IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

CLIMBING KITES LLC, *et al.*, *Plaintiffs*, v. STATE OF IOWA, *et al.*, *Defendants*.	Case No. 4:24-cv-00202-SMR-SBJ
HW PREMIUM CBD, LLC, *et al.*, *Plaintiffs*, v. KIM REYNOLDS, Governor of Iowa in her official capacity, *et al.*, *Defendants*.	Case No. 4:24-cv-00210-SMR-SBJ

DECLARATION OF OWEN PARKER

I, Owen Parker, declare under penalty of perjury that the following is true and correct:

1. I am over the age of 18 years. I have personal knowledge of the facts set forth in this affidavit and would testify competently to those facts if called as a witness.
2. I am the Bureau Chief over the Bureau of Cannabis Regulation ("Bureau") for the Department of Health and Human Services ("HHS"). In that role, I oversee the Department's regulation of the State's medical cannabis and consumable hemp programs. I submitted a previous declaration on July 5, 2024, and hereby incorporate by reference the paragraphs describing my knowledge, training, and experience in this area.

3. I attended the hearing on July 11, 2024, on Plaintiffs' Motion for Preliminary Injunction and heard Plaintiff Climbing Kites' express concern that its hemp registration had been "revoked" by the Department after July 1, 2024. Climbing Kites' registration was not revoked by HHS.

HHS Creates the Consumable Hemp Registrant Portal

4. For background, each consumable hemp manufacturer, establishment, or distributor in Iowa, as defined by Iowa Admin. Code r. 641—156.1, must obtain a consumable hemp registration from HHS. The registration process is overseen by the Bureau. A consumable hemp registration must be renewed annually, otherwise the registration expires. Iowa Admin. Code r. 641—156.2(5).

5. The Bureau has built, and maintains, a Consumable Hemp Registrant Portal ("Portal") to support registration, and specifically, a registrant's ability to maintain its list of approved products for sale pursuant to Iowa Admin. Code r. 641—156.2(1)(*c*).

6. Iowa Admin. Code r. 641—156.2(1)(*c*) and 2(2)(*c*) were adopted on January 27, 2021, and effective March 3, 2021, and implemented House File 2581. That regulation states, in part:

> 156.2(1) and 2(2)(c) (identical for manufacturers/distributors and retailers) *Consumable hemp manufactures/distributors*. Consumable hemp manufacturers shall register with the department at least 30 days prior to manufacturing, processing, packing, holding, preparing, distributing, or selling any consumable hemp product in Iowa or to purchasers located in Iowa. The consumable hemp manufacturer shall:
>
> . . . .
>
> *c.* Submit a complete list of all consumable hemp products the consumable hemp manufacturer intends to manufacture, process, pack, hold, prepare, distribute, or sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

Since the inception of Iowa's consumable hemp industry, HHS has been allowed, by law and regulation, to take up to 30 days to conduct its review when Registrants submit new products for approval.

7. The Portal is a bespoke Salesforce system which was built in-house using a third-party developer. The Portal was developed to support HHS's unique and specific needs for consumable hemp registration and evolving enforcement mandates. Substantial updates were necessary to implement HF2605, so planning began in April 2024 in anticipation that HF 2605 would become law.
8. The Portal is a useful tool for HHS to provide affirmative "approval" or "denial" of products for Registrants.

Obligations of Registrants

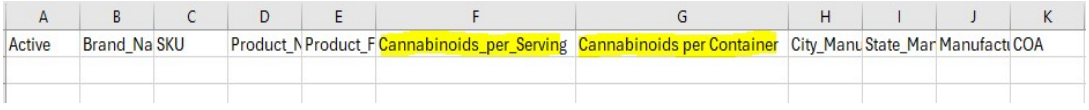
9. When registering, or renewing their registration, on the Portal, each Registrant signs an attestation indicating its understanding of the fundamental tenets of the Iowa Hemp Act and agrees to maintain compliance with state and federal law when selling their consumable hemp products. Registrant attestations from the Portal in the pre- and post-HF2605 era are provided as exhibits #1 and #2, respectively.
10. HHS's approval process for consumable hemp products does not relieve Registrants of their duty to comply with state and federal law.
11. When a new or revised product is pending HHS's review—during HHS's maximum 30-day review period allowed by law—a Registrant could not continue or begin to sell a product that violates state law simply because HHS had not yet processed the denial. Registrants may only sell in Iowa consumable hemp products approved by HHS.

12. But by this time, Registrants often would have an idea whether their product was compliant. When Registrants are in research and development stages, they often engage with HHS to discover whether their in-development products would comply with law and rules. For example, it is my understanding that manufacturers typically develop new products in small test batches. Rather than develop the product in large quantities that may or may not be compliant, manufacturers work on small-test batches. Before and during this research and development stage, they reach out to HHS with compliance inquiries. HHS has often provided the requested guidance on what would be compliant. Outside of the rare circumstance where HHS is a party to litigation over a new law or rules, this back-and-forth is standard practice for HHS.

13. Registrants who sell unapproved consumable hemp products will usually receive a cease-and-desist order. HHS then conducts a follow-up inspection to monitor compliance with the order. HHS's standard spectrum of enforcement typically culminates in some combination of confiscation of the noncompliant product, suspension or revocation of a registration. Those harsher civil enforcement mechanisms typically are issued only after repeated violations.

Pre-HF2605 Product Submission Requirements

14. Between July 1, 2023 and June 30, 2024, Registrants submitted products via upload on a template Excel spreadsheet. HHS provided the template requiring the following information pursuant to administrative rule:



A	B	C	D	E	F	G	H	I	J	K
Active	Brand_Na	SKU	Product_N	Product_F	Cannabinoids_per_Serving	Cannabinoids per Container	City_Manu	State_Mar	Manufacti	COA

Before July 1, 2024, rules required Registrants to disclose the "cannabinoids per serving" and "cannabinoids per container" somewhere on their product. So HHS requested Registrants submit declarations affirming that this requirement was met when they submitted a product for HHS approval.

15. As shown below, *see* ¶ 33, the updated, post-July 1, 2024, template Excel spreadsheet enforcing HF2605 substitutes these "cannabinoid" columns with "Total THC per serving" and "Total THC per container." "Cannabinoids" in these prior columns means the aggregate of cannabinoids (THC, THCA, CBD, CBDA, CBN, synthetic cannabinoids, etc.) per serving and container, while the updated Excel for HF2605 refers only to Total THC (THC, THCA).

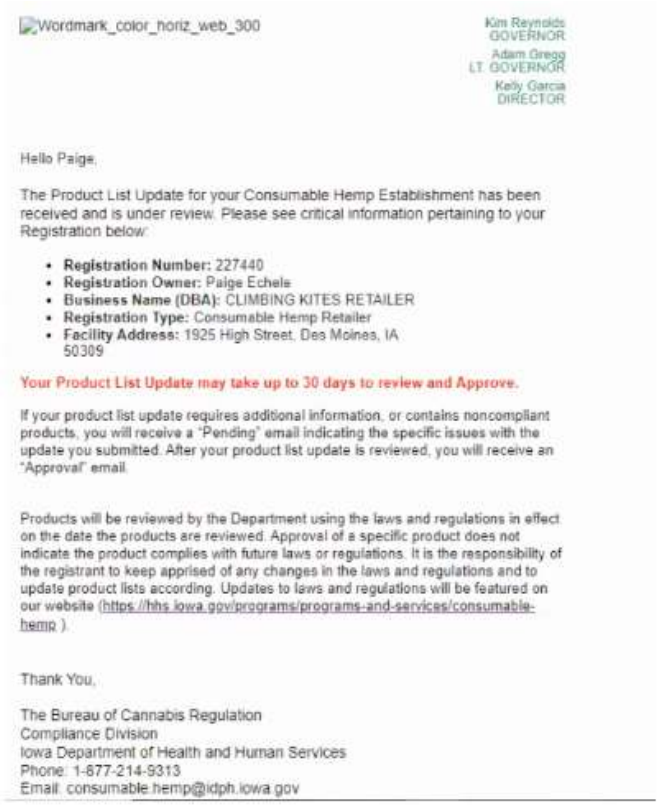
16. No Registrant—not even any of Plaintiffs here—ever complained that the pre-July 1 template's use of "cannabinoids per serving" was confusing. Registrants knew that "cannabinoids per serving" meant cannabinoids per serving of the product you put the cannabinoid in. For a chocolate bar, it meant that Registrants should report the total amount of cannabinoids per serving of the chocolate bar, and for a THC-infused carbonated beverage, it meant the total amount of cannabinoids per serving of the THC-infused carbonated beverage. That is how Registrants reported their products, and that is how HHS enforced the disclosure requirement.

17. HHS provides a "Consumable Hemp Product List Upload Guide" on its website providing Registrants with the necessary information to guide them on compliant product submission. The upload guide for the pre-HF2605 portal is provided as Exhibit #3.

HHS's Standard Review Process

18. Once submitted via the Portal, HHS reviews every submitted product individually for its compliance prior to issuing its decision. Since July 1, 2023, the Bureau has reviewed more than 46,000 products submitted by the nearly 1,200 registered manufacturers and retailers; an average of more than 38 products per registered facility.

19. When a Registrant initiates a product list update on the Portal, HHS provides receipt of the submission via email. The receipt confirms HHS is reviewing the submission, and it explicitly notifies the Registrant that HHS is allowed up to 30 days to review their submission. Here is an example of such a notice:



Wordmark_color_horiz_web_300

Kim Reynolds
GOVERNOR
Adam Gregg
LT. GOVERNOR
Kelly Garcia
DIRECTOR

Hello Paige,

The Product List Update for your Consumable Hemp Establishment has been received and is under review. Please see critical information pertaining to your Registration below:

- **Registration Number:** 227440
- **Registration Owner:** Paige Echele
- **Business Name (DBA):** CLIMBING KITES RETAILER
- **Registration Type:** Consumable Hemp Retailer
- **Facility Address:** 1925 High Street, Des Moines, IA 50309

Your Product List Update may take up to 30 days to review and Approve.

If your product list update requires additional information, or contains noncompliant products, you will receive a "Pending" email indicating the specific issues with the update you submitted. After your product list update is reviewed, you will receive an "Approval" email.

Products will be reviewed by the Department using the laws and regulations in effect on the date the products are reviewed. Approval of a specific product does not indicate the product complies with future laws or regulations. It is the responsibility of the registrant to keep apprised of any changes in the laws and regulations and to update product lists according. Updates to laws and regulations will be featured on our website (https://hhs.iowa.gov/programs/programs-and-services/consumable-hemp).

Thank You,

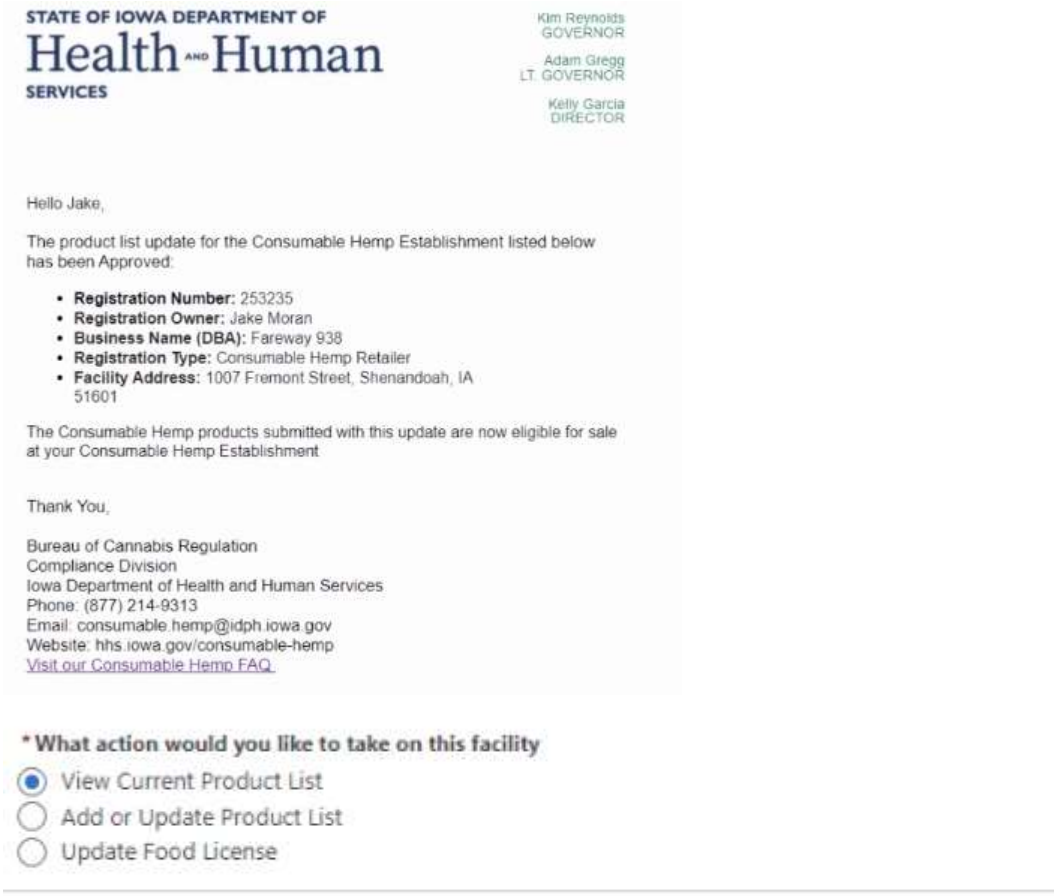
The Bureau of Cannabis Regulation
Compliance Division
Iowa Department of Health and Human Services
Phone: 1-877-214-9313
Email: consumable.hemp@idph.iowa.gov

20. Due to the volume of products submitted for review and the thoroughness of HHS's review process, instantaneous review is not possible. Between July 1, 2023, and June 30, 2024,

across 1,600 open and closed product list updates, HHS averaged four days to issue its decision.

21. No products are approved or denied without HSS providing notice to the Registrant.

22. When a product list update is approved, the Registrant receives a receipt of the approval instantaneously. The Registrant may then view the product in its "approved product list" in the Portal. Between July 1, 2023, and June 30, 2024, Registrants maintained access to their approved product list and could submit new products or update existing products at any time using the Portal. An example of an approval receipt and approved product list visualization is provided below:



STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Kim Reynolds
GOVERNOR

Adam Gregg
LT. GOVERNOR

Kelly Garcia
DIRECTOR

Hello Jake,

The product list update for the Consumable Hemp Establishment listed below has been Approved:

- **Registration Number:** 253235
- **Registration Owner:** Jake Moran
- **Business Name (DBA):** Fareway 938
- **Registration Type:** Consumable Hemp Retailer
- **Facility Address:** 1007 Fremont Street, Shenandoah, IA 51601

The Consumable Hemp products submitted with this update are now eligible for sale at your Consumable Hemp Establishment

Thank You,

Bureau of Cannabis Regulation
Compliance Division
Iowa Department of Health and Human Services
Phone: (877) 214-9313
Email: consumable.hemp@idph.iowa.gov
Website: hhs.iowa.gov/consumable-hemp
Visit our Consumable Hemp FAQ

*** What action would you like to take on this facility**

- (●) View Current Product List
- ( ) Add or Update Product List
- ( ) Update Food License

SKU	Active	Brand Name	Product Name	Status	Pro...	Total THC pe...	Total THC per ...	City Manufactu...	State Manufac...	Manufacturer	COA
CLIMKITE...	Yes	Climbing Kites	Mixed Berry Hot Batch	Approved	Edible			Des Moines	IA	https://www.climbingkites.com/	https://climbingkites.com/wp-content/uploa...
CHIST44...	Yes	Chill State	Pineapple Express	Approved	Edible			Saint Paul	MN	https://fairstate.coop/chillstate/	https://fairstate.coop/chillstate/
CHIST44...	Yes	Chill State	Lemon Haze	Approved	Edible			Saint Paul	MN	https://fairstate.coop/chillstate/	https://fairstate.coop/chillstate/
CHIST44...	Yes	Chill State	Grapefruit Kush	Approved	Edible			Saint Paul	MN	https://fairstate.coop/chillstate/	https://fairstate.coop/chillstate/
D9SIMPL...	Yes	River Bluff	Simple Syrup	Approved	Edible			East Dubuque	IL	https://riverbluffcollective.com/	https://riverbluffcollective.com/product/delt...
THEHAP...	Yes	The Happy Can	Root Brew	Approved	Edible			Morgan	MN	https://www.buythehappycan.com/	https://www.buythehappycan.com/lab-resul...
THEHAP...	Yes	The Happy Can	Purp Slurp	Approved	Edible			Morgan	MN	https://www.buythehappycan.com/	https://www.buythehappycan.com/lab-resul...
THEHAP...	Yes	The Happy Can	Citrus Haze	Approved	Edible			Morgan	MN	https://www.buythehappycan.com/	https://www.buythehappycan.com/lab-resul...
THEHAP...	Yes	The Happy Can	Pride Punch	Approved	Edible			Morgan	MN	https://www.buythehappycan.com/	https://www.gsdis.com/lab-results/
CLIMKITE...	Yes	Climbing Kites	Pineapple Passion Fruit	Approved	Edible			Des Moines	IA	https://www.climbingkites.com/	https://www.gsdis.com/lab-results/
CLIMKITE...	Yes	Climbing Kites	Peach Prickly Pear	Approved	Edible			Des Moines	IA	https://www.climbingkites.com/	https://www.gsdis.com/lab-results/
CLIMKITE...	Yes	Climbing Kites	Orange Mango	Approved	Edible			Des Moines	IA	https://www.climbingkites.com/	https://www.gsdis.com/lab-results/
CLIMKITE...	Yes	Climbing Kites	Mixed Berry	Approved	Edible			Des Moines	IA	https://www.climbingkites.com/	https://www.gsdis.com/lab-results/
WLDWTR...	Yes	Wld Wtr	Tropical Punch	Approved	Edible			Minneapolis	MN	https://shop.wldwtr.com/	https://www.wldwtr.com/lab-results
WLDWTR...	Yes	Wld Wtr	Peach Mango	Approved	Edible			Minneapolis	MN	https://shop.wldwtr.com/	https://www.wldwtr.com/lab-results
WLDWTR...	Yes	Wld Wtr	Blue Razz	Approved	Edible			Minneapolis	MN	https://shop.wldwtr.com/	https://www.wldwtr.com/lab-results

23. An approved product list remains in effect for one year. If a Registrant successfully renews their registration—which they must do annually—the approved product list may carry into the next effective period. When a Registrant submits a product list update during the registration's effective period, only newly submitted products are reviewed, while previously approved products on the list are maintained (unless actively removed from the list by the Registrant during the update).

24. If a product list update is reviewed, and certain products are denied, the Registrant receives an email communication explaining which specific products were denied and why. No products are denied without HHS giving such written notice to the Registrant. The notice includes an Excel spreadsheet listing the specific denied products and explaining each denial. Here is an excerpt from a denial and Excel explanation issued to Plaintiff Field Day Brewing, and which is attached as Exhibit #9 (notice of denial) and Exhibit #10 (Excel explanation of denial):

STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Kim Reynolds
GOVERNOR
Adam Gregg
LT. GOVERNOR
Kelly Garcia
DIRECTOR

Hello Joe,

The attached product(s) is/are **NOT** lawfully permitted to be sold in Iowa. This is due to one or more reasons:

- The product(s) contain a total THC level exceeding 4 mg total THC/serving, 10 mg total THC/container, or both. Per Iowa Code 204.2, products exceeding 4 mg total THC/serving and/or 10 mg total THC/container are not consumable hemp products and are Schedule 1 controlled substances under the Iowa Controlled Substances Act (Iowa Code Chapter 124). Possession, sale, or distribution of these products may result in severe criminal or civil penalties; OR
- The product(s) contain one or more synthetic cannabinoids. Synthetic cannabinoids, such as Delta-8 THC, Delta-10 THC, HHC, THC-P, etc. are not permitted under Iowa Code 204.14A.
- The total THC content, including isomers, derivatives, and analogs, exceeds 0.3%. This violates Iowa Code 124.204(7)(b) and cannot be sold in Iowa.
- The product is in a form that is prohibited. See Iowa Code 204.2, 204.14A. This product cannot be sold in Iowa
- The product contains an ingredient not approved for use in food (aminita, kratom, etc.). Products with non-approved ingredients are considered adulterated and cannot be sold in Iowa under 641481 IAC 15631.3.
- The product failed a toxicant limit set by 641 IAC 156.3(2).
- The product submitted does not contain a consumable hemp ingredient and does not fall under Iowa Code 204. This product does not need to be included on the product list.
- This product fails the packaging and labeling requirements set forth in 641 IAC 156.4(1). This includes products intended for individual retail sale.
- This product does not meet the serving requirements established in table 2 of 21 CFR 101.12 (See 641 IAC 156.1.)

These products will automatically be removed from your product list.

If you believe that you made an error on your product list that resulted in this rejection (for example, you typed "44" instead of "4"), please reach out to us at consumable.hemp@idph.iowa.gov.

Thank You,

The Bureau of Cannabis Regulation
Compliance Division
Iowa Department of Health and Human Services
Phone: 1-877-244-9242

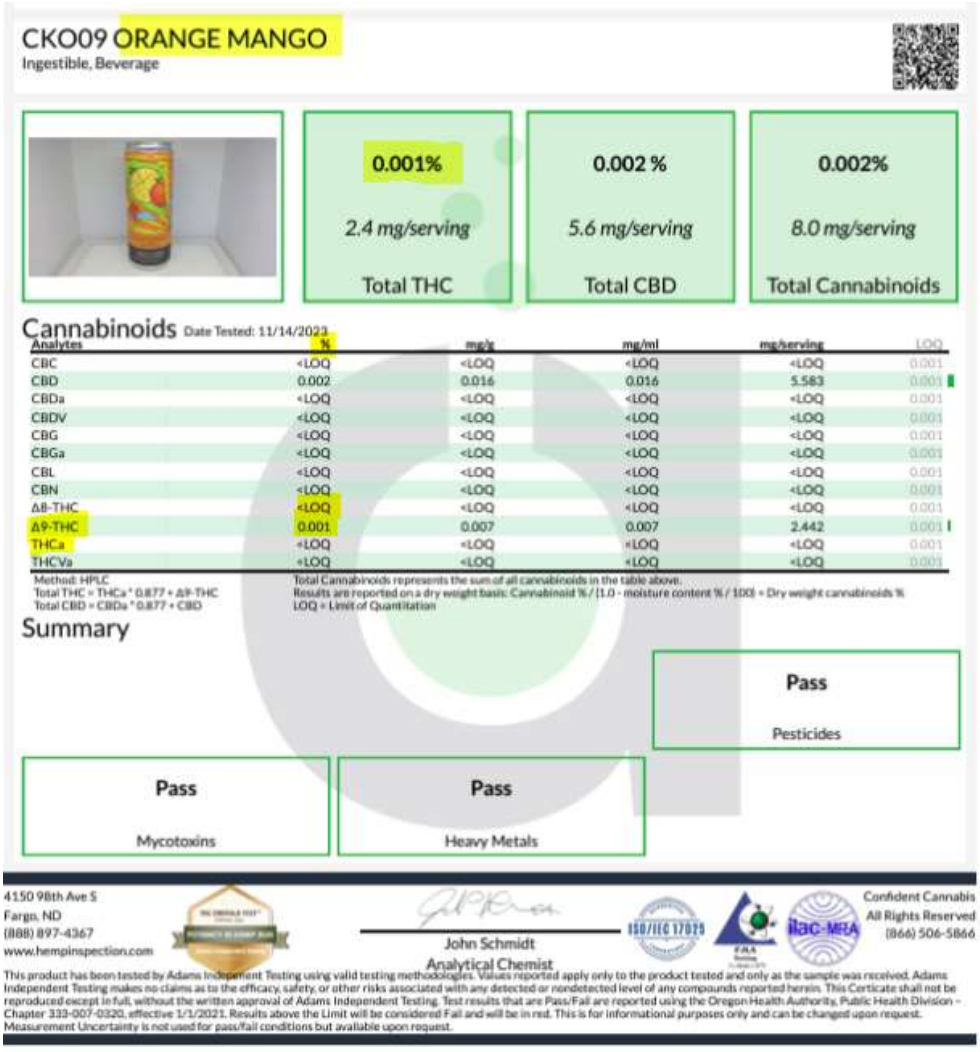
B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
Brand_Nai	SKU__c	Product_Name_	Product_F	Total_THC	Total_THC	City_Mani	State_Mar	Manufacti	COA__c	Non_Com	Other_Description__c												
Day Drean	RH88A0	Classic Raspberr	Edible	4	8	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	LG88A0	Classic Lemon G	Edible	4	8	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	SC1010A0	Fly High Strawbe	Edible	4	10	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	LG1010A0	Fly High Lemon	Edible	4	10	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	RH1010A0	Fly High Raspbe	Edible	4	10	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	RH44A0	Low Key Raspbe	Edible	4	4	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	O1055A0	Sunrise	Edible	4	10	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	SC77A0	Classic Strawber	Edible	3.5	7	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	LG77A0	Classic Lemon G	Edible	3.5	7	North Libe	IA	https://fle	https://fle	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													
Day Drean	RH77A0	Rasberry Hibisu	Edible	3.5	7	North Libe	IA	https://fle	https://or	Nonconforming Product: Exceeds Serving/Container Maximums Permitted - Exceeds >4 mg total THC per serving and/or >10 mg total THC per container.													

Product Potency Criteria (Pre- and Post-HF2605)

25. Before implementing HF2605, HHS's primary criteria for review and approval or denial of a product complied with the <0.3% THC threshold that the 2018 Farm Bill established. The Excel sheet Registrants submitted to HHS did not include this information. It instead asked about total cannabinoids per serving and per container. But HHS used information from the Certificate of Analysis (COA) to confirm compliance.

26. The COA would either expressly list the product's THC by weight, or listed the product's specifications thus allowing HHS to calculate the THC by weight. The calculation HHS uses to determine Total THC is "Total THC = Delta-9 THC + (0.877 × THCa)." *See* Iowa Admin. Code r. 641—156.3 (outlining COA testing and documentation requirements).

27. Additionally, for a manufacturer to receive compliant testing analysis of a product, and thus a sufficient COA, the manufacturer must either declare the weight of the product to the laboratory and/or the laboratory doing the testing will weigh the product itself to provide accurate results and to assess the product's compliance with the federal 0.3% THC threshold. Here is an example of a compliant COA, in which the product's Total THC is clearly indicated and calculatable:



CKO09 ORANGE MANGO
Ingestible, Beverage

0.001%	0.002 %	0.002%
2.4 mg/serving	5.6 mg/serving	8.0 mg/serving
Total THC	Total CBD	Total Cannabinoids

Cannabinoids Date Tested: 11/14/2023

Analytes	%	mg/g	mg/ml	mg/serving	LOQ
CBC	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBD	0.002	0.016	0.016	5.583	0.001
CBDa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBDV	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBG	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBGa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBL	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBN	<LOQ	<LOQ	<LOQ	<LOQ	0.001
Δ8-THC	<LOQ	<LOQ	<LOQ	<LOQ	0.001
Δ9-THC	0.001	0.007	0.007	2.442	0.001
THCa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
THCVa	<LOQ	<LOQ	<LOQ	<LOQ	0.001

Method: HPLC
Total THC = THCa * 0.877 + Δ9-THC
Total CBD = CBDa * 0.877 + CBD

Total Cannabinoids represents the sum of all cannabinoids in the table above.
Results are reported on a dry weight basis: Cannabinoid % / (1.0 - moisture content % / 100) = Dry weight cannabinoids %
LOQ = Limit of Quantitation

Summary

Pass — Pesticides

Pass — Mycotoxins

Pass — Heavy Metals

4150 98th Ave S
Fargo, ND
(888) 897-4367
www.hempinspection.com

John Schmidt
Analytical Chemist

Confident Cannabis
All Rights Reserved
(866) 506-5866

This product has been tested by Adams Independent Testing using valid testing methodologies. Values reported apply only to the product tested and only as the sample was received. Adams Independent Testing makes no claims as to the efficacy, safety, or other risks associated with any detected or nondetected level of any compounds reported herein. This Certificate shall not be reproduced except in full, without the written approval of Adams Independent Testing. Test results that are Pass/Fail are reported using the Oregon Health Authority, Public Health Division – Chapter 333-007-0320, effective 1/1/2021. Results above the Limit will be considered Fail and will be in red. This is for informational purposes only and can be changed upon request. Measurement Uncertainty is not used for pass/fail conditions but available upon request.

28. HHS gave examples of these Total THC calculations, pursuant to HF2605, as in its June 7 FAQ:

- A gummy product contains 3 mg per serving of Delta-9 THC and 1 mg THCa per serving. There are 2 gummies per package, and the serving size is designated as 1 gummy per serving. The total THC per serving would be 3.877 mg. The total THC per container would be 7.754 mg. This product would be permissible.
- A tablet contains 1 mg of Delta-9 THC, and the serving size is designated as 1 tablet per serving. There are 10 tablets per bottle. The total THC per serving would be 1 mg, and the total THC per container would be 10 mg. This product would be permissible.
- A chocolate bar contains 4 mg of Delta-9 THC per square, and there are 12 squares per chocolate bar. The serving size designated is 1 square per serving.

> The total THC per serving would be 4 mg. The total THC per container would be 48 mg. This chocolate bar would NOT be permissible.

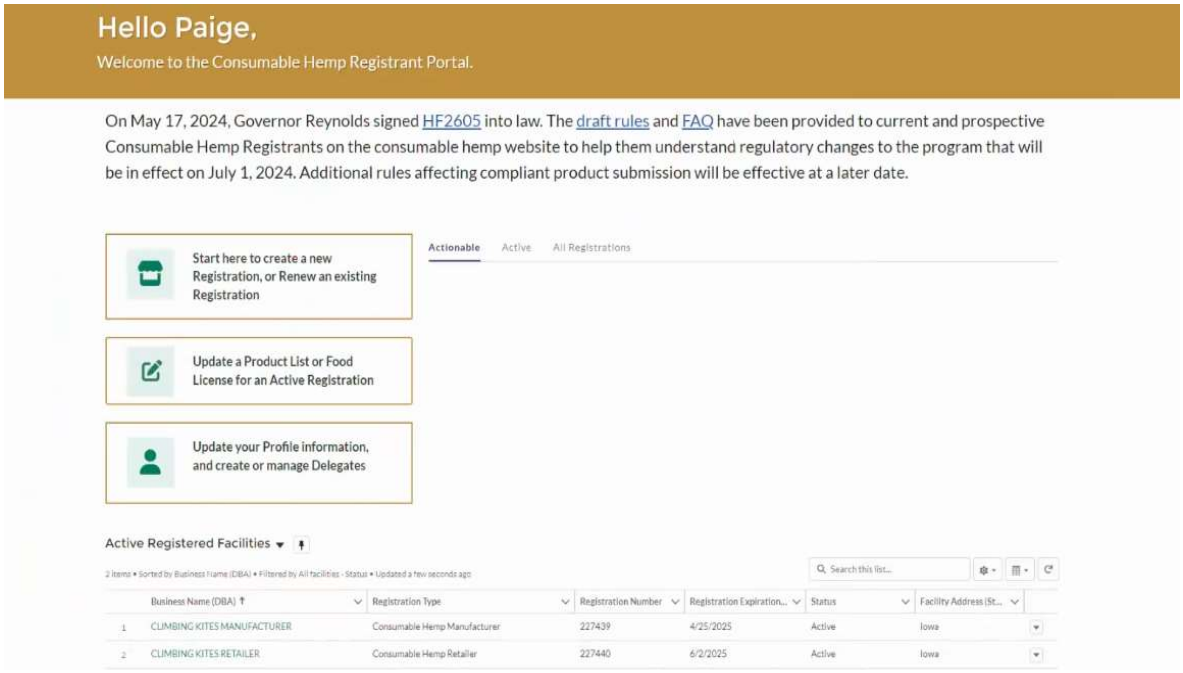
29. HHS had authority and responsibility to continue to approve products meeting the pre-HF2605 standards until July 1, 2024. And HHS had no authority to approve or deny products submitted for review under HF2605's new standards before that law's July 1, 2024 effective date. To ensure a timely rollout of the updated Portal and template, HHS began planning then working on the substantial updates necessary to implement HF2605 in April 2024.

30. To support enforcement of the "4 mg THC per serving" and "10 mg THC per container" potency limits prescribed by HF2605, HHS was required to build and implement substantive, and technical, updates to the Portal ahead of the bill's effective date. This took hard and extensive work by HHS and third-party web developers. Despite the challenges, HHS timely completed the necessary updates, which rolled out on the Portal at midnight on July 1, 2024.

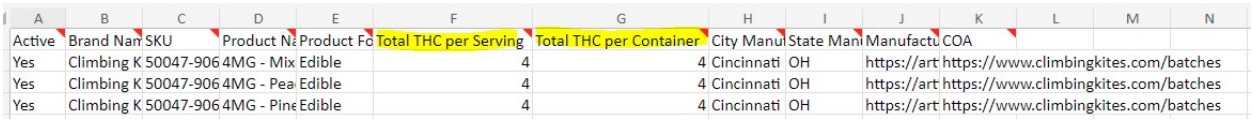
31. Updates to the Portal included the new requirement that Registrants disclose "Total THC per Serving" and "Total THC per Container," instead of total cannabinoids, for any products submitted after July 1, 2024.

HHS Rolls Out Updated Portal on July 1, 2024

32. When entering the Portal starting July 1, 2024, a banner existed on the homepage flagging the substantial changes to the law, highlighting that the changes "will be in effect on July 1, 2024," and providing resources for Registrants. Here is what that homepage looked like:



33. Beginning July 1, 2024, Registrants logging into the Portal to submit a new product or update an existing product were presented with a new template that requests the new information required under HF2605, and a revised "Consumable Hemp Product List Upload Guide" explaining what was required. Here is the new template Excel spreadsheet:



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Active	Brand Nan	SKU	Product Na	Product Fo	Total THC per Serving	Total THC per Container	City Manuf	State Manu	Manufactu	COA			
	Yes	Climbing K	50047-906	4MG - Mix	Edible	4	4	Cincinnati	OH	https://art	https://www.climbingkites.com/batches			
	Yes	Climbing K	50047-906	4MG - Pea	Edible	4	4	Cincinnati	OH	https://art	https://www.climbingkites.com/batches			
	Yes	Climbing K	50047-906	4MG - Pine	Edible	4	4	Cincinnati	OH	https://art	https://www.climbingkites.com/batches			

34. The upload guide outlines the changes for Registrants' per serving and container THC declarations and explains why products may be denied by HHS. The post-HF2605 upload guide is contained within the Portal and attached here as Exhibit #4. Here is a key excerpt from the upload guide explaining the new "Total THC per serving" requirement:

6. **"Total THC per Serving"**

Pursuant to 641—156.1, if THC is contained within, or marketed for the product by the Manufacturer the amount of THC per serving must be provided in milligrams (mg). Consumable hemp products containing more than 4 mg per serving ≥ Delta-9 THC + (0.877 × THCa) total tetrahydrocannabinol (THC) per serving will be prohibited from sale in Iowa on July 1, 2024. Examples of Total THC per Serving may be "2," "2.5," or "4," etc. Enter the total THC rounded to the nearest decimal.

Note: Products containing "synthetic cannabinoids," including but not limited to Delta-8, Delta-10, THC-P, HHC, THC-O etc., may no longer be sold in Iowa on July 1, 2024. Please refer to the product container for this information,or contact the manufacturer.

35. On July 1, 2024, HHS had more than 46,000 approved products on-file, but because those were approved under the prior regulatory regime, HHS did not have "per serving" and "per container" THC information for those products. So HHS made the operational decision to require any Registrant entering the Portal on or after July 1, 2024, whether seeking to renew a registration or make a product list update, to submit an entirely new product list in accordance with the portal updates and newly-effective law. In requiring submission of a new product list, HHS sought administrative efficiency. HHS expected Registrants—consistent with their continuing obligation under their Registrant attestations to comply with state and federal law—to sift out any products that were clearly noncompliant with the new law.

36. So after July 1, 2024, a Registrant logging on to the Portal to engage in an active process (renewal, product list update), would have observed that its on-file, pre-July 1 approved product list was archived by HHS after they submitted their new product list update. That prior approved list was no longer viewable by the Registrant while the new product list was under review.

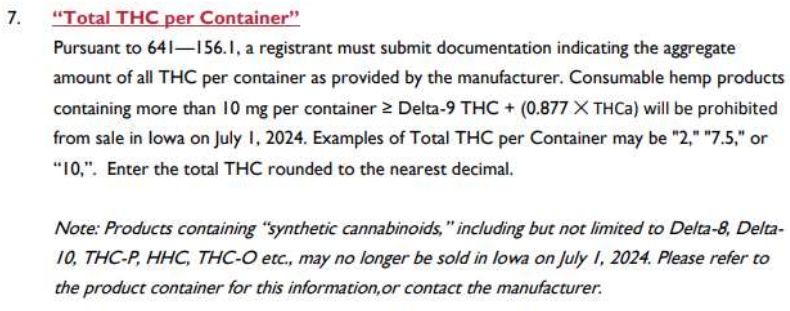
37. I have reviewed Plaintiffs filings in this case, including allegations that HHS has de-approved many of Plaintiffs' previously approved products. That is not true.

38. Previously approved products were not "denied" by HHS. No denial communication was sent to any Registrant, even if the product did not comply with the plain language of the

new law. And HHS does not issue denials without giving Registrants notice. HHS maintains access to any archived approved product lists.

39. For example, in the case of Plaintiff Climbing Kites, which had valid registrations most recently approved on February 28, 2024, for Manufacturing/Distribution (Registration# 227439), and May 6, 2024, for Retail (Registration # 227440) (and still in effect as of the date of this filing), any products it sold or manufactured that HHS had (1) previously approved and (2) which complied with the new requirements set forth in HF2605, can still be sold in Iowa**.** That goes for all Plaintiffs, and all Registrants.

40. Registrants who, since July 1, 2024, have not actively initiated a renewal registration or submitted a product list update are still able to view their pre-July 1, 2024, product list as previously approved by HHS. That is not to say that those products, approved pre-July 1, necessarily comply with the new law's 4 mg THC per serving and 10 mg THC per container limits, or would inevitably be approved upon resubmission. Those previously approved products have not yet been addressed by the Registrant under their responsibility pursuant to Iowa Admin. Code r. 641—156.2(1)(*c*) and 2(2)(*c*) to ensure their products maintain compliance with the new law. As the updated Upload Guide requires, registrants must now submit documentation indicating the amount of THC per serving and THC per container for their products (excerpted here, and attached as Exhibit #4):



7. **"Total THC per Container"**

Pursuant to 641—156.1, a registrant must submit documentation indicating the aggregate amount of all THC per container as provided by the manufacturer. Consumable hemp products containing more than 10 mg per container ≥ Delta-9 THC + (0.877 × THCa) will be prohibited from sale in Iowa on July 1, 2024. Examples of Total THC per Container may be "2," "7.5," or "10,". Enter the total THC rounded to the nearest decimal.

Note: Products containing "synthetic cannabinoids," including but not limited to Delta-8, Delta-10, THC-P, HHC, THC-O etc., may no longer be sold in Iowa on July 1, 2024. Please refer to the product container for this information,or contact the manufacturer.

41. HHS maintained compliance with the 30-day review period for new or updated products. HHS is allowed by regulation up to 30 days to review product list updates. And it has not exceeded that timeframe for any of the pending or recently processed submissions. HHS has timely processed all submissions initiated between July 1 and July 17, 2024.
42. HHS had no obligation to begin issuing approvals and denials before July 1, 2024, so long as it continued to follow the law. The post-July 1 standards were not finalized in the administrative rules until July 17, 2024. Leading up to July 1, HHS still had the responsibility to process submissions within 30 days, and the pre-July 1 standards still governed. Processing products based on HF2605 before July 1 would have risked sending the signal to the public that HHS was enforcing the law before the law was even in effect.
43. As a matter of resources and staffing, HHS could not double its Portal-derived workload—having to review the same product under both the pre- and post- July 1 standards—all while working hard to ensure a clean rollout at midnight on July 1, 2024.
44. As of a July 16 Administrative Rules Review Committee (ARRC) meeting, Administrative Rules for the implementation of HF2605 have been adopted and became effective as of July 17. Those Final, and now-effective, Rules, are attached here as Exhibit #5. The Rules are materially the same as the draft rules noticed on June 12.
45. HHS has also issued a revised FAQ guidance document, attached here as Exhibit #6, which explains the final Rules and, in some instances, addresses concerns raised by community members during the public comment period. For example, public comment revealed requested clarification as to how the serving and container limits should apply to topical products that are not ingested (those products that are not eaten). HHS explained that "serving" relates only to "products intended to be ingested ("eaten") or contain food."

Because topical products—like lotions, creams, and salves—are not eaten, the revised FAQ guidance document explains that the serving limit does not apply to them. Topical products must not "contain >10 mg Total THC per container."

HHS Timely Processes Post-July 1 Portal Submissions

46. Between July 1 and July 17, 2024, Registrants have submitted via the Portal 186 product list updates, 8 new applications for registrations, and 14 renewal applications for HHS's review under the new standards. As of today, July 19, 2024, HHS has processed all such submissions. Notices of approval or denial have been sent out. In the case of a denial, HHS explained to registrants why it determined their product did not comply with HF2605 and administrative rules, per HHS's standard practice as detailed above.

47. Many of these post-July 1 submissions came from Plaintiffs in these cases. HHS has had a series of communications with these Plaintiffs, per HHS's standard operating procedures described above.

48. First, each Plaintiff that submitted new products for approval since July 1 received an email confirming receipt of their submission and stating that their product is under review by HHS. Attached as Exhibit #7 is an example of one such receipt, confirming that HHS had received Plaintiff Climbing Kites's submission of an updated product list for review. This receipt was emailed to Climbing Kites's representative the day of the submission, July 9, 2024. HHS's internal analytics reveal that Climbing Kites's representative opened this email on July 11, 2024. Each Plaintiff that has submitted products for HHS's approval since July 1, 2024, has received a similar email confirming that review is ongoing, as do all Registrants.

49. Second, each Plaintiff that submitted new products for approval since July 1 has received notice that their product was either approved or denied. Attached as Exhibit #8, is an example of one such approval notice, issued July 18, 2024, confirming that HHS has determined that several of Plaintiff Climbing Kites's products complied with HF2605 and so were approved. For example, HHS approved Climbing Kites's product "4MG - Pineapple Passion Fruit," which is a 12-oz carbonated beverage that includes 4 mg of THC per serving and 4 mg of THC per container. The 12-oz can complies because it contains 4 mg or less of THC in the one serving of carbonated beverage.

50. And for each of Plaintiffs' products that were denied, HHS issued written explanation of that denial in the form of a notice and Excel sheet, as detailed above. Attached as Exhibit #9 is a notice of denial issued July 18, 2024, in response to Plaintiff Field Day Brewing's products list submission. And attached as Exhibit #10 is the Excel sheet explaining why each product in that submission was denied. Field Day Brewing had several products denied. The first product denial detailed in the Excel sheet—the Day Dreamer Classic Raspberry Hibiscus, a 12-oz can of carbonated beverage—was denied because it contained more than 4 mg of THC in the 12-oz can, which violates the definition of serving. It did not matter that Field Day reported the product contained 4 mg of THC per serving and 8 mg of THC per container. A 12-oz can of carbonated beverage cannot contain more than 4 mg of THC, and this product contained 8 mg of THC. Another Field Day Brewing product—the Day Dreamer Low Key Raspberry Hibiscus—was denied because, although it was reported on the Excel template that the 12-oz carbonated beverage product contained 4 mg of THC per serving, and 4 mg of THC per container, the testing did not match that

reporting. The Certificate of Analysis revealed that the product contained 4.62 mg of THC per serving, thus exceeding the per-serving limit.

51. HHS has followed its standard operating procedures, reviewing each Registrant and product submission similarly. All pending product list updates and renewal applications—including those submitted by Plaintiffs in this case—have been processed by HHS. And HHS has issued the requisite notice of either approval or denial to all respective Registrants.

52. Despite the substantial changes required to the Portal and review process, HHS has processed all pending product list updates and renewal applications—including all of Plaintiffs' submissions—within the 30-day period required by law.

THE DECLARANT FURTHER SAYETH NOT.

Executed this 19 day of July, 2024.

OWEN PARKER