UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ARROW RELIANCE, INC., dba Darwin's Natural Pet Products,

Plaintiff,

v.

JANET WOODCOCK, United States Commissioner of Food and Drugs; and UNITED STATES FOOD AND DRUG ADMINISTRATION,

CASE NO. 22-1057

ORDER ON PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER

This matter comes before the Court on Plaintiff Arrow Reliance (dba Darwin's Natural Pet Products) ("Darwin's), Motion for a Temporary Restraining Order and Preliminary Injunction. (Dkt. No. 3.) Having reviewed the Motion, Defendant's Opposition (Dkt. No. 11), the declarations and supporting materials filed by the Parties, and having held oral argument on August 2, 2022, the Court DENIES the Motion.

BACKGROUND

Darwin's is a pet food manufacturing company that produces raw pet food containing USDA inspected meat and vegetables. (Declaration of Gary Tashjian ¶ 3 (Dkt. No. 4).) Darwin's sells and delivers the pet food directly to customers on a subscription basis. (Id. at ¶ 6.) Defendant is the U.S. Food and Drug Administration ("FDA"), which regulates pet food and is mandated to "protect the public health by ensuring that. . . foods are safe, wholesome, sanitary, and properly labeled. . ." (Pl Mot. at 6; Def. Opp. at 1.) The FDA derives its authority through the Federal Food, Drug, and Cosmetic Act ("FDCA"). See 21 U.S.C. § 301 et seq. In carrying out this mandate, the FDA is authorized to conduct investigations and examinations. Id. §§ 372(a)(1); 374. And the FDA has the authority to communicate information to the public, including the results of these investigations. Id. § 375(b).

Darwin's alleges that it has been the target of the FDA for its use of raw meat. Darwin's claims that the FDA has a "zero tolerance" standard when it comes to the presence of Salmonella in pet food, which it contends is in violation of 21 U.S.C. § 342(a)(1) and unnecessary given the science. (Pl. Mot. at 6-7.) Darwin's states there are over 2,500 different serotypes (or "strains") of Salmonella, only thirty-two (32) of which have ever been shown to cause human illness. (Pl. Mot. at 4.) In general, food contaminated with Salmonella is not "adulterated" (contaminated), unless the serotype is one that causes disease for the intended consumer, be it human or animal, and that it is present in a sufficient enough amount to pose a risk. (Id.)

In 2017 and 2018, the FDA claimed to have found Salmonella in Darwin's products. (Tashjian Decl. at ¶ 11.) In each instance, the FDA did not provide the company with samples so that the test results could be corroborated. (Id.) Darwin's contends that absent a sample to test, it has no way to determine whether the Salmonella present in its products is a serotype that can

cause harm and whether it is present in a sufficient enough quantity to render anyone or their pet sick. (Id.) After each instance where the FDA found Salmonella, it asked Darwin's to issue a recall and notify customers who received the products, or in the alternative, the FDA would issue its own statement. (Id. at ¶¶ 12, 15.) Darwin's objected, but ultimately complied each time with the FDA's requests and issued the statements and recalls. (Id.) Despite Darwin's compliance, the FDA nevertheless published a statement of the recall on its own website, where it was subsequently picked up by news outlets. (Id.) Darwin's alleges that after each instance, it saw a dramatic increase in cancelled subscriptions and a reduction in the number of new subscribers. (Id. at ¶¶ 14, 16.)

On July 22, 2022, the FDA again alerted Darwin's to the presence of Salmonella in one of its products. (Id. at ¶ 19.) A week later, on July 29, 2022, the FDA requested Darwin's issue a recall of the product and submit a press release. (Id. at ¶ 20.) The FDA informed Darwin's that if it did not issue the press release, the FDA would issue its own within 24 hours of the email. (Id.) In response, Darwin's brought this Motion to restrain the FDA from making any statement.

In bringing this suit, Darwin's alleges violations under the Administrative Procedures Act ("APA") and the First Amendment. First, Darwin's challenges the FDA's authority to make such a statement under the APA absent substantial evidence that the food is adulterated, or another violation of applicable law. (Pl. Mot. at 6.) Second, Darwin's claims that the FDA cannot issue a public statement without a finding of "imminent danger," which it did not do. (Id. at 9.) And finally, Darwin's asserts that the FDA's directive to Darwin's to issue a public statement constitutes compelled speech in violation of the First Amendment. (Id. at 17.)

ANALYSIS

A. The Matter is Not Ripe for Judicial Action

The FDA's main argument in response to Darwin's request for a temporary restraining order is that the Court lacks jurisdiction because the requirements that the issue be ripe and that there be "final agency action" are missing. (Def. Opp. at 4.) The Court agrees.

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" Lance v. Coffman, 549 U.S. 437, 439 (2007). "The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 538 U.S. 803, 808 (2003) (internal quotation marks omitted). The ripeness doctrine "is peticuliarly a question of timing," Reg'l Rail Reorg. Act Cases, 419 U.S. 102, 140, (1974), designed "to separate matters that are premature for review because the injury is speculative and may never occur from those cases that are appropriate for federal court action," Portman v. County of Santa Clara, 995 F.2d 898, 902 (9th Cir.1993) (internal quotation marks omitted). "[T]hrough avoidance of premature adjudication," the ripeness doctrine prevents courts from becoming entangled in "abstract disagreements." Abbott Labs. v. Gardner, 387 U.S. 136, 148 (1967), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99 (1977).

1. Constitutional Ripeness

Ripeness has two components: constitutional ripeness and prudential ripeness. Thomas v. Anchorage Equal Rights Comm'n, 220 F.3d 1134, 1138 (9th Cir.2000) (en banc). "The constitutional ripeness of a declaratory judgment action depends upon 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a

declaratory judgment.'" United States v. Braren, 338 F.3d 971, 975 (9th Cir.2003) (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)). The issues and injury presented must be "definite and concrete, not hypothetical or abstract." Thomas, 220 F.3d at 1139 (internal quotation marks omitted). "The constitutional component of ripeness is a jurisdictional prerequisite." United States v. Antelope, 395 F.3d 1128, 1132 (9th Cir.2005).

Here, the injury as Darwin's has alleged it remains too hypothetical and abstract to satisfy constitutional ripeness. The deadline that the FDA initially gave to Darwin's regarding the press release has passed. It is currently undetermined whether the FDA will issue a statement. And even if such a statement is issued, the content of the statement is unknown. The Court cannot evaluate an injury on a statement it is unable to read. The Court is therefore presented with two hypotheticals – first, that the FDA will issue a statement and second, that the statement will have information that contains an actionable injury to Darwin's. These hypotheticals are too removed for the Court to be able to speculate about in order to provide a favorable determination for Darwin's. Additionally, given that the initial deadline has passed and a second has not been issued, there is currently no immediacy present that suffices to warrant a declaratory judgment. As such, the case is not constitutionally ripe.

2. Prudential Ripeness

Turning to prudential ripeness, the Supreme Court developed a two-part test for determining the prudential component of ripeness in the administrative contexts: (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. Abbott Labs v. Gardner, 387 U.S. 136, 149 (1967), overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977). When considering whether an administrative action is ripe for judicial review, courts are instructed to consider whether review is being sought of a

final agency action within the meaning of Section 10 of the APA, 5 U.S.C. § 704. Id. at 149. The APA defines agency action to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13).

Darwin's argues the FDA's demand that Darwin's issue a press release or, in the alternative, the FDA's threat to issue its own constitutes a final agency action subject to judicial review. In contrast, the FDA argues this case is similar to Wedgewood Vill. Pharmacy, LLC v. U.S. Food & Drug Admin., No. 22CV02649KMWSAK, 2022 WL 1591787 (D.N.J. May 19, 2022) and asks the Court to follow the rationale set forth by the court in Wedgewood. The Court agrees with the FDA.

In Wedgewood, the plaintiff asked the district court to issue a preliminary injunction enjoining the FDA from issuing a public statement about insanitary conditions at plaintiff's facility. Id. at *2-3. The court determined the issue was not ripe for three reasons. Id. at *5. First, the plain reading of the APA's definition of agency action "precludes the interpretation of the statements as agency action." Id. Second, in order for the court to review agency action under the APA, there needed to actually be agency action. Id. The yet to be issued statement was a potential and theoretical publication that the court could not review. Id. And lastly, the court found that even if the issuance of statement were imminent, the contents and ramifications of the statement remained too hypothetical and speculative absent the court's ability to review the contents. Id. As such, the court found that there was no "final agency action" within the meaning of the APA. Id.

The Court finds the same rationale applies here. The APA clearly defines when agency action occurs, the issuing of a notice or press release is not included in that definition. And even if it were included in the definition, the APA affords the Court judicial review only over final

agency actions. See 5 U.S.C. § 704. A currently unissued and unpublished statement cannot be considered a final agency action, because the statement has yet to be made. And the Court's inability to meaningfully review the statement means that any injury is predicated on an unknown statement, making it too hypothetical for the court to take any action on. The Court finds the case is not ripe and that it therefore lacks jurisdiction to review Darwin's Motion.

B. Plaintiff Cannot Prevail on its First Amendment Claim

Darwin's cause of action as to the First Amendment fails to state a claim upon which relief can be granted. Darwin's brings a cause of action under the Federal Civil Rights Act, 42 U.S.C. § 1983 alleging a violation of the First Amendment and requesting declaratory and injunctive relief under Section 1983. Critical here, is that Section 1983 creates a cause of action for plaintiffs injured under the color of law by any State or Territory. See 42. U.S.C. § 1983. Section 1983, therefore, is of limited scope and does not reach the actions of the Federal Government and its officers. D.C. v. Carter, 409 U.S. 418, 424-25 (1973). Because Darwin's brings this suit against a Federal agency, any cause of action under Section 1983 will fail. As such, the Court cannot grant Darwin's Motion for a Temporary Restraining Order based on its First Amendment claim.

CONCLUSION

Having review the record as presented and heard oral argument, the Court finds the issue is not ripe for judicial review. The Court also finds that Darwin's cause of action under 42 U.S.C. 1983 fails to state a claim upon which relief can be granted. The Court therefore DENIES Darwin's Motion for a Temporary Restraining Order.

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The clerk is ordered to provide copies of this order to all counsel.

Dated August 4, 2022.

Marsha J. Pechman
United States Senior District Judge