am the CEO of Plaintiff RE Botanicals, Inc. ("REB"). REB is a member of the Hemp Industries Association ("HIA").

2. Shortly after the 2018 Farm Bill became law, REB saw an increase in revenue and investment. REB attributes that increase to the 2018 Farm Bill's legitimizing effect on the hemp industry. Shortly after DEA promulgated the Interim Final Rule ("IFR"), however, REB's revenues decreased substantially. For example, comparing the seven-month period immediately preceding the IFR with the seven-month period immediately following it REB's gross revenue fell by approximately 19% during the seven-month period of time following the IFR. This trend continued. Additionally, wholesalers of consumer products that had previously agreed to carry REB's hemp products when the 2018 Farm Bill was passed refused to carry them because of the IFR. Also, some wholesalers that were carrying REB's consumable hemp products ceased carry them after the IFR was published.

3. REB felt compelled to change its business practices in light of the increased risk of civil and criminal liability associated with handling natural tetrahydrocannabinols during hemp manufacturing and processing. In the wake of the 2018 Farm Bill, REB expanded its hemp-processing operations and thus its involvement with natural tetrahydrocannabinols. A significant factor in REB's decision to do so was REB's reliance on the 2018 Farm Bill's amendment of the Controlled Substances Act's listing of "Tetrahydrocannabinols" in schedule I to exclude

"tetrahydrocannabinols in hemp." When DEA promulgated the IFR, however, REB feared that third-party regulators at the state and federal levels as well as local law enforcement officers would view DEA's assertion of authority to enforce its regulatory definition of "Tetrahydrocannabinols" against natural tetrahydrocannabinols—i.e. "tetrahydrocannabinols in hemp"—as undermining the legitimacy of REB's hemp-processing operations.

4. The IFR's criminalization of natural tetrahydrocannabinols also made it more difficult for REB to obtain banking services. In the wake of the 2018 Farm Bill, REB found banking services more accessible for REB's hemp business. REB attributes this change to the 2018 Farm Bill's legitimizing effect on hemp businesses generally. REB believes that the 2018 Farm Bill's 2018 Farm Bill's amendment of the Controlled Substances Act's listing of "Tetrahydrocannabinols" in schedule I to exclude "tetrahydrocannabinols in hemp" was an important factor in bringing about this change in the way banks perceived and interacted with hemp companies generally and REB's business in particular. Shortly after DEA promulgated the IFR, however, REB found it more difficult to access banking services.

5. REB has lost a significant number of its employees due to the IFR. Immediately prior to publication of the IFR, REB had 31 employees. Currently, it only has 15 employees.

Further, this Affiant sayeth not.

Janel Ralph

Dated: 5/6/22

Janel Ralph

State of North Carolina
County of Horry

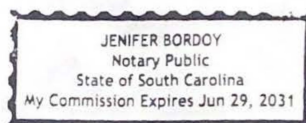
Before me, the undersigned notary public, this day, personally, appeared Janel Ralph, who being duly sworn according to law, deposes and asserts that the statement contained in her Affidavit, above, is true and correct to the

best of her knowledge.

Subscribed and sworn to before me this 6TH day
of May, 2022.

Jenifer Bordoy
STATE OF SOUTH CAROLINA
Notary Public [Printed name]

My commission expires: 6/29/31



**IN THE UNITED STATES COURT OF APPEALS
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HEMP INDUSTRIES ASSOCIATION and)
RE BOTANICALS, INC.,)

Petitioners,)

v.)

Case No. 20-1376

DRUG ENFORCEMENT ADMINISTRATION;)
and ANNE MILGRAM, ADMINISTRATOR,)
DRUG ENFORCEMENT ADMINISTRATION.)

Respondents.

DECLARATION OF JOHN MITCHELL

1. My name is John Mitchell. I am over 18 years of age, of sound mind and fully competent to make this Declaration. I have never been convicted of a felony or a crime of moral turpitude. I have personal knowledge of all the facts stated herein, and they are true and correct.


2. I am the Senior Vice President for Product Development of NuSachi Inc. a Delaware Corporation ("Nusachi").

3. NuSachi is based in Nashville, Tennessee. It is a member of Petitioner Hemp Industries Association and has been since February 2020.

4. Before DEA's Interim Final Rule, NuSachi was developing a proprietary hemp extract refinement process that would allow the company to produce more compelling hemp extracts for its customers. This proprietary process was a key part of NuSachi's business and growth strategy.

5. DEA's promulgation of the Interim Final Rule and subsequent statements by DEA related to hemp production and hemp extracts alarmed NuSachi. NuSachi is a contract manufacturer, and the increased financial and business risk due to the Interim Final Rule and DEA's position on its authority to regulate hemp production forced the company to halt development of the proprietary process. As a result, NuSachi has foregone the development of Intellectual Property and the manufacturing of new hemp products.

Executed in Davidson County, Nashville, Tennessee on the 6th day of May 2022.



John Mitchell