FILED
United States Court of Appeals
Tenth Circuit

September 3, 2021

Christopher M. Wolpert
Clerk of Court

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

LYSTN, LLC, d/b/a Answers Pet Food,

Plaintiff - Appellant,

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; UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendants - Appellees.

No. 20-1369
(D.C. No. 1:19-CV-01943-PAB-KLM)
(D. Colo.)

ORDER AND JUDGMENT*

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* After examining the briefs and appellate record, this panel has determined unanimously that oral argument would not materially assist in the determination of this appeal. *See* Fed. R. App. P. 34(a)(2); 10th Cir. R. 34.1(G). The case is therefore ordered submitted without oral argument. This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. It may be cited, however, for its persuasive value consistent with Fed. R. App. P. 32.1 and 10th Cir. R. 32.1.

Before **TYMKOVICH**, Chief Judge, **KELLY**, and **HOLMES**, Circuit Judges.

Lystn, LLC, filed an action seeking review under the Administrative Procedure Act (APA). The district court dismissed the action for lack of subject matter jurisdiction, holding it lacked jurisdiction under 5 U.S.C. § 704 because Lystn's complaint failed to allege final agency action. The court subsequently denied in part and granted in part Lystn's motion to alter or amend the judgment and dismissed the action without prejudice. On appeal, Lystn challenges the district court's holding regarding final agency action and argues the court abused its discretion in denying jurisdictional discovery and in failing to allow Lystn to amend its complaint. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

I. Background

A. Lystn's Complaint[1]

Lystn manufactures and sells raw pet food that may contain certain microorganisms, including salmonella, that Lystn claims are naturally occurring and not harmful to humans. Lystn filed this action against the Food and Drug Administration and the Department of Health and Human Services (hereafter, the Federal Defendants); the Colorado Department of Agriculture (CDA) and several CDA employees (hereafter, the State Defendants); and the Association of American Feed Control Officials (AAFCO), which Lystn described as "a voluntary membership

[1] Our factual summary is derived from the allegations in Lystn's complaint.

association of local, state and federal agencies charged by law to regulate the sale and distribution of animal feeds," Aplt. App., Vol. 3 at 662 (internal quotation marks omitted). Lystn sought to challenge the FDA's alleged "nationwide zero-tolerance standard for *Salmonella* presence in pet food that is unsupported by science and ultra vires of powers properly delegated to it by Congress." *Id.*

Lystn based its claims on an FDA Compliance Policy Guide (CPG) titled "*Salmonella* in Food for Animals" issued in July 2013. *Id.* at 672; *see id.*, Vol. 2 at 409-15. The stated purpose of the CPG "is to provide guidance for FDA staff on the presence of *Salmonella* in food for animals." *Id.*, Vol. 2 at 411. 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))." *Id.* at 413. A food is "adulterated" under the FDCA "[i]f 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). The CPG recommends that FDA staff should consider the following risk-based criteria in deciding whether to recommend seizure or import refusal of a pet food or pet food ingredients on the basis of adulteration:

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 *Salmonella*.
>
> 3. The *Salmonella* is of any serotype.

Aplt. App., Vol. 2 at 414.

As acknowledged in Lystn's complaint, the CPG specifies that it contains only nonbinding recommendations. *See, e.g.*, *id.* at 411 (stating that "guidance documents . . . do not establish legally enforceable responsibilities" and "should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited"). The CPG also advises that "[y]ou can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance." *Id.* Lystn alleged that it "uses both a science and time proven alternative approach through fermentation[, technology,] and proprietary processes for protection of [its] products to a level that would not ordinarily render it injurious to health." *Id.*, Vol. 3 at 672.

Lystn further alleged that the CDA has adopted the CPG's definition of "adulteration," which is also similar to the definition in the AAFCO's Model Bill and Regulations. It contended that these definitions are at odds with 21 U.S.C. § 342's provision that a naturally occurring substance will not render a product adulterated unless the quantity of the substance is injurious to health.

In April 2018, a CDA inspector collected a sample of Lystn's pet food from a store in Colorado. Lystn alleged that the CDA mishandled this sample, which it then

tested for adulterants according to the CPG/AAFCO definition. The CDA concluded the sample contained an unspecified quantity of salmonella. The CDA is prosecuting Lystn in state proceedings based on this sample.

In January 2019, after Lystn refused to conduct a voluntary recall, the FDA issued a public warning notice stating that one of Lystn's products was adulterated under the FDCA and represented a serious threat to human and animal health. This public warning notice was based upon a product sample taken by the State of Nebraska, allegedly at the behest of the FDA. Lystn alleged that the public warning notice falsely stated that federal law requires all pet food to be free of pathogens, including salmonella.

B. Motions to Dismiss Lystn's Complaint

All defendants moved to dismiss Lystn's complaint on various grounds. As relevant to Lystn's appeal, the Federal Defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(1), arguing the complaint failed to allege final agency action subject to review under § 704 of the APA. Lystn asserted various theories in opposition, all of which the district court rejected. The court first held the FDA had not taken final agency action by promulgating the CPG, noting that "the substance of the CPG provides guidance only and does not create any legal right," and "[t]he FDA . . . derives no enforcement authority from the CPG." Aplt. App., Vol. 5 at 1142-43. The court also held Lystn's reliance on the FDA's public warning notice was misplaced, noting that cases have consistently held the issuance of a warning letter by the FDA does not constitute final agency action ripe for judicial review.

Lystn also asserted that the CPG constitutes final agency action because the FDA is enforcing it through a shadow regulation scheme involving the other defendant entities. The district court noted that Lystn had alleged that, through the AAFCO, the FDA compels states to enforce the CPG in exchange for federal funding; if a manufacturer denies a request by the FDA based upon its zero-tolerance salmonella policy, the FDA causes a state to threaten punitive action; the CDA has an interagency agreement with the FDA under which the FDA asked the CDA to sample Lystn's raw pet food products; and the CDA's prosecution of Lystn is a thinly veiled enforcement attempt by the FDA.

The district court held that Lystyn's "shadow regulation" allegations were conclusory and unsupported by facts. *Id.* at 1144. In particular, it concluded that Lystn "fail[ed] 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." *Id.* at 1145. Moreover, even assuming Lystn had plausibly pleaded that the FDA had induced another entity to collect samples of Lystn's products, the court held an alleged initiation of an investigation by the FDA was insufficient to constitute final agency action. The court therefore granted the Federal Defendants' motion to dismiss for lack of subject matter jurisdiction.[2]

[2] The district court also dismissed Lystn's claims against the State Defendants and AAFCO for lack of jurisdiction because the APA does not apply to state agencies or private parties. We do not address these rulings because Lystn does not challenge them in its opening brief. *See Tran v. Trs. of State Colls. in Colo.*, 355 F.3d 1263, 1266 (10th Cir. 2004) ("Issues not raised in the opening brief are deemed abandoned or waived." (internal quotation marks omitted)).

C. Lystn's Motions for Jurisdictional Discovery

The district court also denied Lystn's two motions for jurisdictional discovery. Its first motion sought leave to require the defendants to identify and produce "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." *Id.* at 1152-53 (ellipsis and internal quotation marks omitted). The district court denied this request because (1) Lystn "raise[d] no allegations of facts or evidence that it believes its wide-reaching discovery request would reveal," and (2) Lystn "ha[d] not argued . . . that it is prejudiced by the denial of jurisdictional discovery," and instead had stated that it possessed "2,600 documents that firmly establish the proof of a final agency action." *Id.* at 1153 (brackets and internal quotation marks omitted).

Lystn's second motion sought to depose defendant Scott Ziehr, a CDA employee, about the defendants working in concert to enforce the CPG. The district court denied this motion because Lystn failed to confer with defendants per the local court rules, and alternatively because Lystn "provide[d] 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." *Id.* at 1155.[3]

[3] The district court also denied Lystn's motion to amend its complaint to add a new claim, once again for failure to confer with defendants, and alternatively because Lystn's proposed additional claim was unrelated to its pending action. Lystn does not challenge this ruling on appeal.

D. Lystn's Rule 59(e) Motion

Lystn filed a motion to alter or amend the judgment under Federal Rule of Civil Procedure 59(e). The district court first addressed Lystn's failure, once again, to confer with the defendants before filing this motion. It rejected Lystn's contention that the duty to confer did not apply in this instance; it found that Lystn had misrepresented to the court its attempts to confer with defendants; and it credited the defendants' representations that Lystn had not, in fact, attempted to confer. The court noted that Lystn's violation of the local rule requiring conferral was a sufficient basis to deny the Rule 59(e) motion.

The court also held that Lystn's motion failed on the merits. Observing that Lystn had not identified the bases of its motion, the court construed it as raising four contentions. First, Lystn contended that two executive orders issued in October 2019 demonstrated that AAFCO's Animal Feed Regulatory Program Standards (AFRPS) "constitute a final agency action." *Id.* at 1124.[4] The court first held the executive orders were not unavailable when it issued its prior order and therefore were not new evidence. It also held the executive orders had no bearing on the court's prior order because Lystn "did not challenge the AFRPS as final agency action in its complaint."

[4] The AFRPS figure prominently in Lystn's arguments on appeal. In its opening brief, Lystn asserts that, in partnership with the AAFCO, the FDA "developed" the AFRPS, which are "designed to transform the animal feed regulatory programs of participating state agencies to be 'equivalent in effect' to the Federal animal feed regulations by paying AFRPS participating states to enact Federal guidelines (which are supposed to be non-binding and create no legal effect) as state regulations and then prosecute companies for violating those state regulations." Aplt. Opening Br. at 15.

Id. at 1124-25. Rather, Lystn "argued that the final agency action at issue was the FDA's [CPG] . . . [a]nd because the complaint focused solely on the CPG, so did the Court's order." *Id.* at 1125. The district court declined to allow Lystn to "make its complaint a moving target to salvage a lost case by untimely suggestion of new theories of recovery." *Id.* (internal quotation marks omitted).

Second, Lystn argued the district court had misapprehended certain facts it alleged regarding the FDA's enlistment of states to pull and test product samples. Lystn asserted that "this all started with the FDA's 2016 Warning Letter based on Plaintiff's product pulled off the shelf in Colorado in 2015." *Id.* (brackets and internal quotation marks omitted). But the district court held that, like the AFRPS, Lystn's "complaint makes no mention of a warning letter," *id.*, and given that the cited letter was issued in 2016, before Lystn filed its complaint, it could not be grounds for reconsideration based on new evidence.

Third, Lystn argued the district court erred in ruling its allegations of final agency action were conclusory without considering the "numerous documents" Lystn attached to its opposition to the motions to dismiss, which Lystn asserted "demonstrate[d], unquestionably, the allegations' actual truth." *Id.* at 1127 (brackets and internal quotation marks omitted). The court rejected this contention because the additional facts that Lystn asserted the court failed to consider related to Lystn's theory regarding "the FDA's enforcement of AFRPS," which, as the court had explained, "was not at issue in plaintiff's complaint, was not a subject of the Court's

order, and cannot be a basis to revisit the Court's order." *Id.* at 1127 (internal quotation marks omitted).

Finally, Lystn argued that the district court erred by dismissing the action with prejudice. The court agreed with that contention, granted the Rule 59(e) motion in part, and amended its final order to dismiss without prejudice.

II. Discussion

Under § 704 of the APA:

> Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.

5 U.S.C. § 704.

> As a general matter, two conditions must be satisfied for agency action to be final: First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (citation and internal quotation marks omitted). Under the APA, courts have jurisdiction to review only final agency actions. *Farrell-Cooper Mining Co. v. U.S. Dep't of Interior*, 864 F.3d 1105, 1109 (10th Cir. 2017).

Lystn raises the following issues on appeal:

> (1) The FDA took final agency action when it partnered with AAFCO to create the AFRPS to implement an unlawful policy preference for zero-tolerance for salmonella in raw pet food and paid participating states to enforce that unlawful policy through AFRPS with a goal of making state

> regulations equivalent in effect to Federal guidance, which resulted in a state prosecution of Lystn.
>
> (2) The FDA took final agency action when it sent a warning letter to Lystn where it found that Lystn violated the law, demanded corrective action, and then threatened Lystn with penalties for failing to take corrective action.
>
> (3) The district court abused its discretion by denying Lystn's request for jurisdictional discovery or a jurisdictional hearing when Lystn requested factual discovery to rebut the Defendants' factual allegations regarding jurisdiction.
>
> (4) The district court abused its discretion by denying Lystn's request for leave to amend its complaint to more fully allege final agency action.

Lystn does not "cite the precise references in the record where [these] issue[s] [were] raised and ruled on" by the district court, as required by Tenth Circuit Rule 28.1(A).[5] We construe Lystn's first two appeal issues as challenging the district court's denial of its Rule 59(e) motion. Its third issue asserts error in the district court's denial of its motions for jurisdictional discovery. Finally, Lystn's fourth contention addresses an issue that was not raised in or ruled on by the district court.

A. Denial of Rule 59(e) Motion

In its first two appeal issues, Lystn argues the FDA took final agency action by either (1) paying states to enforce its zero-tolerance policy on salmonella through the AFRPS, or (2) issuing a warning letter in 2016. The district court construed Lystn's

[5] In fact, Lystn includes no citation to the Appellant's Appendix in its opening brief. Much of Lystn's factual assertions are supported by no citations at all. And its frequent citations to a declaration by its attorney and exhibits thereto, as well as its (apparent) citations to exhibits to its opening brief—exhibits it failed to file with the court—do not satisfy the requirement to cite the appendix "by volume and page number." *See* 10th Cir. R. 28.1(A)(1).

Rule 59(e) motion as making these same arguments. Lystn now asks this court to rule on the merits of these issues in the first instance without acknowledging that the district court declined to do so in denying its motion.

We review the district court's denial of a Rule 59(e) motion for an abuse of discretion. *See Nelson v. City of Albuquerque*, 921 F.3d 925, 929 (10th Cir. 2019). Lystn fails to demonstrate any abuse of discretion. First, Lystn ignores the district court's initial finding that its violation of the local rule requiring conferral was a sufficient basis to deny its Rule 59(e) motion. Lystn also entirely fails to address the district court's holding that neither the AFRPS nor the FDA's 2016 warning letter provided a basis to revisit the court's prior order because Lystn did not assert the AFRPS or that warning letter as final agency action in its complaint.

As it did in its Rule 59(e) motion, Lystn argues that, in deciding whether its allegations were conclusory, the district court erred by failing to consider the documents it attached to its opposition to the motions to dismiss. *See* Aplt. Opening Br. at 30-32. The district court rejected this contention, holding these documents related to the FDA's alleged enforcement of AFRPS and were therefore untethered to the allegations in Lystn's complaint. Lystn's bald contentions of error on appeal fail to address the district court's reasoning.

To the extent Lystn argues its documents were relevant to the district court's jurisdictional analysis because the Federal Defendants' motion to dismiss "made factual challenges to jurisdiction," *id.* at 44, the record does not support that assertion. As the district court observed, a motion to dismiss for lack of jurisdiction

under Rule 12(b)(1) can either "(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." *Merrill Lynch Bus. Fin. Servs., Inc. v. Nudell*, 363 F.3d 1072, 1074 (10th Cir. 2004) (internal quotation marks omitted). Contrary to Lystn's unsupported assertion, the Federal Defendants' motion raised a facial attack on Lystn's complaint. It did not present any evidence; rather, it referenced the complaint's allegations, *see* Aplt. App., Vol. 4 at 959-73, and attached as an exhibit only a copy of the CPG, which the complaint cited at length.[6] The district court construed the Federal Defendants' motion as a facial attack and limited its analysis to the allegations in Lystn's complaint. Lystn does not demonstrate any error in that treatment.

Lystn raised its first two appeal issues in its Rule 59(e) motion. On appeal, it fails to show the district court abused its discretion in denying that motion.

B. Denial of Motions for Jurisdictional Discovery

We "review the district court's handling of jurisdictional discovery under an abuse-of-discretion standard." *Breakthrough Mgmt. Grp., Inc. v. Chukchansi Gold Casino & Resort*, 629 F.3d 1173, 1189 (10th Cir. 2010). Lystn argues the district

[6] Lystn failed to include Exhibit A to the Federal Defendants' motion to dismiss in the Appellant's Appendix.

court's failure to allow jurisdictional discovery prejudiced it. *See id.* ("We have held that a refusal to grant jurisdictional discovery constitutes an abuse of discretion if the denial results in prejudice to a litigant . . . ." (brackets and internal quotation marks omitted)).[7] But Lystn does not address the district court's bases for denying its discovery motions. It simply ignores the district court's finding that, not only had Lystn not argued prejudice in its first discovery motion, its stated possession of 2,600 documents firmly establishing final agency action demonstrated that Lystn would not be prejudiced. Lystn also makes no attempt to demonstrate the court abused its discretion in denying Lystn's request to depose a CDA employee because Lystn did not confer with defendants before filing the motion. Lystn has not shown any abuse of discretion in the district court's denial of jurisdictional discovery.

C. Failure to Allow Amendment of Lystn's Complaint

Lastly, Lystn argues the district court should have allowed it to amend its complaint to cure any jurisdictional defects. But it did not file a written motion asking for leave to do so, as required by Federal Rule of Civil Procedure 7(b)(1)(A). *See Garman v. Campbell Cnty. Sch. Dist. No. 1*, 630 F.3d 977, 986 (10th Cir. 2010) (applying Rule 7(b)(1)(A) to amendment of pleadings under Federal Rule of Civil Procedure 15(a)).[8] Lystn does not indicate how it believes it raised this issue in the

[7] Lystn also asserts the district court's failure to allow a jurisdictional hearing was prejudicial. But it fails to cite where in the record it sought such a hearing, and we conclude it made no such request.

[8] As previously noted, Lystn did move to amend its complaint to add a new claim—a motion the district court denied and an issue not pertinent to this appeal.

district court. Clearly, its statement at the conclusion of its Rule 59(e) motion asking the district court to "allow[] Plaintiff to amend its complaint consistent herewith," Aplt. App., Vol. 1 at 31, was insufficient to preserve the issue, *see Calderon v. Kan. Dep't of Soc. & Rehab. Servs.*, 181 F.3d 1180, 1185-87 (10th Cir. 1999). A court need not "address a motion never placed before it." *Calderon*, 181 F.3d at 1187. Accordingly, Lystn identifies no error by the district court.

III. Conclusion

We affirm the district court's judgment.

Entered for the Court

Timothy M. Tymkovich
Chief Judge