UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

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| XLEAR, INC.,<br><br>Plaintiff,<br><br>v.<br><br>UNITED STATES FEDERAL TRADE COMMISSION and ANDREW N. FERGUSON, in his official capacity,<br><br>Defendants. | **MEMORANDUM DECISION AND ORDER GRANTING [26] DEFENDANTS' MOTION TO DISMISS**<br><br>Case No. 2:25-cv-00484-DBB-CMR<br><br>District Judge David Barlow |

Before the court is Defendants United States Federal Trade Commission ("FTC") and Andrew N. Ferguson's (collectively, "Defendants") Motion to Dismiss.[1] Plaintiff Xlear, Inc. ("Xlear") seeks a declaratory judgment asking the court to strike down the FTC's substantiation requirement in Sections 5(a) and 12 of the FTC Act.[2] Defendants contend the court must dismiss Xlear's First Amended Complaint ("FAC") for lack of subject matter jurisdiction.[3] Alternatively, Defendants seek dismissal for failure to state a claim upon which relief can be granted.[4] For the reasons below, the court grants the Motion.

[1] Defs.' Mot. to Dismiss First Am. Compl. ("Mot."), ECF No. 26, filed Feb. 24, 2026.
[2] Pl.'s First Amended Complaint ("FAC") 43, ECF No. 21, filed Dec. 12, 2025.
[3] Mot. 1–4.
[4] *Id.*

## BACKGROUND

*Statutory Framework*

Section 5 of the FTC Act bars "unfair or deceptive acts or practices in or affecting commerce."[5] The "primary purpose of § 5 is to protect the consumer public."[6] Section 12 of the FTC Act prohibits false advertising likely to induce the purchase of "food, drugs, devices, services, or cosmetics."[7] Section 12 also declares that the dissemination of false advertisement is "an unfair or deceptive act or practice."[8] Section 15 defines a "false advertisement" as one that misleads "in a material respect" not just express representations but also "the extent to which the advertisement fails to reveal facts material in the light of such representations."[9]

Congress has "empowered and directed" the FTC to enforce these provisions.[10] "Section 5, consistent with its purpose, requires the FTC to show the business entity made material representations likely to mislead ordinary consumers to their detriment.[11] And Section 18 "grants the FTC rulemaking authority to define specific acts or practices as unfair" or deceptive.[12] The FTC's rules "may include requirements prescribed for the purpose of preventing such [unfair or deceptive] acts or practices."[13] The FTC and the courts have long interpreted Sections 5 and 12 of the FTC Act as requiring advertisers making health-related

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[5] 15 U.S.C. § 45(a)(1).
[6] *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1202 (10th Cir. 2005).
[7] 15 U.S.C. § 52.
[8] *Id.*
[9] *Id.* § 55(a)(1).
[10] *Id.* § 45(a)(2).
[11] *Freecom*, 401 F.3d at 1203.
[12] *California State Bd. of Optometry v. FTC*, 910 F.2d 976, 978 (D.C. Cir. 1990).
[13] 15 U.S.C. § 57a(a)(1).

claims to substantiate them with "competent and reliable scientific evidence."[14] In some cases, particularly those regarding health-related products, that level of evidence has required a randomized controlled clinical trial ("RCT").[15]

*Prior Lawsuit*

In 2021, the FTC brought a civil action against Xlear ("Enforcement Action"). [16] Earlier that year, the FTC had sent Xlear a warning letter, which stated that Xlear's COVID-19 claims lacked substantiation and violated the FTC Act.[17] Xlear is a developer and manufacturer of xylitol-based hygiene products such as nasal sprays, toothpastes, mouthwashes, and chewing gums that allegedly promote good health and reduce the risk of disease.[18] Xlear also develops and markets similar dental hygiene products under the Spry brand name.[19]

The United States alleged that Xlear was engaged in deceptive practices by advertising its nasal spray as effective for the prevention and treatment of COVID-19.[20] The Complaint alleged that this conduct violated Sections 5 and 12 of the FTC Act, as well as the COVID-19 Consumer Protection Act of 2021 ("CCP Act"), which prohibited deceptive practices related to the "treatment, cure, prevention, mitigation, or diagnosis of COVID-19" for as long as COVID-19 remained a public health emergency.[21] The United States sought a permanent injunction and

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[14] *See, e.g.*, *Miller v. Basic Research, LLC*, No. 2:07-cv-871, 285 F.R.D. 647, 655 (D. Utah Sept. 2, 2010); *POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478, 500 (D.C. Cir. 2015); *F.T.C. v. Lane Labs-USA, Inc.*, 624 F.3d 575, 578 (3d Cir. 2010); *Bristol-Myers Co. v. .TC*, 738 F.2d 554, 557 (2d Cir. 1984).
[15] *See, e.g.*, *POM Wonderful, LLC*, 777 F.3d at 505.
[16] *See United States v. Xlear, Inc.*, No. 2:21-cv-00640-RJS (D. Utah).
[17] FAC ¶ 23; Mot. 11.
[18] FAC ¶ 8.
[19] *Id.* ¶ 15.
[20] Compl. 4–6 (2021 Compl.), ECF No. 2, filed Oct. 28, 2021 in No. 2:21-cv-00640-RJS (D. Utah). The court must "consider the complaint in its entirety, including 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" *In re Overstock Sec. Litig.*, 119 F.4th 787, 794 n.3 (10th Cir. 2024) (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007)).
[21] Pub. L. No. 116-260, div. FF, tit. XIV, § 1401, 134 Stat. 1182, 3275 (2020) (codified at 15 U.S.C. § 45 note).

monetary civil penalties in the lawsuit.[22] On March 10, 2025, the parties stipulated to dismiss the Enforcement Action with prejudice, and the court terminated the case shortly thereafter.[23]

*Procedural History*

On June 18, 2025, Xlear filed a complaint against Defendants, seeking a declaratory judgment—under the Administrative Procedure Act ("APA")[24] and the Declaratory Judgment Act[25]—that Sections 5 and 12 of the FTC Act "do not and cannot impose an affirmative burden of substantiation on regulated parties."[26] Alternatively, Xlear asks the court to determine that Sections 5(a) and 12 do not require a regulated party making a statement to have RCTs as proof that the statement is not false or deceptive.[27]

In its Complaint,[28] Xlear alleges that its xylitol-based hygiene products are effective "against various pathogens," yet fear of the likelihood of future FTC enforcement prevents Xlear from taking steps to advertise its products' benefits, including protection against COVID-19, which it alleges "remains a serious health risk" to Americans.[29] Xlear fears that because the Enforcement Action did not concern its "Spry dental hygiene products," the FTC may bring a new lawsuit against Xlear for those products.[30] Xlear also alleges that the issue now before the court is solely legal and "requires no additional factual inquiry."[31] Finally, Xlear alleges that

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[22] 2021 Compl. 16.
[23] *See* Stipulation of Dismissal, ECF No. 169, filed Mar. 10, 2025, and Notice from the Court, ECF No. 170, filed Mar. 13, 2025 in No. 2:21-cv-00640-RJS (D. Utah).
[24] *See* 5 U.S.C. §§ 552–559, 702–706.
[25] *See* 28 U.S.C. § 2201.
[26] Mot. 10; FAC ¶ 32.
[27] Pl.'s Opp'n to Defs.' Mot. to Dismiss ("Opp'n") 2, ECF No. 39, filed Apr. 21, 2026.
[28] Xlear's operative complaint is the First Amended Complaint ("FAC"), which the court refers to as the "Complaint" throughout the opinion.
[29] FAC ¶¶ 56, 59, 64.
[30] *Id.* ¶ 68.
[31] *Id.* ¶ 73.

precedent upholding the FTC's substantiation requirement is no longer good law under *Loper Bright Enterprises v. Raimondo*, and that the requirement chills Xlear's First Amendment speech rights and violates its Equal Protection rights by allegedly shifting the burden of proof to defendants to show that their advertising claims are substantiated.[32]

Notably, Xlear does not allege that the FTC has sent warning letters to Xlear about advertising claims for any of its other advertising claims, including those for the Spry products.[33] And there is no pending administrative proceeding or lawsuit brought by the FTC against Xlear.[34]

**STANDARD**

Under Federal Rule of Civil Procedure 12(b)(1), a court will dismiss an action if it lacks subject matter jurisdiction.[35] "Subject matter jurisdiction defines the court's authority to hear a given type of case" and "represents the extent to which a court can rule on the conduct of persons or status of things."[36] Because "[f]ederal courts are courts of limited jurisdiction," it is "presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction."[37]

Under Federal Rule of Civil Procedure 12(b)(6), a court will dismiss an action that fails "to state a claim upon which relief can be granted."[38] "Dismissal under Rule 12(b)(6) is appropriate only if the complaint, viewed in the light most favorable to the plaintiff, lacks

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[32] *Id.* ¶¶ 97–99, 101, 103–112.
[33] Mot. 11.
[34] *Id.* 1; Opp'n 3–9.
[35] Fed. R. Civ. P. 12(b)(1).
[36] *City of Albuquerque v. Soto Enters., Inc.*, 864 F.3d 1089, 1092–93 (10th Cir. 2017) (internal quotation marks and citations omitted).
[37] *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (citations omitted).
[38] Fed. R. Civ. P. 12(b)(6).

enough facts to state a claim to relief that is plausible on its face."[39] "In evaluating a motion to dismiss, the court must take as true all well-pleaded facts, as distinguished from conclusory allegations, view all reasonable inferences in favor of the nonmoving party, and liberally construe the pleadings."[40] However, a "complaint cannot rely on labels or conclusory allegations —a 'formulaic recitation of the elements of a cause of action will not do.'"[41] Instead, a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face."[42] In other words, a "plaintiff's complaint must 'nudge the claim across the line from conceivable or speculative to plausible.'"[43]

## DISCUSSION

Defendants move to dismiss Xlear's request for declaratory relief under Rule 12(b)(1) on the basis that Xlear's complaint against the agency is not ripe for review, as it does not involve a live case or controversy.[44] Alternatively, Defendants argue the case should be dismissed under Rule 12(b)(6) for failure to state a claim.[45]

### I. Subject Matter Jurisdiction

[39] *Abdi v. Wray*, 942 F.3d 1019, 1025 (10th Cir. 2019) (quoting *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 764 (10th Cir. 2019)).
[40] *McNellis v. Douglas Cnty. Sch. Dist.*, 116 F.4th 1122, 1131 (10th Cir. 2024) (quoting *Reznik v. inContact, Inc.*, 18 F.4th 1257, 1260 (10th Cir. 2021)) (also quoting *Ruiz v. McDonald*, 299 F.3d 1173, 1181 (10th Cir. 2002)) (cleaned up).
[41] *Greer v. Moon*, 83 F.4th 1283, 1292 (10th Cir. 2023), *cert. denied*, 144 S. Ct. 2521 (2024) (quoting *Bell Atl. Corp.* v. *Twombly,* 550 U.S. 544, 555 (2007)).
[42] *Ashcroft* v. *Iqbal,* 556 U.S. 662, 678 (2009).
[43] *Audubon of Kan., Inc. v. U.S. Dep't of Int.*, 67 F.4th 1093, 1108 (10th Cir. 2023) (quoting *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021).
[44] Mot. 13. Defendants also argue that the Enforcement Action is moot because the parties entered a voluntary dismissal, but Xlear responds that their claims are not mooted by that action because they are asserted against different products and statements than those in the Enforcement Action. *See* Mot. 15–16; Opp'n 9–11. The court's ruling on ripeness forecloses the need to address mootness.
[45] Mot. 14.

"The threshold question for the court is always its jurisdiction."[46] Federal courts may decide only "cases" or "controversies" under Article III of the Constitution.[47] "A case or controversy is a live dispute between adverse parties over some concrete interest."[48] "An actual controversy must be extant at all stages of review, not merely at the time the complaint is filed."[49] "For a declaratory judgment to issue, there must be a dispute which 'calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts.'"[50] In other words, "[t]o satisfy Article III's case-or-controversy limitation, 'a litigant must have suffered some actual injury that can be redressed by a favorable judicial decision.'"[51]

Defendants argue that this court lacks jurisdiction over the current case because it is not ripe.[52] They argue there is no current FTC enforcement proceeding against Xlear, let alone final agency action, which means the court would be ruling on an abstract proposition of law to prevent hypothetical, future FTC enforcement regarding unspecified claims about unspecified products.[53] Xlear responds that that the FTC's substantiation requirement "currently chills Xlear from engaging in protected speech" and the declaratory relief Xlear seeks "would have the real-world effect of eliminating these current and threatened harms."[54]

### A. Ripeness

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[46] *Tosco Corp. v. Hodel*, 804 F.2d 590, 591 (10th Cir. 1986) (per curiam).
[47] U.S. Const. art. III, § 2.
[48] *Gays Against Groomers v. Garcia*, 169 F.4th 981, 990 (10th Cir. 2026) (citing *Prison Legal News v. Fed. Bureau of Prisons*, 944 F.3d 868, 879 (10th Cir. 2019)).
[49] *Brown v. Buhman*, 822 F.3d 1151, 1165 (10th Cir. 2016) (citation omitted).
[50] *Ashcroft v. Mattis*, 431 U.S. 171, 172 (1977) (per curiam) (citation omitted).
[51] *Audubon of Kan.*, 67 F.4th at 1102 (quoting *Iron Arrow Honor Soc'y v. Heckler*, 464 U.S. 67, 70 (1983)).
[52] Mot. 16–29; Defs.' Reply to Opp'n ("Reply") 1–9, ECF No. 43, filed June 2, 2026.
[53] Reply 1.
[54] Opp'n 11.

"A claim is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'"[55] Thus, "ripeness is peculiarly a question of timing intended to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements."[56] "As applied to review of agency actions, the ripeness doctrine has two underlying rationales."[57] First, the doctrine prevents "courts from becoming entwined in 'abstract disagreements over administrative policies.'"[58] Second, "it protects the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."[59] "In short, the doctrine of ripeness is intended to forestall judicial determinations of disputes until the controversy is presented in 'clean-cut and concrete form.'"[60]

Two factors determine whether a case is ripe for judicial review: "(1) the fitness of the issue for judicial review, and (2) the hardship to the parties of withholding judicial review."[61] To examine the first prong of the ripeness test, the Tenth Circuit considers "(1) whether the issues involved are purely legal, (2) whether the agency's action is final, (3) whether the action has or will have an immediate impact on the petitioner, and (4) whether resolution of the issue will assist the agency in effective enforcement and administration."[62] "Here, the second factor—the

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[55] *Utah Republican Party v. Cox*, 892 F.3d 1066, 1092 (10th Cir. 2018) (quoting *Texas v. United States*, 523 U.S. 296, 300 (1998).
[56] *New Mexicans for Bill Richardson v. Gonzales*, 64 F.3d 1495, 1499 (10th Cir. 1995) (cleaned up).
[57] *Utah v. U.S. Dep't of the Interior*, 535 F.3d 1184, 1191 (10th Cir. 2008) quoting *Abbott Labs v. Gardner*, 387 U.S. 136, 148–49 (1967).
[58] *Id.* at 1191–92 (quoting *Abbott Labs v. Gardner*, 387 U.S. 136, 148–49 (1967)).
[59] *Basic Research, LLC v. F.T.C.*, 807 F. Supp. 2d 1078, 1091 (D. Utah May 23, 2011) (quoting *Utah v. U.S. Dep't of the Interior*, 535 F.3d at 1192 (cleaned up) (also quoting *Abbott Labs*, 387 U.S. at 148).
[60] *Gonzales*, 64 F.3d at 1499 (quoting *Renne v. Geary*, 501 U.S. 312, 322 (1991)).
[61] *United States v. Cabral*, 926 F.3d 687, 693 (10th Cir. 2019) (internal quotation marks and citations omitted) (quoting *United States v. Bennett*, 823 F.3d 1316, 1326 (10th Cir. 2016)) (also citing *Abbott Labs*, 387 U.S. at 149).
[62] *Los Alamos Study Grp. v. U.S. Dep't of Energy*, 692 F.3d 1057, 1065 (10th Cir. 2012) (quoting *Qwest Commc'ns Int'l, Inc. v. FCC*, 398 F.3d 1222, 1231–32 (10th Cir. 2005)).

finality of agency action—is all [the court] need consider, because the absence of final agency action is dispositive."[63]

### 1. Final Agency Action

"The APA defines 'agency action' as an 'agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.'"[64] The Plaintiff bears the burden of identifying agency conduct and explaining how it is "final agency action" under Section 551(13) of the APA.[65] The Supreme Court has established a two-factor test for whether agency actions are 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."[66] Both Supreme Court and Tenth Circuit precedent interpret "the finality element in a pragmatic way," meaning that "if an agency has issued a definitive statement of its position, determining the rights and obligations of the parties, the agency's action is final notwithstanding the possibility of further proceedings in the agency on related issues, so long as judicial review at

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[63] *Id.* (citing *Friends of Marolt Park v. U.S. Dep't of Transp.*, 382 F.3d 1088, 1093–94 (10th Cir. 2004) ("[W]hether the issues are fit for review depends on whether the plaintiff challenges a final agency action.")).

[64] *Colorado Farm Bureau Fed'n v. U.S. Forest Serv.*, 220 F.3d 1171, 1173 (10th Cir. 2000) (citing 5 U.S.C. § 551(13)).

[65] *Id.* Here, the atypical posture of this case—where there is no pending administrative proceeding or action taken by the FTC against Xlear—presents a threshold question of what agency action is at issue. Xlear's Complaint contains both a litany of the FTC's statements and actions that it alleges are final agency actions and a statement that the FTC's "substantiation scheme" is a de facto rule, which also allegedly amounts to final agency action. *See* FAC ¶¶ 39–40. Defendants' Motion analyzed whether the actions listed in Xlear's FAC—the FTC's adoption of its 1984 policy statement, 1998 guidance, and 2002 guidance; its 2020 warning letter to Xlear; and the FTC's prior decision to file the Enforcement Action against Xlear—constitute final agency action. *See* Mot. 17–25. However, Xlear argues that its claim should not be limited to those actions and, rather than responding to the Defendants' arguments for each, asserts that the substantiation requirement is the reviewable agency action. *See* Opp'n 15–16; FAC ¶ 40. This dispute highlights one reason ripeness matters. Without it, there is uncertainty about what agency action is before the court. Because Xlear alleges, at least originally, that all of the above constitute agency action, the court will include both the substantiation requirement and the listed actions in its analysis.

[66] *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).

the time would not disrupt the administrative process."[67] Put differently, consummation of the agency's decisionmaking process occurs when "the initial decisionmaker has arrived at a definitive position on the issue that inflicts an actual, concrete injury."[68]

Here, Xlear cannot point to a definitive position the FTC has taken on advertising claims it has yet to make—let alone one that inflicts an actual, concrete injury—because whether an advertisement is deceptive turns on its content, making it a fact-specific inquiry.[69] Section 15 of the FTC Act states that whether an advertisement is deceptive depends on "representations made or suggested" as well as "the extent to which the advertisement fails to reveal facts material in the light of such representations."[70] The FTC's warning letter from 2020, for instance, discusses the advertising claims Xlear previously made, which are not at issue here.[71] Thus, whether Xlear's possible future advertising claims violate the FTC Act if made without sufficient substantiation requires an inquiry that cannot be done in the abstract.[72]

Xlear resists this outcome in two ways. First, it alleges that because it is asserting "a facial challenge to the FTC's authority to impose a categorical substantiation requirement," application of the requirement to the advertising claims at issue here is unnecessary.[73] A facial

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[67] *Ctr. for Native Ecosystems v. Cables*, 509 F.3d 1310, 1329 (10th Cir. 2007) (cleaned up) (citing *FTC v. Standard Oil of Cal.*, 449 U.S. 232, 239 (1980)).
[68] *Farrell-Cooper Mining Co. v. U.S. Dep't of the Interior*, 864 F.3d 1105, 1114 (10th Cir. 2017).
[69] Xlear alleges that it "brings no claim based on, nor seeks a declaration about, any of its previously made statements." *See* Opp'n 10. And it has not alleged that the FTC has issued a warning letter, or otherwise specifically weighed in, on the marketing of those products. *See* Mot. 11.
[70] 15 U.S.C. § 55(a)(1).
[71] *See* FTC Warning Letter to Xlear, July 29, 2020, https://www.ftc.gov/system/files/warning-letters/covid-19-letter_to_xlear_inc.pdf [https://perma.cc/3ATJ-8ZR9].
[72] *See, e.g.*, *Am. Home Prods. Corp. v. F.T.C.*, 695 F.2d 681, 686 (3d Cir. 1982) (concluding that a finding that "advertisements are deceptive or tend to mislead is obviously an impressionistic determination more closely akin to a finding of fact than to a conclusion of law") (internal quotation marks and citation omitted).
[73] Opp'n 28.

challenge imposes a "heavy burden"[74] "To prevail in such a facial challenge, [the party asserting it] must establish that no set of circumstances exists under which the regulation would be valid."[75] This heavy burden is imposed "for a host of good reasons."[76] For example, "[t]he delicate power of pronouncing [legislative acts] unconstitutional is not to be exercised with reference to hypothetical cases thus imagined."[77] "Facial challenges also run contrary to the fundamental principle of judicial restraint that courts should neither 'anticipate a question of constitutional law in advance of the necessity of deciding it' nor 'formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied.'"[78] And "facial challenges threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution."[79] The Supreme Court "has therefore made facial challenges hard to win."[80]

To prevail, Xlear must show that Sections 5 and 12 of the FTC Act *never* require a health claim to be substantiated, but it has not done so here. Instead, Xlear seems to suggest that *Loper* negates prior case law upholding the FTC's substantiation requirement, so the lack of authority to support its facial challenge is immaterial.[81] Granted, *Loper* overturned *Chevron* deference and changed the extent to which federal courts should defer to federal agencies' interpretations of statutes.[82] However, the court is not interpreting the statute, much less deferring to agency

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[74] *United States v. Salerno*, 481 U.S. 739, 745 (1987).
[75] *Reno v. Flores*, 507 U.S. 292, 301 (1993) (cleaned up).
[76] *Moody v. NetChoice, LLC*, 603 U.S. 707, 723 (2024).
[77] *United States v. Raines,* 362 U.S. 17, 22 (1960).
[78] *Washington State Grange*, 552 U.S. at 450 (quoting *Ashwander v. TVA,* 297 U.S. 288, 346–347 (1936) (Brandeis, J., concurring)).
[79] *Washington State Grange*, 552 U.S. at 451.
[80] *Moody*, 603 U.S. at 723.
[81] FAC ¶¶ 103–112. Opp'n 7 (citing 603 U.S. 369 (2024)).
[82] *See* 603 U.S. 369, 412 (2024).

action. Rather, the court is determining the ripeness of the case and addressing the standard for a successful facial challenge. Therefore, the posture of this case makes *Loper* inapplicable. In sum, Xlear has not met its heavy burden on a facial challenge to "establish that no set of circumstances exists under which [the substantiation requirement] would be valid."[83]

Second, Xlear argues the FTC has taken a definitive position by highlighting the substantiation requirement, rather than the FTC's statements listed in the Complaint, as final agency action, in the vein of a course-of-conduct claim.[84] Specifically, Xlear cites FTC guidance and policy statements going back to 1984 to argue that the FTC's substantiation requirement has become a de facto rule that imposes legal consequences.[85] The FTC, however, argues it is a general policy statement.[86] The "distinction between 'general statements of policy' and 'rules' is critical" because "'general statements of policy' . . . neither determine rights or obligations nor occasion legal consequences."[87] An agency's "policy statements 'do not establish a binding norm—or in other words, do not have the force and effect of law."[88] Nor can they be "enforced against parties" or "expose them to civil and criminal liability."[89] Thus, even if the court were to agree that the substantiation requirement represents the FTC's definitive statement of its position under the first prong of the final agency action test, the requirement still fails under the second

[83] *Reno v. Flores*, 507 U.S. 292, 301 (1993) (cleaned up).
[84] *See, e.g.*, *AT&T Co. v. E.E.O.C.*, 270 F.3d 973, 974 (D.C. Cir. 2001) (holding that "course of conduct does not constitute final agency action and is therefore unreviewable" in a case involving a challenge to the agency's policy).
[85] Opp'n 20–22.
[86] Reply 5–7.
[87] *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 807 (D.C. Cir. 2006).
[88] *Jake's Fireworks Inc. v. Acosta*, 893 F.3d 1248, 1262 (10th Cir. 2018) (cleaned up) (quoting *Am. Mining Cong. v. Marshall*, 671 F.2d 1251, 1263 (10th Cir. 1982)).
[89] *Id.*

prong because the FTC's substantiation requirement does not determine the rights and obligations of the parties.

For example, the FTC's guidance document from 2022[90] states, "This document is intended as business guidance only. It interprets and explains FTC advertising law pursuant to the FTC Act and as set out in case law, and Commission policy statements. The guide, however, doesn't have the force or effect of law."[91] It also states that "whether a particular advertising claim is deceptive or otherwise violates the FTC Act will depend on the facts of the specific case."[92] Granted, Xlear may feel constrained by the guidance. "But while regulated parties may feel pressure to voluntarily conform their behavior because the writing is on the wall about what will be needed to [comply]," such compliance does not change the fact that the guidance is not an "order compelling the regulated entity to do anything."[93]

Similarly, the FTC's warning letter to Xlear in 2020 does not constitute final agency action because it does not impose legal consequences on Xlear, nor does it address the marketing claims about products other than those at issue in the Enforcement Action.[94] The Tenth Circuit has often held that such letters are not final actions subject to judicial review.[95] Likewise, the

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[90] The FAC lists the FTC's guidance documents from 1998, 2002, and 2022 as actions at issue here. However, Xlear concedes that the 1998 guidance was updated and replaced by the 2022 guidance document. *See* FAC ¶ 40(b)(xi).
[91] 2022 Guidance 1, ECF No. 26-1, filed Feb. 24, 2026.
[92] *Id.*
[93] *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014) (holding that the agency's "Final Guidance is not a final agency action subject to pre-enforcement review").
[94] *See* FTC Warning Letter to Xlear, July 29, 2020, https://www.ftc.gov/system/files/warning-letters/covid-19-letter_to_xlear_inc.pdf [https://perma.cc/3ATJ-8ZR9].
[95] *See, e.g.*, *Kansas ex rel. Schmidt v. Zinke*, 861 F.3d 1024, 1031 (10th Cir. 2017) (holding that the National Indian Gaming Counsel's opinion letter was not final agency action under the second *Bennett* factor); *Oklahoma v. Hobia*, 775 F.3d 1204 (10th Cir. 2014) (holding that the agency's legal opinion did not constitute reviewable final action); *Miami Tribe of Okla. v. United States*, 198 F. App'x 686, 690 (10th Cir. 2006) (holding that a DOI opinion letter was not final agency action because it was "only a part of the process that [would] eventually result in [a] final NIGC action").

Tenth Circuit and the Supreme Court have held that "an administrative complaint filed by the FTC [is] not 'definitive' final agency action" because it has "no legal force" but rather "serve[s] merely to institute agency action."[96] Without final agency action for the court to review, a ruling at this point on the merits of Xlear's claims would be a "premature adjudication" on "abstract disagreements" that the doctrine of ripeness prohibits.[97]

In sum, Xlear has not adequately pled "the fitness of the issue for judicial review"[98] because the FTC's substantiation requirement is not agency action "by which rights or obligations have been determined, or from which legal consequences will flow."[99] Consequently, it cannot meet the second element of the Supreme Court's test for final agency action, and the case is not ripe for judicial review. Therefore, the court lacks subject matter jurisdiction over the claims, does not reach Defendants' alternative Rule 12(b)(6) argument, and dismisses this action without prejudice.

**ORDER**

Accordingly, Defendants' motion to dismiss is granted.[100]

Signed July 27, 2026.

BY THE COURT

David Barlow
United States District Judge

[96] *Sierra Club v. Yeutter*, 911 F.2d 1405, 1417–18 (10th Cir. 1990) (quoting *Standard Oil*, 449 U.S.at 239–42).
[97] *New Mexicans for Bill Richardson v. Gonzales*, 64 F.3d 1495, 1499 (10th Cir. 1995) (cleaned up).
[98] *Cabral*, 926 F.3d at 693 (internal quotation marks and citations omitted).
[99] *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).
[100] ECF No. 26.