IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Chief Judge Philip A. Brimmer

Civil Action No. 19-cv-01943-PAB-KLM

LYSTN, LLC, d/b/a Answers™ Pet Food,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS,
COLORADO DEPARTMENT OF AGRICULTURE,
KATE GREENBERG, individually, and officially in her capacity as Commissioner of the Colorado Department of Agriculture,
LAUREL HAMLING, individually, and officially in her capacity as Feed Program Administrator for the Colorado Department of Agriculture,
SCOTT ZIEHR, individually, and officially in his capacity as Feed Program Regulatory Administrator for the Colorado Department of Agriculture, and
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

AMENDED ORDER

This matter is before the Court on Federal Defendants' Motion to Dismiss [Docket No. 64],[1] State Defendants' Motion to Dismiss Plaintiff's Complaint Under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) [Docket No. 63],[2] and Defendant Association of American Feed Control Officials' Motion to Dismiss [Docket No. 65]. Plaintiff raises claims under the Administrative Procedure Act ("APA"), 5 U.S.C. § 704, and contends

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[1] "Federal defendants" refers to the Food and Drug Administration and the United States Department of Health and Human Services.

[2] "State defendants" refers to the Colorado Department of Agriculture ("CDA") and to the three individual defendants, who are CDA employees.

that the Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1367. Docket No. 1 at 12.

I. BACKGROUND

Plaintiff is a pet food manufacturer that produces and sells raw pet food. Docket No. 1 at 18, ¶ 60. Due to its manufacturing process, plaintiff's products naturally contain certain microorganisms at scientifically detectable levels that plaintiff claims are not harmful to humans. *Id.*, ¶ 61; *id.* at 19, ¶ 64. One type of microorganism that may be present in plaintiff's pet food products is *Salmonella*. *Id.* at 18, ¶ 61.

In July 2013, the Food and Drug Administration ("FDA") issued a final version of its Compliance Policy Guide ("CPG") § 690.800, "*Salmonella* in Food for Animals." *See U.S. Food & Drug Ass'n, Guidance for FDA Staff: Compliance Policy Guide Sec. 690.800* Salmonella *in Food for Animals* (2013), https://www.fda.gov/media/86247/download; *see also* Docket No. 64-1. The CPG states that the "FDA considers an animal feed or pet food that may be injurious to health because it is contaminated with *Salmonella* to be adulterated under section 402(a)(1) of the [Food, Drug, and Cosmetic Act ("FDCA")] (21 U.S.C. 342(a)(1))." Docket No. 64-1 at 6. A food is "adulterated" under the FDCA if it "bears or contains any poisonous or deleterious substance which may render it injurious to health," but is not considered adulterated if the substance is not an added substance and "if the quantity of such substance in such food does not ordinarily render it injurious to health." 21 U.S.C. § 342(a)(1). In the CPG, the FDA recommends that its staff members should consider the following risk-based criteria in deciding whether to

recommend seizure or import refusal of a pet food, animal feed, or their ingredients on the basis that it is adulterated:

> 1. *Salmonella* is present in one or more subsamples of the pet food or pet food ingredient; and
> 2. The pet food or pet food ingredient will not be, or information is not available to determine whether the pet food or pet food ingredient will be, further processed with a heat treatment or other method during the commercial manufacturing or processing to eliminate the *Salmonella*.
> 3. The *Salmonella* is of any serotype.

Docket No. 64-1 at 7. The CDA has adopted a definition of "adulteration" that mirrors the FDA's CPG. Docket No. 1 at 14, ¶ 41. The Model Bill and Regulations of the Association of American Feed Control Officials[3] ("AAFCO") provide a similar definition. *Id.*, ¶ 43. Plaintiff contends that the CPG, and the similar state definitions, is at odds with 21 U.S.C. § 342 and its provision that a naturally occurring substance will not render a product adulterated if the substance is in such quantity as to not render it injurious to health. Docket No. 1 at 29-30, ¶¶ 107-116.

On April 11, 2018, a CDA inspector collected a sample of plaintiff's pet food from a pet store in Littleton, Colorado. *Id.* at 26, ¶ 93. The sample allegedly contained *Salmonella* and *Listeria monocytogenes* in an unspecified quantity. *Id.* at 27, ¶ 94. The CDA is "currently prosecuting" plaintiff in the Colorado Office of Administrative

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[3] The AAFCO is a private, "voluntary membership association of local, state and federal agencies charged by law to regulate the sale and distribution of animal feeds." Docket No. 1 at 3. Plaintiff alleges that the AAFCO is a "quasi-legislative enterprise created by local, state, federal, and international regulators to define and establish regulations for pet food and feed ingredients, in addition to setting standards for nutritional adequacy." *Id.* at 10, ¶ 28. "Most states in the U.S. have adopted the Model Bill and Regulations established by AAFCO. While participation and membership in AAFCO is voluntary, if a state agency wishes to receive monies from the FDA, [it] must agree to enforce the FDA's policies and procedures in full." *Id.*

Courts ("COAC") based on this sample. *Id.* at 12 n. 21. Plaintiff attributes such prosecution to the FDA, asserting that "[t]he FDA, through the CDA, has chosen to prosecute Plaintiff for alleged violations of the [CPG]." *Id.* at 15, ¶ 47. Specifically, plaintiff contends that the CDA acted "pursuant to interagency agreement(s) between Colorado and the FDA and the FDA's call to the states for sampling of raw products." *Id.* at 26, ¶ 93.

On January 9, 2019, the FDA issued a Public Warning Notice for plaintiff's A+ ANSWERS™ Straight Beef Formula for Dogs on the basis that the product represented a serious threat to human and animal health. *Id.* at 25, ¶ 90. The FDA issued the warning after plaintiff refused to conduct a voluntary recall of its product. *Id.* The public warning stated that "[f]ederal law requires all pet food to be free of pathogens, including *Salmonella*." *Id.* at 26, ¶ 90. The FDA recommended that pet owners throw the product away and clean the areas in which the product was stored, as well as all items that may have come into contact with the product. *Id.*, ¶ 91.

Plaintiff sued the FDA, the AAFCO, the CDA, three CDA employees, and the United States Department of Health and Human Services on July 5, 2019. *See generally id.* Plaintiff seeks a declaratory judgment that plaintiff was denied its due process rights and seeks an injunction (a) preventing the FDA and the AAFCO from applying or enforcing the CPG and (b) requiring them to suspend any pending related enforcement actions specific to the CPG. *Id.* at 34. Plaintiff also seeks to enjoin defendants from reintroducing similar compliance policy guides, from circumventing the

APA, and from "creating artificial, false, and misleading appearances with respect to raw pet food products, safety, security, commodity, and currency (including removal of such from existing federal government websites and other means of publications)." *Id.* In addition, plaintiff requests that all claims and references of plaintiff distributing an adulterated product, and any other federal report or record related to the § 690.800 enforcement, "be expunged from all federal and state records." *Id.*

The federal defendants move to dismiss plaintiff's action on the basis that, among other reasons, the Court lacks subject matter jurisdiction over plaintiff's lawsuit. Docket No. 64 at 5, 9. The state defendants also argue that the Court lacks subject matter jurisdiction over this case. Docket No. 63 at 5. Finally, the AAFCO moves to dismiss the claims against it on the basis that the Court lacks personal jurisdiction over the association. Docket No. 65 at 3.

II. LEGAL STANDARD – SUBJECT MATTER JURISDICTION

Dismissal pursuant to Federal Rule of Civil Procedure 12(b)(1) is appropriate if the Court lacks subject matter jurisdiction over claims for relief asserted in the complaint. *Merrill Lynch Bus. Fin. Servs., Inc. v. Nudell*, 363 F.3d 1072, 1074 (10th Cir. 2004). Rule 12(b)(1) challenges are generally presented in one of two forms: "[t]he moving party may (1) facially attack the complaint's allegations as to the existence of subject matter jurisdiction, or (2) go beyond allegations contained in the complaint by presenting evidence to challenge the factual basis upon which subject matter jurisdiction rests." *Id.* (quoting *Maestas v. Lujan*, 351 F.3d 1001, 1013 (10th Cir. 2003)). "In reviewing a facial attack on the complaint, a district court must accept the

allegations in the complaint as true." *Holt v. United States*, 46 F.3d 1000, 1002 (10th Cir. 1995). However, "[w]hen reviewing a factual attack on subject matter jurisdiction, a district court may not presume the truthfulness of the complaint's factual allegations." *Id.* at 1003. "The substantive distinction between a facial attack and a factual attack is that in a facial attack the defendant contests the sufficiency of the complaint, while a factual attack challenges the existence in fact of federal subject matter jurisdiction." *LaLoup v. United States*, 29 F. Supp. 3d 530, 536 (E.D. Pa. 2014). "Because the jurisdiction of federal courts is limited, there is a presumption against our jurisdiction, and the party invoking federal jurisdiction bears the burden of proof." *Merida Delgado v. Gonzales*, 428 F.3d 916, 919 (10th Cir. 2005) (citation omitted).

III. ANALYSIS

A. Federal Defendants

The federal defendants argue that the Court lacks subject matter jurisdiction over plaintiff's claims because plaintiff seeks pre-enforcement review of an FDA enforcement action. Docket No. 64 at 5-6. "It has long been established that courts lack jurisdiction to enjoin FDA from initiating enforcement proceedings under the FDCA." *Cody Labs., Inc. v. Sebelius*, 2010 WL 3119279, at *8 (D. Wyo. July 26, 2010) (citation omitted).

The APA, on which plaintiff bases subject matter jurisdiction, provides that "[a]gency action[s] made reviewable by statute and final agency action[s] for which there is no other adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704. "A preliminary, procedural, or intermediate agency action or ruling not directly

reviewable is subject to review on the review of the final agency action." *Id.* Plaintiff "[has] the burden of identifying specific federal conduct and explaining how it is 'final agency action.'" *Colo. Farm Bureau Fed'n v. U.S. Forest Serv.*, 220 F.3d 1171, 1173 (10th Cir. 2000) (quotation omitted).

In arguing that the Court lacks subject matter jurisdiction over this case, the federal defendants rely upon *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). In *Ewing*, a distributor of nutritional supplements challenged the seizure by the FDA of its product under 21 U.S.C. § 334(a), which permitted seizures of misbranded articles where there was probable cause to believe that the misbranded article was dangerous to public health or that the labeling of the article was fraudulent. *Id.* at 595, 597.[4] The statute permitted such seizures "when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or customer." *Id.* at 595-96 (quoting 21 U.S.C. § 334(a)). The Supreme Court held that the district court "had no jurisdiction to review the administrative determination of probable cause." *Id.* at 600. Specifically, the Supreme Court stated that "[j]udicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]." *Id.* The *Ewing* Court noted that "Congress made numerous administrative

[4] The Attorney General had also instituted eleven "libel suits" against the distributor based on the FDA's finding of probable cause, which the distributor also challenged. *Id.* at 596-99.

determinations under the [FDCA] reviewable by the courts," but the administrative finding of probable cause was not one of them. *Id.*

In arguing that it seeks not pre-enforcement review, but review of a final agency action, plaintiff relies upon *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). In *Abbott*, the Supreme Court noted that, while *Ewing* was "quite clearly correct," it did not govern the case before it – a declaratory judgment action challenging an administrative regulation that had already been promulgated. *Id.* at 147. Specifically, the Supreme Court found that *Ewing* "bears no analogy to the promulgation, after formal procedures, of a rule that must be followed by an entire industry" and that to find otherwise "would immunize nearly all agency rulemaking activities from the coverage of the Administrative Procedure Act." *Id.* "[O]nly upon a showing of clear and convincing evidence of a contrary legislative intent should the courts restrict access to judicial review." *Id.* at 141 (quotations omitted). Plaintiff argues that its lawsuit is a challenge to a final FDA rule and, for this reason, *Ewing* does not apply. Docket No. 78 at 3.

The Supreme Court has stated that, for an agency action to be considered "final," two conditions must be satisfied: "[f]irst, the action must mark the 'consummation' of the agency's decision making process," and "second, the action must be one by which 'rights or obligations have been determined, or from which legal consequences will flow.'" *Bennett*, 520 U.S. at 178 (quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948) and *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). A final agency

action must "determine rights or obligations, or produce legal consequences." *Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 714 (D.C. Cir. 2015). "In litigation over guidance documents, the finality inquiry is often framed as the question of whether the challenged agency action is best understood as a non-binding action, like a policy statement or interpretive rule, or a binding legislative rule." *Id.* at 716. A policy statement "explains how the agency will enforce a statute or regulation – in other words, how it will exercise its broad enforcement discretion . . . under some extant statute or rule," *id.* (internal quotation marks omitted), while an interpretive rule is "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Id.* (quoting *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015)). A legislative rule "'modifies or adds to a legal norm based on the agency's own authority' flowing from a congressional delegation to engage in supplementary lawmaking." *Id.* at 717 (emphasis omitted) (quoting *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997)). "The most important factor in differentiating between binding and nonbinding actions is 'the actual legal effect (or lack thereof) of the agency action in question.'" *Id.* (quoting *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014)).

Plaintiff alleges that "the FDA has taken final agency action by promulgating [the CPG] and is enforcing that rule through a shadow regulation scheme to disguise their role in the actions taken against the Plaintiff." Docket No. 78 at 3. Specifically, it argues that the FDA's action marks the consummation of its decision-making process because (1) the FDA took a definitive legal position regarding its statutory authority;

(2) the CPG concerns a legal question of statutory interpretation; and (3) the CPG "burdens the Plaintiff directly because of how the FDA engages [in] this type of shadow regulation." *Id.* at 6-7 (citing *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 489 (D. Md. 2019)).

The Court finds that the CPG is not a final agency action. On its face, this policy guide simply provides information to staff members concerning how to interpret 21 U.S.C. § 342 for the purpose of determining whether further administrative proceedings are necessary. The CPG provides that FDA employees "should consider the following risk-based criteria *in deciding whether to recommend seizure or import refusal of a pet food, animal feed, or their ingredients*." Docket No. 64-1 at 7 (emphasis added). The Tenth Circuit has "specifically held that an agency action is not final – and thus not reviewable – if it serves to 'initiate further proceedings' necessary for a final determination of the parties' rights." *Potash Ass'n of N. M. v. U.S. Dep't of Interior*, 367 F. App'x 960, 964 (10th Cir. 2010) (unpublished). While plaintiff argues that the contents of the guidance, not the agency's label, dictates "whether statutory notice-and-comment demands apply," *see* Docket No. 78 at 5 (quoting *Azar v. Allina Health Servs.*,139 S. Ct. 1804, 1812 (2019)), the substance of the CPG provides guidance only and does not create any legal right. "[T]he FDA's guidance documents do not provide any legal basis from which the FDA can institute civil or criminal legal proceedings." *BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 975 (D. Ariz. 2009); *see also* 21 U.S.C. § 371(h)(1)(A) ("[G]uidance documents . . . shall not create or confer any rights for or on any person."). The FDA, moreover, derives no

enforcement authority from the CPG. *See* Docket No. 64-1 (the CPG). Instead, the FDA's enforcement power stems from 21 U.S.C. § 334. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 830 (1986) ("Congress has provided the FDA with a wide-ranging arsenal of weapons to combat violations of the FDCA, including authority to obtain an ex parte court order for the seizure of goods subject to the Act, *see* 21 U.S.C. § 334, authority to initiate proceedings in a federal district court to enjoin continuing violations of the FDCA, see § 332, and authority to request a United States Attorney to bring criminal proceedings against violators, see § 333.").

Plaintiff relies on its claim that the FDA has enforced the CPG through "public health warnings, punitive inspections, and through . . . the [CDA]." Docket No. 78 at 8. In particular, plaintiff states that, after plaintiff refused to conduct a voluntary recall of one of its products, "the FDA issued a Public Warning Notice for A+ ANSWERS™ Straight Beef Formula for Dogs stating [it] was doing so because the product represents a serious threat to human and animal health and is adulterated under the [FDCA]." Docket No. 1 at 25, ¶ 90.[5] Moreover, it alleges that, "pursuant to an interagency agreement(s) between Colorado and the FDA and the FDA's call to the states for sampling of raw products, an inspector working for the Colorado Department of Agriculture collected a sample of raw pet food manufactured by the Plaintiff [from] a pet store located in Littleton, CO." *Id.* at 26, ¶ 93.

However, "[c]ourts have consistently held . . . that the issuance of a warning

[5] Plaintiff alleges that this action was based upon a sample of its pet food taken by the state of Nebraska. *Id.* at 25, ¶ 90.

letter by FDA does not constitute final agency action ripe for judicial review." *Cody Labs.*, 2010 WL 3119279, at *11; *see also Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983) ("[T]he type of informal letter issued by the FDA . . . does not constitute the kind of formal or final agency action the Supreme Court had in mind.") (citation omitted). At best, the issuance of a warning letter "indicate[s] a readiness on the part of the FDA to initiate enforcement procedures." *Biotics*, 710 F.2d at 1378. Such an action, however, "do[es] not commit the FDA to enforcement action." *Id.*

Moreover, to the extent that plaintiff alleges that the CDA's prosecution of plaintiff is a thinly-veiled enforcement attempt by the FDA, this argument is without merit. Plaintiff claims that the CPG "is being enforced against the Plaintiffs through . . . punitive inspections[] and through the FDA's enforcement agent, the [CDA]." Docket No. 78 at 8. Plaintiff appears to argue that the CPG constitutes a final agency action because, according to plaintiff, other defendant entities are indirectly enforcing the CPG – which plaintiff refers to as "shadow regulation." *See* Docket No. 1 at 24, ¶ 87. For example, plaintiff claims that "the FDA – through AAFCO, compels state regulatory agencies to enforce [its guidelines] in exchange for a piece of roughly $11,100,000.00 in FDA funding," *id.* at 13, ¶ 39, and that the "CDA . . . funded by the FDA, pulled Plaintiff's products from the shelves of one of its Colorado retail stores selling Plaintiff's products." *Id.* at 11, ¶ 33.

The Court finds that plaintiff has failed to sufficiently plead facts to plausibly support its "shadow regulation" allegations. For example, while plaintiff claims that "the

FDA enlisted the CDA to pull product from shelves to be tested by [its] state laboratory and slandered the Plaintiff's products," the example it gives of such action is conduct performed by the state of Nebraska, not the CDA or AAFCO. *See* Docket No. 1 at 24-25, ¶ 89. Further, while plaintiff alleges that "[t]he FDA, through the CDA has chosen to prosecute Plaintiff," *see* Docket No. 1 at 15, ¶ 47, plaintiff fails to allege in its complaint any facts supporting its claim that the CDA's state prosecution of plaintiff was at the behest of the FDA or was a condition to the CDA receiving federal funding. *See generally* Docket No. 1. A complaint must allege enough factual matter that, taken as true, makes the plaintiff's "claim to relief . . . plausible on its face." *Khalik v. United Air Lines*, 671 F.3d 1188, 1190 (10th Cir. 2012) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but has not shown – that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). "[A] court need not accept conclusory allegations." *McGettigan v. Di Mare*, 173 F. Supp. 3d 1114, 1121 (D. Colo. 2016) (citing *Moffett v. Halliburton Energy Servs., Inc.*, 291 F.3d 1227, 1232 (10th Cir. 2002)).

Even if plaintiff had set forth sufficient facts to plausibly support the existence of "shadow regulation," the FDA's alleged act – through itself or through another entity – of either collecting or inducing another entity to collect samples from plaintiff's pet food does not allege final agency action. The initiation of an investigation does "not consummate the type of decisionmaking process envisioned by the Supreme Court in *Abbott Laboratories* and *Standard Oil* as final agency action." *Mobil Expl. & Producing*

U.S., Inc. v. Dep't of Interior, 180 F.3d 1192, 1198 (10th Cir. 1999). Various courts have held that investigatory processes similar to those at issue here are not final agency actions. *See id.* (collecting cases). In sum, plaintiff has failed to allege specific actions taken by the FDA that would constitute the "consummation" of the agency's decision-making process. The Court finds that plaintiff's allegations do not "identify[] specific federal conduct and explain[] how it is 'final agency action.'" *Colo. Farm Bureau*, 220 F.3d at 1173. Because plaintiff seeks review of a non-final agency action, the Court does not have subject matter jurisdiction over plaintiff's claims against the federal defendants. As a result, the Court will grant the federal defendants' motion to dismiss.[6]

B. State Defendants and the AAFCO

The state defendants argue that the Court does not have subject matter jurisdiction over plaintiff's claims against them because plaintiff's claims do not arise under federal law. Docket No. 63 at 6. The AAFCO has joined in the state defendants' argument. Docket No. 65 at 1 n.2. Specifically, they argue that the APA cannot be

[6] Even if the Court had jurisdiction to consider plaintiff's challenge to the CPG, its request for injunctive relief is improper. Plaintiff asks the Court to enjoin the FDA from conducting an enforcement action in this matter and to "suspend any pending related enforcement actions specific to the application of [the CPG]." Docket No. 1 at 34. "[T]he law is well-settled that the district courts lack jurisdiction to enjoin enforcement proceedings brought pursuant to the FDCA." *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 882 (N.D. Ill. 2003). In essence, plaintiff's lawsuit is an attempt to test its defense – that *Salmonella* is a naturally occurring substance that cannot render its pet food adulterated – at the pre-enforcement stages. But "[w]hether an enforcement action is simply contemplated or has already been filed, those subject to enforcement action may not file an anticipatory challenge; they must raise any defenses they have in the enforcement action itself." *Cody Labs*., 2010 WL 3119279, at *8.

used to review state agency decisions and that the APA does not create a private cause of action against state agencies. Docket No. 63 at 6. Plaintiff responds that its claims arise under federal law because the state entities have consented to be sued in federal court. Docket No. 79 at 5-6.

The APA provides for judicial review of "[a]gency action[s] made reviewable by statute and final agency action[s] for which there is no other adequate remedy in a court." 5 U.S.C. § 704. "Agency" is defined as "each authority of the Government of the United States, whether or not it is within or subject to review by another agency." 5 U.S.C. § 701(b)(1). As such, "the APA does not apply to state agencies" and an entity intending to challenge a state agency action "must seek relief under the state administrative procedures act." *Felmlee v. Oklahoma*, 2014 WL 5592399, at *2 (N.D. Okla. Nov. 3, 2014), *aff'd*, 620 F. App'x 648, 652-53 (10th Cir. 2015) (unpublished) (finding that plaintiff "ha[d] not alleged any cognizable . . . APA claim against" the state-agency and state-employee defendants); *see also Town of Portsmouth v. Lewis*, 813 F.3d 54, 64 (1st Cir. 2016) (stating that the APA "only provides for review of federal agency action" and "does not provide a right of action against a state agency.").

Plaintiff cites *Zeppelin v. Federal Highway Administration*, 293 F. Supp. 3d 1267 (D. Colo. 2017), and *Ross v. Federal Highway Administration*, 162 F.3d 1046 (10th Cir. 1998), arguing that "state agencies are subject to the APA when they consent to be the vehicle of a Federal agency's action." Docket No. 79 at 5. The Court finds these cases inapplicable here. In *Ross*, the Tenth Circuit determined that a state's highway construction project was a "major federal action" requiring state compliance with the

National Environmental Policy Act ("NEPA") where the state received federal funding and in which federal participation was lengthy. 163 F.3d at 1053. The court noted that "[t]he state of Kansas and Douglas County chose to develop this trafficway in conjunction with the federal government as a federal-aid highway project and proceeded in that manner for more than ten years before attempting to 'defederalize' a portion of the project." *Id.* at 1055. The court affirmed the district court's injunction against the state agency from taking further action on the project without conducting further environmental review. *Id.* at 1050, 1055.

The issue in *Zeppelin* – also a NEPA case – was whether the court could enjoin the Colorado Department of Transportation ("CDOT") from sending money to the City of Denver to assist it in rebuilding a highway. 293 F. Supp. 3d at 1270, 1283. Relying on *Ross*, the court determined that it had the authority to enjoin the non-federal entity on the basis that CDOT had consented to the court's jurisdiction, "given CDOT's thorough, long-standing, and active consent to federal involvement, and its request for federal funds." *Id.* at 1285. "CDOT therefore has effectively conceded that it must obey the dictates of this Court with respect to NEPA and the APA." *Id.*

The Court is unpersuaded by plaintiff's reliance on *Ross* and *Zeppelin*. Both cases involved judicial review under NEPA, and no court has adopted plaintiff's theory outside of this context. Plaintiff has made no argument explaining why the Court should expand the holdings in these cases to permit judicial review of a state agency action outside of the NEPA context. Moreover, even if the Court were to follow *Zeppelin*'s analysis, plaintiff has not demonstrated that the CDA has sufficient federal

connections to render it subject to the Court's jurisdiction. In *Zeppelin*, the court concluded that, "in the Tenth Circuit[,] a non-federal entity may be enjoined in an APA case under a consent theory – the state or local government took federal money and participated in a federal process, so it may fairly be subjected to federal requirements – but such consent is not in all cases irrevocable." 293 F. Supp. 2d at 1284. The court compared two cases – *Ross*, in which "federal involvement [in the state agency action] was pervasive and long-standing," and *Village of Los Ranchos de Albuquerque v. Barnhart*, 906 F.3d 1477 (10th Cir. 1990), where "there was comparatively little federal involvement (although the municipality certainly took federal money)." *Id.* "Somewhere in between those two poles, a non-federal entity's participation with the federal government becomes irrevocable consent to federal statutory requirements, such as NEPA, which is enforceable through the APA." *Id.*

The Court finds that plaintiff's allegations are insufficient to find consent to federal statutory requirements. Plaintiff alleges that the "AAFCO and its state government members, at the behest of the FDA, using FDA monies and directives, . . . acted in concert and/or coordination with the FDA to sample and debase Plaintiff's products . . . within the State of Colorado." Docket No. 1 at 11, ¶ 31. Plaintiff asserts that the CDA "is an active participating member of AAFCO who – funded by the FDA, pulled Plaintiff's products from the shelves of one of its Colorado retail stores . . . after what is believed will be proved the CDA's mishandling Plaintiff's products." *Id.*, ¶ 33; *see also id.* at 24, ¶ 89. Additional allegations include plaintiff's statement that, "[a]rmed with their policy guidance and cooperating states that adopt AAFCO's very

different definition of adulteration, the FDA attempts to compel Plaintiff to recall its products, to justify [its] public shaming of Plaintiff for allegedly distributing adulterated foods, and to conduct frequent punitive inspections of the Plaintiff's manufacturing and other operational facilities," *id.* at 14-15, ¶ 44, and that the FDA "is actually using AAFCO and participating member states to apply a zero-tolerance *Salmonella* standard to raw pet food" and that the FDA, "through its regulating State agency . . . threatens criminal and/or monetary punitive action" when manufacturers refuse to comply with its recall requests. *Id.* at 24, ¶¶ 86-87. Finally, plaintiff contends that, "pursuant to an interagency agreement(s) between Colorado and the FDA . . ., an inspector working for the [CDA] collected a sample of raw pet food manufactured by the Plaintiff," *id.* at 26, ¶ 93, – a decision plaintiff alleges was "orchestrated and directed by the FDA and its agent AAFCO." *Id.* at 27, ¶ 98. Plaintiff asserts that the CDA's prosecution of plaintiff comes "at the direction of the FDA." *Id.* at 29, ¶ 103.

These allegations are insufficient for the Court to find that it has subject matter jurisdiction over the state entities in this case. Plaintiff alleges that the CDA, in prosecuting plaintiff, is acting at the behest of the FDA. *See id.* But plaintiff alleges no facts supporting this allegation, and the Court need not accept conclusory allegations. *See Hackford v. Babbitt*, 14 F.3d 1457, 1465 (10th Cir. 1994) (stating that the court is "not bound by conclusory allegations, unwarranted inferences, or legal conclusions"). And while the state defendants admit that the CDA "receives some federal funding for its optional compliance with the [Animal Feed Regulatory Program Standards]," Docket No. 90 at 3, the receipt of federal funding does not provide the Court subject matter

jurisdiction over state agencies under the APA. *See Merryfield v. Disability Rights Ctr. of Kan.*, 439 F. App'x 677, 679 (10th Cir. 2011) (unpublished) (holding that the receipt of federal funds does not render a state agency a federal agency for APA purposes). The Court finds that plaintiff has failed to meet its burden of demonstrating that the Court has subject matter jurisdiction over the claims against the state defendants. *See Merida Delgado*, 428 F.3d at 919 ("[T]he party invoking federal jurisdiction bears the burden of proof.").[7]

C. Motions for Jurisdictional Discovery

Plaintiff has also filed two motions for discovery in aid of jurisdiction. Docket No. 62; Docket No. 70. In its first motion, plaintiff states that it "desires not only to produce 2,600 documents [it] believe[s] firmly establish the proof of final agency action but also to get the un-redacted versions thereof directly from the Defendants themselves." Docket No. 62 at 8, ¶ 19. In its second motion, plaintiff requests leave to depose Scott Ziehr, the co-administrator of the CDA's Feed Program. Docket No. 70 at 3, ¶ 2. It argues that deposing Mr. Ziehr "would clear up the factual dispute about whether or not [the Court] has jurisdiction to hear the Plaintiff's complaint," *id.*, because it would reveal

[7]The AAFCO has filed a motion to dismiss based on a lack of personal jurisdiction and for failure to state a claim. *See* Docket No. 65. The APA does not permit actions against private parties. *See Midland Farms, LLC v. U.S. Dept. of Agric.*, 35 F. Supp. 3d 1056, 1062 (D.S.D. 2014) ("The APA is not an independent source of jurisdiction, . . . nor does it provide a private right of action against a private party.") (citations omitted); *Window Sys., Inc. v. Manchester Mem'l Hosp.*, 424 F. Supp. 331, 336 (D. Conn. 1976) ("[T]he APA is not applicable to suits between private parties."). Accordingly, the Court finds that it lacks subject matter jurisdiction over this case to the extent that plaintiff raises claims against the AAFCO. Accordingly, Court does not reach the AAFCO's arguments and will deny its motion as moot.

"the Federalization of the CDA and its prosecution of the Plaintiff." *Id.* at 8, ¶ 23.

"When a defendant moves to dismiss for lack of jurisdiction, either party should be allowed discovery on the factual issues raised by that motion." *Sizova v. Nat'l Inst. of Standards & Tech.*, 282 F.3d 1320, 1326 (10th Cir. 2002) (citation omitted). "In determining whether to allow jurisdiction discovery[,] however, the trial court 'is vested with broad discretion.'" *Grynberg v. Ivanhoe Energy, Inc.*, 666 F. Supp. 2d 1218, 1227 (D. Colo. 2009) (quotation omitted). An abuse of discretion occurs upon the denial of jurisdictional discovery "if the denial results in prejudice to a litigant." *Sizova*, 282 F.3d at 1326. "Prejudice is present where pertinent facts bearing on the question of jurisdiction are controverted . . . or where a more satisfactory showing of the facts is necessary." *Id.* (quotation and citation omitted). A district court will not abuse its discretion in denying a request for jurisdictional discovery where there is a "very low probability that the lack of discovery affected the outcome of th[e] case." *Magpul Indus., Corp. v. Blue Force Gear, Inc.*, No. 14-cv-01470-RBJ, 2014 WL 6845851, at *2 (D. Colo. Dec. 4, 2014) (quoting *Bell Helicopter Textron, Inc. v. Heliqwest Int'l, Ltd.*, 385 F.3d 1291, 1299 (10th Cir. 2004)).

Plaintiff has failed to present a sufficient factual predicate to support its argument that subject matter jurisdiction can be established through additional discovery. In its first motion, plaintiff seeks leave to serve an interrogatory and request for production on defendant, seeking the identification of "ALL documents . . . reflecting in any way communication by and among the Defendants, their agents, employees, or the like – or any combination thereof, regarding Plaintiff, its products, and/or any

officer, employee, or agent thereof." Docket No. 62-1 at 18. Plaintiff also seeks the production of "[a]ll documents identified above." *Id.* Plaintiff argues that it "merely seeks the materials demonstrating[,] [] unquestionably, the cooperation by and among defendants to enforce this 'non-binding' policy against Plaintiff with impunity, throughout the country, and with significant deleterious effects to Plaintiff and others in its industry." Docket No. 62 at 11, ¶ 29. But plaintiff raises no allegations of facts or evidence that it believes its wide-reaching discovery request would reveal. *See* Docket No. 62; *see also First Magnus Fin. Corp. v. Star Equity Funding*, 2007 WL 635312, at *10 (D. Kan. Feb. 27, 2007) (denying jurisdictional discovery where plaintiff "ha[d] not stated any facts that it believe[d] jurisdictional discovery would likely reveal"). A party "may not use discovery as a fishing expedition." *Anthony v. United States*, 667 F.2d 870, 880 (10th Cir. 1981).

Further, plaintiff has not argued in its first discovery motion that it is prejudiced by the denial of jurisdictional discovery. *See* Docket No. 62. Plaintiff states that "prejudice occurs where – as herein: 'pertinent facts bearing on the question of jurisdiction are controverted,'" Docket No. 62 at 7-8, ¶ 18 (quoting *Sizova*, 282 F.3d at 1326), but sets forth no argument demonstrating facts in dispute that would render the denial of additional discovery prejudicial. Instead, plaintiff states that it is in possession of "2,600 documents [that] firmly establish the proof of a final agency action." *Id.* at 8, ¶ 19. If, as plaintiff contends, the documents in its possession "firmly establish" a final agency action, it is unclear to the Court why additional discovery is necessary to establish the Court's subject matter jurisdiction or how plaintiff could be prejudiced by

the denial of additional discovery. As such, plaintiff has failed to demonstrate that it is entitled to additional jurisdictional discovery.

In its second motion, plaintiff seeks to depose Mr. Ziehr on the basis that such deposition will uncover the fact that the FDA, CDA, and AAFCO have worked in concert to enforce the CPG. *See, e.g.*, Docket No. 70 at 8, ¶¶ 23-24. However, plaintiff violated the Local Rules by failing to confer with defendants before filing this second motion in aid of jurisdictional discovery. "Before filing a motion, counsel for the moving party . . . shall confer or make reasonable good faith efforts to confer with any opposing counsel or unrepresented party to resolve any disputed matter. The moving party shall describe in the motion, or in a certificate attached to the motion, the specific efforts to fulfill this duty." D.C.COLO.LCivR 7.1(a). This rule "mandates that the Court not consider any motion, other than a motion under Fed. R. Civ. P. 12 or 56, unless" counsel has conferred with the opposing party. *Ballard v. Tritos, Inc.*, No. 10-cv-02757-PAB-KMT, 2010 WL 5559544, at *1 (D. Colo. Dec. 30, 2010).

Even if plaintiff had complied with the Local Rules, its motion for additional jurisdictional discovery is without merit. Plaintiff argues that "[t]wo new important facts . . . were drawn out [from] two [CDA] employees during depositions for the State prosecution that indicate that the Defendants' denials of concerted action between the FDA, AAFCO, and the [CDA] are false." Docket No. 70 at 4, ¶ 5. Specifically, plaintiff states that a CDA employee testified that the CDA's biochemistry lab receives federal funding from the FDA that is contingent on following the FDA and AAFCO's Animal Feed Regulatory Program Standards. *Id.*, ¶ 7. Further, plaintiff claims that a CDA

inspector who took the sample of plaintiff's pet food testified that Mr. Ziehr told him to inspect plaintiff's food "because of a 'recall,'" but there was no recall of plaintiff's pet food at the time of the sampling. *Id.* at 5, ¶ 10-11.[8] Plaintiff asserts that this was a "cover-up [of] Federal involvement in the request." *Id.* at 3, ¶ 13. Plaintiff seeks to depose Mr. Ziehr "to obtain facts regarding the Federalization of the CDA and its prosecution of the Plaintiff." *Id.* at 8, ¶ 23.

Plaintiff provides no support, beyond its bare allegations, that Mr. Ziehr's directive to the CDA inspector to sample plaintiff's pet food was at the behest of the FDA. This is insufficient to demonstrate that additional jurisdictional discovery is warranted. *See First Magnus Fin. Corp.*, 2007 WL 635312, at *10 (jurisdictional discovery not required when movant has not stated any facts it believes jurisdictional discovery will reveal). Given the Court's noted deficiencies in plaintiff's complaint – i.e., the lack of plausible allegations that the state prosecution was initiated at the directive of the FDA – additional discovery would not change the Court's conclusion that it lacks subject matter jurisdiction over this case. The Court will deny plaintiff's second motion for jurisdictional discovery. *See Bell Helicopter*, 385 F.3d at 1298-99 (holding that the district court did not abuse its discretion in denying jurisdictional discovery where there was a "very low probability that the lack of discovery affected the outcome of the case").

D. Motion to Amend the Complaint

On November 12, 2019, plaintiff filed Plaintiff's Application for a Temporary

[8]Plaintiff does not provide the Court with the transcripts from these depositions. *See* Docket No. 70.

Restraining Order and/or Preliminary Injunction [Docket No. 104]. Plaintiff sought either a temporary restraining order or a preliminary injunction (1) "[r]equiring [d]efendants to comply with Section 10 of [the Federal Advisory Committee Act ("FACA")] – opening their meetings and committees to the public"; and (2) "[r]equiring [d]efendants to comply with the non-discretionary duties of Section 5 of FACA to ensure fair, balanced, and equal representation of ALL pet food manufacturers and their positions, including, but not limited to, natural pet food manufacturers and their trade groups." Docket No. 104 at 14. The Court denied the motion on November 14, 2019. Docket No. 105. The Court's denial was based on the fact that plaintiff's complaint did not raise a claim under FACA and "contain[ed] no allegations relevant to the relief plaintiff [sought] in its injunctive relief motion." *Id.* at 3; *see also Alley v. Aurora Loan Servs. LLC*, No. 10-cv-02163-REB-CBS, 2011 WL 3799035, at *14 (D. Colo. July 21, 2011), *report and recommendation adopted by* 2011 WL 3799585 ("[T]o obtain preliminary injunctive relief, the moving party bears the burden of establishing, a[m]ong other elements, that he or she has a likelihood of success on the merits *of the underlying claims*." (emphasis added)) (citation omitted). The Court also rejected plaintiff's request to "graft" its new allegations into its complaint, noting that plaintiff had failed to file a motion to amend its complaint under Rule 15 of the Federal Rules of Civil Procedure and could not move for amendment in its motion for injunctive relief. Docket No. 105 at 5.

On November 15, 2019, plaintiff filed Plaintiff's Motion to Amend Complaint Solely to Incorporate Claims Under Federal Advisory Committee Act (("FACA"), 5

U.S.C. app. 2 §§ 1-16) [Docket No. 106]. Plaintiff asserts that it "has revised its operative Complaint herein to include its claims for FACA which only first accrued on November 5, 2019." Docket No. 106 at 3, ¶ 8. Plaintiff asserts that its amendment will not prejudice defendant or delay these proceedings because it "intentionally avoided" making any changes to the complaint "other than inserting its claims under FACA," so that the amendment will "not disturb and/or otherwise derail the Court's considerations of the motions to dismiss." *Id.*, ¶ 11.

"Rule 15(a) provides that leave to amend 'shall be freely given when justice so requires.'" *Frank v. U.S. West*, 3 F.3d 1357, 1365 (10th Cir. 1993). "The liberal granting of motions for leave to amend reflects the basic policy that pleadings should enable a claim to be heard on its merits." *Calderon v. Kansas Dep't of Soc. and Rehab. Servs.*, 181 F.3d 1180, 1186 (10th Cir. 1999); *see also Minter v. Prime Equip. Co.*, 451 F.3d 1196, 1204 (10th Cir. 2006) ("The purpose of the rule is to provide litigants 'the maximum opportunity for each claim to be decided on its merits rather than on procedural niceties.'" (citation omitted)).

The Court has discretion to grant a party leave to amend its pleadings. *Foman v. Davis*, 371 U.S. 178, 182 (1962). "Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment." *Frank*, 3 F.3d at 1365 (citation omitted). "The non-moving party bears the burden of showing that the proposed amendment is sought in bad faith, that it is futile, or that it would cause substantial prejudice, undue delay or injustice." *Corp.*

Stock Transfer, Inc. v. AE Biofuels, Inc., 663 F. Supp. 2d 1056, 1061 (D. Colo. 2009) (citation omitted).

A court may also "on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). Courts apply the same standard when deciding whether to permit a party to supplement a pleading under Rule 15(d) as they do for amendment of a pleading under Rule 15(a)(2). *See Sw. Nurseries, LLC v. Florists Mut. Ins., Inc.*, 266 F. Supp. 2d 1253, 1256 (D. Colo. 2003).

The Court finds that the motion should be denied. First, unrelated to Rule 15(a)'s requirements, it does not appear that plaintiff adequately complied with D.C.COLO.LCivR 7.1(a), and may have misrepresented what happened in connection with the attempted conferral. Plaintiff states in its Rule 7.1(a) certification that it contacted defendants by e-mail and by sending them a redlined version of the proposed supplemental complaint, and that "Defendants remained mute." Docket No. 106 at 1-2, ¶¶ 1-3. AAFCO asserts, however, that all three defendants emailed plaintiff's counsel the day before the motion was filed to oppose the amendment, and that paintiff therefore "blatantly misrepresented the facts." Docket No. 114 at 1-2; *see also* Docket No. 110 at 1 (stating that "counsel for the Federal Defendants responded to Plaintiff's counsel's first email within a few hours, opposing amendment of the complaint"). The federal defendants also state that, fewer than twenty-four hours after plaintiff's counsel sent a redlined version of the proposed complaint to defendants, and before counsel had an opportunity to consider the proposed amendment and to consult

with their client, plaintiff's counsel filed the motion to amend. Docket No. 110 at 1. The Court finds that plaintiff's counsel merely informed defendants that plaintiff planned to file a motion, and there is no indication that any actual conferral took place. This violates the requirements of Rule 7.1(a) that the "the parties must hold a conference, possibly through the exchange of correspondence but preferably through person-to-person telephone calls or face-to-face meetings, and must compare views and attempt to reach an agreement, including by compromise if appropriate." *Hoelzel v. First Select Corp.*, 214 F.R.D. 634, 636 (D. Colo. 2003) (quotations omitted). The motion to amend is thus subject to denial for plaintiff's violation of Rule 7.1(a).

Moreover, the Court finds that, notwithstanding plaintiff's Local Rule violation, its motion should be denied on the merits. "The principal factors which are considered in connection with the offer of an amendment are, first, whether it will cause delay and, second, whether the adversary will suffer prejudice." *R.E.B. Inc. v. Ralston Purina Co.*, 525 F.2d 749, 752 (10th Cir. 1975). The Court finds that the proposed supplement to add the FACA claim will cause both delay and prejudice, and will also impact efficiency and judicial economy.

The FACA claim is distinct from and unrelated to the APA claim asserted in the original complaint. *See* Docket No. 1. Indeed, in denying the TRO motion, the Court stated that the motion for a temporary restraining order, Docket No. 104, "is not reasonably related to, and seeks relief that is wholly separate from, the relief sought in its complaint." Docket No. 105 at 4-5. The Court further noted plaintiff's acknowledgment of the fact "that the relief it now seeks is not of the same character as

the relief it seeks in its underlying complaint." *Id*. at 5. Courts have held that supplementation of a complaint should be denied when the new claim is unrelated to the initial action. *See Planned Parenthood of S. Ariz. v. Neely*, 130 F.3d 400, 402 (9th Cir. 1997); *Clervrain v. United States,* 2019 WL 130288, at *1 (D. Kan. Jan. 8, 2019); *see also Minter*, 451 F.3d at 1208 (stating that prejudice "occurs when the amended claims arise out of a subject matter different from what was set forth in the complaint and raise significant new factual issues"). The Court has, in this order, determined that it does not have subject matter jurisdiction over this case and has dismissed plaintiff's APA claims. To allow the plaintiff to add wholly unrelated claims to its complaint at this point in the proceedings would be unduly prejudicial to defendants, who have each filed meritorious motions to dismiss for lack of subject matter jurisdiction. From the foregoing, the Court finds that allowing plaintiff to file a supplemental complaint adding the FACA claim would prejudice defendants and impact the interests of efficiency and judicial economy. Moreover, plaintiff does not explain why justice would be served by granting the amendment. Denial of the motion thus appears to be warranted. *See* 6A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 1506 at 271 (3d. ed. 2010) ("[W]hen the matters alleged in a supplemental pleading have no relation to the claim originally set forth and joinder will not promote judicial economy or the speedy disposition of the dispute between the parties, refusal to allow the supplemental pleading is entirely justified.").[9]

[9] As the Court has found that the motion to amend [Docket No. 106] should be denied on grounds of undue delay, prejudice, and the other factors discussed herein, it has not addressed the futility argument.

Because the Court finds that it lacks subject matter jurisdiction over plaintiff's claims, and finds that justice does not require amendment of plaintiff's claim, this matter will be dismissed in its entirety.

IV. CONCLUSION

Wherefore, it is

ORDERED that Federal Defendants' Motion to Dismiss [Docket No. 64] is **GRANTED**. It is further

ORDERED that State Defendants' Motion to Dismiss Plaintiff's Complaint Under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) [Docket No. 63] is **GRANTED**. It is further

ORDERED that Defendant Association of American Feed Control Officials' Motion to Dismiss [Docket No. 65] is **DENIED AS MOOT**. It is further

ORDERED that Plaintiff's Motion for Discovery in Aid of Jurisdiction [Docket No. 62] is **DENIED**. It is further

ORDERED that Plaintiff's Second Motion for Discovery in Aid of Jurisdiction [Docket No. 70] is **DENIED**. It is further

ORDERED that Plaintiff's Motion to Amend Complaint Solely to Incorporate Claims Under Federal Advisory Committee Act ((“FACA”), 5 U.S.C. app. 2 §§ 1-16) [Docket No. 106] is **DENIED**. It is further

ORDERED that Plaintiff's Combined Motion and Memorandum for Injunctive Relief Pursuant to F.R.C.P. 65(a)(2) [Docket No. 12] is **DENIED AS MOOT**. It is further

ORDERED that Next Generation Pet Food Manufacturers Association, Inc.'s

Motion to Intervene [Docket No. 86] is **DENIED AS MOOT**. It is further

ORDERED that Weston A. Price Foundation's Motion to Intervene [Docket No. 100] is **DENIED AS MOOT**. It is further

ORDERED that plaintiff's complaint is dismissed without prejudice.

ORDERED that this case is closed.

DATED September 14, 2020.

BY THE COURT:

PHILIP A. BRIMMER
Chief United States District Judge