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

CLIMBING KITES, LLC and FIELD DAY BREWING COMPANY, LLC, Plaintiffs, v. THE STATE OF IOWA; KELLY GARCIA, in her official capacity as Director of the Iowa Department of Health and Human Services; and IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 4:24-cv-00202 **SUPPLEMENTAL DECLARATION OF DAN CARAHER IN SUPPORT OF RENEWED MOTION FOR PRELIMINARY INJUNCTION**

I, Dan Caraher, pursuant to 28 U.S.C. § 1746(2), declare under penalty of perjury, the following:

1. I am over the age of 21 and have personal knowledge of several items set forth below. To the extent I have no personal knowledge of such items, I have consulted with employees and colleagues of Field Day Brewing Company, LLC ("Field Day Brewing"), and my knowledge is based on my investigation. I am acting in a representative capacity for Field Day Brewing, and I am competent to testify about the matters set forth herein.

2. I am the Director of Operations for Field Day Brewing. Field Day Brewing was formed in 2023 and is headquartered in North Liberty, Iowa.

BACKGROUND ON THE REGISTRATION OF HEMP PRODUCTS

3. Iowa law requires any business that manufactures or sells any consumable hemp product at retail to register with the Department of Health and Human Services ("DHHS") in advance of the sale of that product within Iowa. Field Day Brewing has maintained a hemp registration through DHHS throughout its existence.

4. DHHS maintains registrations through an online Consumable Hemp Registration Portal (the "Portal"). Field Day Brewing maintains a registration as a manufacturer. Retailers that do not manufacture their own products maintain a separate registration, but must list on the Portal all products sold at its establishment.

5. Consequently, a consumable hemp product commonly exists within the Portal under multiple "accounts": first, as a product registered by the *manufacturer*, then on as many other accounts that sell the same product at *retail*.

6. In order for a manufacturer to register a consumable hemp product, a manufacturer must first manufacture, package, and label the product. The manufacturer must also have the product tested by an independent lab to obtain a certificate of analysis. Only after those two steps are completed can a manufacturer submit the required information and ask DHHS, through the Portal, for approval to sell the already-manufactured product.

7. There is no mechanism to ask DHHS in advance of manufacturing a product whether it complies with the law. Manufacturers must guess. In other words, if DHHS denies a product, by the time a manufacturer receives that denial, it will have already incurred the financial expenditures required to produce the product and committed a crime of manufacturing and possessing a product that does not meet DHHS's interpretation of the law.

8. Although DHHS publicly lists the name, contact information and registration number of all registrants, DHHS does not publicly list individual approved products manufactured or sold by each registrant (the "Approved Products List"). This means manufacturers, distributors, retailers, consumers, or other members of the public—including law enforcement—cannot readily view a manufacturer's or retailers' Approved Products List without the say-so of DHHS.

9. The Approved Products List is the primary mechanism by which market participants determine if they are complying with the law. For example, as a condition of receiving its manufacturer's registration, Field Day Brewing is required to verify that Field Day Brewing's products are on all retailers' Approved Products Lists before Field Day Brewing can sell its products to that retailer. Likewise, retailers may not sell Field day Brewing's products if those products are not on Field Day Brewing's Approved Products List.

10. Thus, in order for manufacturers, distributors, and retailers to ensure all market participants are complying with the law, those parties regularly share their Approved Products Lists with each other.

11. Before DHHS approves the sale of any product within Iowa, a manufacturer or retailer must upload certain information into the Portal. DHHS Maintains a troubleshooting guide on how to upload products to the Portal. *See* Consumable Hemp Product List Upload Guide ("The Guide"), *available at* https://hhs.iowa.gov/media/9189/download?inline=.

12. At the July 11 hearing, attorneys for DHHS represented that DHHS does not know the number of servings in a container when it approved products prior to July 1, 2024. Tr. at 66:22–24, 67:3–4, 74:3–5, 74:17–19 ("The Court: So you didn't have that information in your process? Mr. Valencia: That is my understanding."); 75:2-3 ("The Department was not receiving information about serving sizes and approving that."); 80:6-8 ("serving sizes [were] not in the pre-July 1 world."). I do not believe that to be accurate. Prior to July 1, to receive approval for a product, DHHS ***required*** manufacturers to submit both the "total cannabinoids per serving" of a product—which "should represent the aggregate amount of all cannabinoids…***per serving as provided by the manufacturer***"—and the "total cannabinoids per container" of a product, "as provided by the manufacturer." The Guide pp. 3–4 (emphasis added). By requiring this

information, DHHS knew—prior to the approval of any product before July 1, 2024—the potency of each serving, the total potency of the container, and the number of servings per container.

13. Therefore, prior to July 1, it was impossible to gain approval from DHHS for a consumable hemp product without disclosing to DHHS the number of servings in the container of that hemp product.

14. Moreover, as the Guide states, DHHS required market participants to provide the "serving" of a consumable hemp product as stated by a ***manufacturer***. In other words, HHS approved "servings" as recommended by the manufacturer, consistent with THC servings being considered a "dosage" (i.e., an additive).

15. Prior to July 1, once a product's information was submitted into the Portal by a registrant, the product was visible to the registrant as "pending approval" before ultimately becoming approved or denied. Submitting a new product for registration did not clear, delete, or otherwise modify other products on a registrant's Approved Products List.

16. Since maintaining a hemp registration, Field Day Brewing has not had a product "denied" upon submission of information through the Portal.

17. Since maintaining a hemp registration, Field Day Brewing has not "renewed" a product for approval because once approved, a product stays presumptively approved. In other words, DHHS's approval does not "expire" and is not subject to re-approval by a manufacturer or retailer. Indeed, prior to July 1, 2024, none of Field Day Brewing's previously approved products were ever cleared, deleted, or otherwise modified from its Approved Products List.

18. As of July 2, 2024, Field Day Brewing's Portal contained eighteen active products:

	A	B	C	D	E	F	G	H	I	J	K
1	Active	Brand Name	SKU	Product Name	Product F	THC per S	THC per C	City Manufactured	State	Manufacture	COA
2	Yes	Day Dreamer	SC88A0	Classic Strawberry Citrus	Edible	4	8	North Liberty	IA	https://field	https://fie
3	Yes	Day Dreamer	RH88A0	Classic Raspberry Hibiscus	Edible	4	8	North Liberty	IA	https://field	https://fie
4	Yes	Day Dreamer	LG88A0	Classic Lemon Ginger	Edible	4	8	North Liberty	IA	https://field	https://fie
5	Yes	Day Dreamer	SC1010A0	Fly High Strawberry Citrus	Edible	4	10	North Liberty	IA	https://field	https://fie
6	Yes	Day Dreamer	LG1010A0	Fly High Lemon Ginger	Edible	4	10	North Liberty	IA	https://field	https://fie
7	Yes	Day Dreamer	RH1010A0	Fly High Raspberry Hibiscus	Edible	4	10	North Liberty	IA	https://field	https://fie
8	Yes	Day Dreamer	LG44A0	Low Key Lemon Ginger	Edible	4	4	North Liberty	IA	https://field	https://fie
9	Yes	Day Dreamer	BL45A0	NightCap	Edible	4	4	North Liberty	IA	https://field	https://fie
10	Yes	Day Dreamer	SC44A0	Low Key Strawberry Citrus	Edible	4	4	North Liberty	IA	https://field	https://fie
11	Yes	Day Dreamer	RH44A0	Low Key Raspberry Hibiscus	Edible	4	4	North Liberty	IA	https://field	https://fie
12	Yes	Day Dreamer	O1055A0	Sunrise	Edible	4	10	North Liberty	IA	https://field	https://fie
13	Yes	Day Dreamer	BL55A0	Night Cap	Edible	2.5	5	North Liberty	IA	https://field	https://fie
14	Yes	Day Dreamer	LG22A0	Low Key Lemon Ginger	Edible	2	2	North Liberty	IA	https://field	https://fie
15	Yes	Day Dreamer	SC77A0	Classic Strawberry Citrus	Edible	3.5	7	North Liberty	IA	https://field	https://fie
16	Yes	Day Dreamer	LG77A0	Classic Lemon Ginger	Edible	3.5	7	North Liberty	IA	https://field	https://fie
17	Yes	Day Dreamer	RH22A0	Low Key Raspberry Hibiscus	Edible	2	2	North Liberty	IA	https://field	https://fie
18	Yes	Day Dreamer	SC22A0	Low Key Strawberry Citrus	Edible	2	2	North Liberty	IA	https://field	https://fie
19	No	Day Dreamer	SC22A0-001	Low Key Strawberry Citrus	Edible	2	2	North Liberty	IA	https://field	https://fie
20	No	Day Dreamer	RH22A0-001	Low Key Raspberry Hibiscus	Edible	2	2	North Liberty	IA	https://field	https://fie
21	No	Day Dreamer	RH77A0-001	Day Dreamer Classic Raspberry Hibiscus	Edible	3.5	7	North Liberty	IA	https://field	https://fie
22	Yes	Day Dreamer	RH77A0	Rasberry Hibisucs	Edible	3.5	7	North Liberty	IA	https://field	https://or

19. As noted in Paragraph 18, because Field Day Brewing was required to list both the cannabinoids-per-serving and the cannabinoids-per-container, DHHS was aware of the number of servings in each product Field Day Brewing submitted for approval. For example, the top SKU (Classic Strawberry Citrus) contains 4 milligrams total THC per serving and 8 milligrams of total cannabinoids per container, meaning the can contains two servings. Other approved cans contained one or two-and-a-half servings per can, depending on the THC concentration of the can. Thus, among Field Day Brewing's active products as of July 2, DHHS (1) knew Field Day Brewing submitted for approval beverages that contained one, two, or two-and-a-half "servings" per container, and (2) approved those beverages containing one, two, or two-and-a-half "servings" per container.

20. In my prior Declaration, I provided examples of several cans containing up to 10 servings in a container that DHHS had approved. At the July 11 hearing, attorneys for DHHS repeatedly represented the Department did not have information about serving sizes in its possession and that these cans were approved only because the Department was not approving

serving sizes. *See* Tr. 80:22–81:6. This is not true. As noted above, DHHS required that manufacturers submit information on serving and container. Based on this requirement and on information and belief, DHHS knew that these cans contained as many as ten servings per can. With that knowledge, DHHS approved those cans.

21. Those products (i.e., those containing multiple "servings" in a twelve-ounce can) were approved and therefore lawful for sale by Iowa retailers when the legislature enacted HF2605. As noted above, at the time the legislature enacted HF2605, HHS required manufacturers to provide information both on "servings" and "containers." Unlike statutes enacted in other states, the legislature did not define "serving" (and, importantly, did not include language changing HHS's then-utilized definition of "serving"), nor did it limit the number of servings a manufacturer may provide in a container.

ENACTMENT OF HF2605

22. At the time the legislature passed HF2605, and as demonstrated above, HHS was approving "serving" and "serving size" as recommended by the manufacturer, as an additive dosage. Yet after the legislature passed HF2605, and despite the legislature doing nothing to change the term "serving," DHHS unilaterally pivoted to defining "serving" as defined by the FDA, as focused on the underlying product. ***This unilateral change—without any authorization by the legislature—means that products approved both before and after the passage of HF2605 became illegal.***

23. All industry stakeholders believed that "serving" as used in the statute means what the Department said it meant before the passage of HF2605. DHHS's statements to this Court that there is only one reasonable interpretation of "serving" (whatever the FDCA says) goes against the history of Iowa's hemp law, the FDA's statements on hemp, the legislature's understanding of

Iowa's hemp laws, and the Department's own actions in approving products that it knew contained "servings" contrary to what it wants to require today.

24. Up to and through July 1, DHHS relied upon manufacturers to provide standard servings based on the amount (i.e., dosage) of THC recommended to be consumed—not the amount of inert product consumed.

IMPLEMENTATION OF HF2605

25. Upon the enactment of HF2605, Field Day Brewing submitted through the Portal—***and DHHS approved***—cans containing one, two, and two-and-a-half servings (with 2, 7, 8, or 10 milligrams of THC). These submissions (and approvals) were intended to comply with HF2605.

26. At the July 11 hearing, attorneys for DHHS repeatedly represented that the Department instructed manufacturers and retailers to "resubmit" or "renew" all products on a registrant's Approved Products List after July 1, 2024 as a result of the law change. Tr. 62:21–25; 78:21–23. That is not accurate. At no point was Field Day requested to resubmit any products. We also were not told that our products would no longer be present on the website, and we only discovered that by logging onto the Portal ourselves.

27. Prior to July 1, 2024, Field Day Brewing's product list had never been cleared, deleted, or otherwise modified even when it submitted applications for new products. Based on information and belief, no other market participants had ever had their previously Approved Products List cleared or altered.

28. DHHS has informed Field Day Brewing and other participants that they must ensure their own compliance with Iowa's consumable hemp laws, and that the proper way to do that is to only sell products that are on a manufacturer's or retailer's Approved Products List. Distributors and retailers often ask Field Day Brewing to provide to them an up-to-date copy of

Field Day Brewing's Approved Products List so that the distributor or retailer can ensure it is only selling legal products.

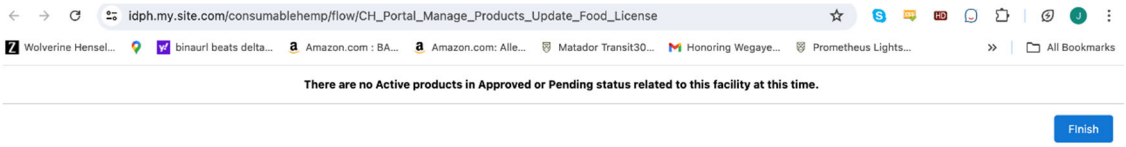
29. As confirmed by the Department at the July 11 hearing, the difference in Iowa between a legal consumable hemp product and an illegal one is whether it is an approved product in the Portal. Tr. 65:13–18; 66:19–21. DHHS requires that retailers and manufacturers maintain a complete product list of those intended to be submitted and approved by the Department. *See* Iowa Admin. Code r. 641–156.2(1), (2). DHHS considers any product that is not active and/or approved on an Approved Products List as illegal, regardless whether that product in fact complies with Iowa law. *See* Tr. 65:13–18; 66:19–21.

30. This stance—taken by DHHS but not confirmed by any provision in Iowa law—puts Iowa hemp manufacturers in a difficult position. Manufacturers cannot produce products lawfully until they have been approved by DHHS, but they cannot apply for approval from DHHS until after the product has already been produced. DHHS, unlike other states, does not have a good-faith exception to its regulatory scheme to solve this Catch-22.

31. In short, it is impossible to overstate how heavily participants in the market rely on the Portal and a registrant's Approved Products List. As the Department recognizes, it is the ***only*** difference between legal business and felonies. *See id.* When products are pulled without notice, or when DHHS requires (without any notice) that market participants resubmit products for approval after arbitrary dates, manufacturers are unable to "maintain" an approved products list and are placed into legal limbo and their economic interests jeopardized.

32. Absent some directive to "resubmit" or "renew" products for manufacture or sale, Field Day Brewing would have no need to do so to comply with DHHS's interpretation of HF2605 because Field Day Brewing's products were already approved by DHHS. *See* Paragraph 25, *supra*.

33. In preparing for the July 11 hearing, on or about July 7, Field Day Brewing consulted its approved-products list only to find it completely eliminated. As of July 15, Field Day Brewing's Portal contained zero active products:



34. Field Day Brewing's current Active Products List is not just empty, the Portal affirmatively states "[t]here are no Active products in Approved or Pending status related to this facility at this time."

35. At the July 11 hearing, DHHS did not provide a credible reason as to why DHHS—through its Portal—affirmatively informed Field Day Brewing it had zero active products. Tr. 61:11–62:25; 78:13–79:1.

36. By clearing Field Day Brewing's product list and affirmatively stating that Field Day Brewing has "no Active products," DHHS affirmatively removed Field Day Brewing's ability to sell *anything*. It is unreasonable for any market participant to believe *any* Field Day Brewing products remain "approved" by DHHS for manufacture or sale within Iowa when such products affirmatively are not "approved" according to the Portal and DHHS refuses to provide any independent verification—verbally or in writing—that products remain approved. Indeed, retailers have decided to stop selling Field Day Brewing's products after the de-approval of all its products. DHHS has constructively denied Field Day Brewing's ability to manufacture and sell any consumable hemp products in Iowa.

37. I was contacted by other registrants concerned about continuing to sell any Field Day Brewing products if Field Day Brewing itself held no valid active registration for those products.

38. For example, future orders of all of Field Day Brewing's products have been paused from numerous stores of a prominent local grocer—even cans containing 2 milligrams of THC. Based on information and belief, the grocer is pausing ordering Field Day Brewing's products because it is unwilling to take the risk of selling *any* of Field Day Brewing's products due to the uncertainty (*i.e.*, vagueness) of the current state of the law and Field Day Brewing's products.

39. Upon learning of the de-approval of its products, on or about July 8, Field Day Brewing immediately attempted to re-register its products on the Portal. Although information was submitted through the Portal and Field Day Brewing received confirmation of its submission, the submissions were (and are) not visible to Field Day Brewing as "pending approval." Indeed, the Portal currently states Field Day Brewing has "no…products in…Pending status." In other words, Field Day Brewing is unable to submit *any* new products to DHHS for it to review.

40. DHHS has been aware for at least seven days that Field Day Brewing has been unable to sell its products because they were de-approved in the Portal. DHS contends this was an unintentional mistake, ***but has taken no steps to remedy this purported mistake***. As of today, Field Day Brewing's Portal still states that Field Day Brewing has "no Approved products."

41. At the July 11 hearing, attorneys for DHHS represented that post-July 1, Department will begin considering Portal submissions differently in light of HF2605. *See, e.g.*, Tr: 64:19–21; 66:22–67:10; 80:3–12. Yet the Portal requires substantially the same information today to submit a product for approval as it did prior to July 1, 2024. DHHS requires a manufacturer to submit the amount of THC-per-serving and THC-per-container as recommended by a manufacturer. DHHS *still* does not require the size of a container. In other words, even today, Field Day Brewing is not required to submit the size of its cans, whether 8, 12, 24, or 128 fluid ounces.

42. It is not possible for a manufacturer to submit additional information through the Portal. The requirements for uploading applications is precise, and if those requirements are not met, a registrant will be unable to submit an application for approval (i.e., the system will reject the application and provide an error message). ***In other words, if Field Day Brewing wanted or needed to submit the size of a container (which it must do, according to the Department's interpretation of HF2605), there is no way to do that.***

43. Absent information concerning the size of a container, it would appear to be impossible for DHHS to determine whether a product complies with DHHS's interpretation of HF2605's per-serving potency limit. It also appears impossible for DHHS to determine whether any product complies with its directive that beverages must contain at least twelve ounces in a container. At the very least, contrary to what DHHS represented at the hearing, DHHS does not require materially different information to be submitted after July 1 than it did before July 1.

44. DHHS de-approved Field Day Brewing's previously-approved products that no one—at any time—has disputed remain legal under HF2605 (i.e., 2 milligrams total THC per 12-ounce beverage).

45. DHHS de-approved Field Day Brewing's products with no notice, rationale, or opportunity to clarify whether such products should be de-approved. DHHS has refused to respond to Field Day Brewing's repeated emails and phone calls asking for an explanation.

46. It is my understanding DHHS will not communicate with *any* manufacturer, distributor, or retailer with questions regarding implementation of HF2605, including but not limited to the parties to this case. Due to that lack of clarity, some distributors and retailers are refusing to carry Field Day Brewing's products.

47. Manufacturers had no legal recourse to ascertain whether DHHS would continue to approve of (and allow sales of) previously-approved products after July 1. Manufacturers and retailers are utterly confused as to the status of *any* products. DHHS has created a void whereby, between July 1 and July 30, it is impossible for a manufacturer, retailer, or distributor to know whether it may sell a previously-approved product or whether it is unintentionally committing a crime. While we have resubmitted all products for "re-approval," and also have submitted new products for first-time approval after July 1, ***we were not able to (and thus cannot) submit the product's container size***. Thus, we are entirely unclear how DHHS will determine whether these products meet the Department's "not yet final" guidance on serving sizes or container sizes."

48. DHHS had over two weeks to discover this issue (i.e., that the Portal does not request, require, or allow the size of a container to be submitted), yet it has done nothing to fix the issue. It appears this is because—as the Department indicated at the hearing—it has not been reviewing applications submitted after July 1. Tr. 65:6–9.

49. Field Day Brewing is fearful that DHHS will reject product submissions as "not compliant" because DHHS failed to request or require adequate information to make its determination. DHHS obviously failed to give any mechanism to provide this information. Thus, on or about July 30, DHHS will reject our products through no fault of Field Day Brewing. At that time, Field Day Brewing would remain unable to sell any products for up to sixty more days while we re-submit products, then wait on retailers to follow suit, and gain *their* product approval before Field Day Brewing's products could be sold.

50. At the July 11 hearing, attorneys for the Department represented that hemp manufacturers *must* understand the Department's interpretation of the law based on Field Day Brewing's compliance with the Department's guidance thus far. Tr. 66:6–11. This statement is

entirely misleading. The fact that I directed my company to take the most cautious approach so I can ensure that I—or my partners or employees—do not face significant civil penalties or criminal violations does not mean that I, or my company, understand the law or agree with the Department's interpretation of the law.

51. After HF2605 was enacted and before DHHS finalized any purported administrative rules, Field Day Brewing continues to suffer harm and significant market confusion regarding the manufacture and/or sale of consumable hemp beverages.

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Dan Caraher