United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 11, 2020 Decided August 6, 2021

No. 19-5252

BELLION SPIRITS, LLC AND CHIGURUPATI TECHNOLOGIES PRIVATE LTD.,
APPELLANTS

v.

UNITED STATES OF AMERICA, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:17-cv-02538)

Jonathan W. Emord argued the cause for appellants. With him on the briefs was *Peter A. Arhangelsky*.

Leif Overvold, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Joseph H. Hunt*, Assistant Attorney General, and *Daniel Tenny*, Attorney.

Before: SRINIVASAN, *Chief Judge*, KATSAS, *Circuit Judge*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Chief Judge* SRINIVASAN.

SRINIVASAN, *Chief Judge*: Bellion Spirits, LLC produces and distributes vodka. Bellion infuses its vodka with NTX, a proprietary blend that Bellion contends mitigates alcohol's damage to a person's DNA.

In 2016, Bellion filed a petition with the Alcohol and Tobacco Tax and Trade Bureau (TTB), the agency that regulates alcoholic beverage labeling and advertising. The petition sought to determine whether Bellion could lawfully make certain claims on labels and in advertisements about the alleged health benefits of NTX. TTB denied the petition on the grounds that the claims were scientifically unsubstantiated and misleading. TTB thus concluded that including the claims on vodka labels and in advertisements would violate the Federal Alcohol Administration Act and TTB's regulations.

Bellion then brought this suit in the district court. Bellion contends, among other things, that TTB's denial of the petition violates Bellion's First Amendment rights and that the standards under which TTB rejected the proposed claims about NTX are unconstitutionally vague. The district court granted TTB's motion for summary judgment. Because we agree with the district court that Bellion's various challenges lack merit, we affirm.

I.

A.

The Federal Alcohol Administration Act regulates the production, sale, labeling, and advertising of alcoholic beverages. *See* 27 U.S.C. §§ 201–219a. The Act requires product labels and advertisements for alcoholic beverages to comply with regulations issued by the Secretary of the Treasury. *Id.* § 205(e), (f). And the Act calls for those

regulations to prevent "deception of the consumer" and to "prohibit, irrespective of falsity, such statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters as the Secretary of the Treasury finds to be likely to mislead the consumer." *Id.* The regulations also must "prohibit statements" in labeling or advertising that are "false, misleading, obscene, or indecent." *Id.* The Secretary of the Treasury has delegated responsibility for issuing those regulations to the Administrator of TTB. U.S. Dep't of Treasury, *Treasury Order 120-01* (Dec. 10, 2013), https://home.treasury.gov/about/general-information/orders-and-directives/treasury-order-120-01.

TTB's regulations addressing alcoholic beverage labels and advertisements prohibit statements that are "false or untrue in any particular, or that, irrespective of falsity, directly, or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific or technical matter, tend[] to create a misleading impression." 27 C.F.R. § 5.42(a)(1); *see id.* § 5.65(a)(1). The regulations also specifically address claims made on labels and in advertisements about the relationship between alcohol consumption and human health. Those regulations address two categories of claims about alcohol's effects on health.

First, the broader category of "[h]ealth-related statements" encompasses "any statement related to health," including "statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, and health benefits or effects on health." *Id.* § 5.65(d)(1)(i). TTB's regulations pertaining to health-related statements state that an alcoholic-beverage label or advertisement "may not contain any health-related statement that is untrue in any particular or tends to create a

misleading impression as to the effects on health of alcohol consumption." *Id.* §§ 5.42(b)(8)(ii)(A); 5.65(d)(2)(i). TTB evaluates health-related statements "on a case-by-case basis," and the agency may require "a disclaimer or some other qualifying statement to dispel any misleading impression" created by health-related statements. *Id.* § 5.65(d)(2)(i).

TTB describes the second, narrower type of claims about alcohol and human health as "specific health claims." *Id.* § 5.65(d)(1)(ii). A specific health claim is "a type of health-related statement that, expressly or by implication, characterizes the relationship of the distilled spirits, alcohol, or any substance found within the distilled spirits, to a disease or health-related condition." *Id.* A specific health claim must comply with the more general regulations applicable to health-related statements. *See id.* In addition, a specific health claim will be approved only if it is supported by scientific or medical evidence, contains appropriate qualifiers, and discloses relevant health risks. *See id.* §§ 5.42(b)(8)(ii)(B)(2); 5.65(d)(2)(ii). If a specific health claim is accompanied by a qualifier or disclaimer, that information "must appear as part of the specific health claim." *Id.*

B.

TTB provides an avenue for regulated entities to seek advisory rulings on matters relating to the Act and its implementing regulations. "Any person who is in doubt as to any matter arising in connection with the [Act] may request a ruling thereon by addressing a letter to the appropriate TTB officer." *Id.* § 70.471(a). There is no requirement for a regulated entity to seek such a ruling before including a health-related statement or a specific health claim in advertisements. *See* 27 U.S.C. § 205(e), (f).

While regulated entities thus need no preapproval to make health-related statements or specific health claims in advertisements, they generally do need preapproval to make such statements or claims on labels. In particular, before bottlers and importers introduce alcoholic beverages into interstate or foreign commerce, they generally must obtain a certificate of label approval (COLA) from TTB. *Id.* § 205(e). As part of that process, TTB reviews statements made on an alcoholic-beverage label—including health-related statements and specific health statements—to determine whether the proposed label "complies with applicable laws and regulations." 27 C.F.R. § 13.21(a). TTB has 90 days after receiving a COLA application to "notify the applicant whether the application has been approved or denied," unless TTB extends that period by 90 days under "unusual circumstances." *Id.* § 13.21(b). When TTB denies a COLA application, it must issue a notice setting forth the reasons for the denial. *Id.* § 13.23. The applicant may then submit a new amended application or file up to two administrative appeals. *See id.* §§ 13.25, 13.27.

Although TTB has primary responsibility for regulating the labeling and advertising of alcoholic beverages, the Food and Drug Administration (FDA) also plays a role. For instance, the rulemaking that led to the regulations concerning health-related statements noted that TTB's predecessor agency had "always utilized, as TTB does now, the scientific and public health expertise of FDA in approving ingredients in alcohol beverages, requiring label disclosure of certain substances, and identifying adulterated alcohol beverages that are deemed mislabeled." Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 Fed. Reg. 10,076, 10,078 (Mar. 3, 2003). Consistent with that recognition, TTB's regulations addressing specific health claims state that "TTB will consult with [FDA],

as needed, on the use of a specific health claim on a distilled spirits label." 27 C.F.R. § 5.42(b)(8)(ii)(B)(1).

C.

In April 2016, Bellion Spirits, LLC, and Chigurupati Technologies Private Ltd. filed a petition with TTB. Bellion Spirits is the producer and distributor of Bellion brand vodka. Chigurupati Technologies is a research and development institution that developed a proprietary blend of ingredients known as NTX, which Bellion includes in its vodka. Bellion's petition inquired about whether it could lawfully make certain statements about the health benefits of NTX on its vodka labels and in its advertising.

The petition asked TTB to review eight proposed statements, two of which are in issue here. Those two proposed statements are: (i) "NTX helps protect DNA from alcohol-induced damage," and (ii) "NTX reduces alcohol-induced DNA damage." Bellion Petition for Health Claims, J.A. 426. Bellion also submitted a proposed disclaimer that would accompany those claims. The disclaimer states:

> NTX does not protect against all health risks associated with moderate and heavy levels of alcohol consumption, including, but not limited to, motor vehicle accidents, high blood pressure, stroke, cancer, birth defects, psychological problems, and alcohol dependency. Do not consume alcohol if: you are younger than the legal drinking age; you are pregnant or may become pregnant; you are taking medicine that can interact with alcohol; you have a medical condition for which alcohol is contraindicated; you plan to drive; or you cannot restrict your drinking to moderate levels. If you consume alcohol, only consume it

> in moderation. "Moderation" means up to one drink per day for women and up to two drinks per day for men.

Id. at 427.

Bellion did not file a COLA application. And its petition stated that "[p]etitioners are not requesting the use of specific health-related statements on a specific label." *Id.* at 433. Rather than make use of the preapproval process for labels, Bellion sought advisory guidance from TTB under 27 C.F.R. § 70.471(a) about whether its claims would comply with the Act and the agency's regulations. Shortly after Bellion filed its petition, Frank-Lin Distillers Products, Ltd.—a separate entity that is not a party to this litigation—submitted nine COLA applications for Bellion vodka labels that also included the specific health claims listed in Bellion's petition.

TTB acknowledged receipt of Bellion's petition in May 2016. The agency stated that, consistent with its regulations, it had forwarded the petition and accompanying exhibits to FDA. After corresponding with TTB, Bellion supplemented its petition. In total, Bellion submitted 112 scientific articles or studies in support of its petition.

In May 2017, TTB denied Bellion's petition in a 47-page ruling letter. The agency explained that the proposed statements about NTX's effects on DNA are both "health-related statements" and "specific health claims." TTB found that the claims failed to comply with the regulations governing either category. TTB concluded that the claims, even with the proposed disclaimer, "would violate the [Act] and its implementing regulations by making specific health claims that are not adequately substantiated, and by misleading consumers as to the serious health consequences of both moderate and

heavy levels of consumption of alcohol beverages containing NTX." TTB Ruling Letter at 2, J.A. 1056.

TTB further explained that it had "consulted with FDA" and "drawn on that agency's substantial expertise in assessing scientific studies." *Id.* at 1070. Based on its review of FDA's analysis of the materials submitted by Bellion, TTB concluded that "there is no credible evidence to support these proposed claims." *Id.* at 1089. TTB also stated that "the proposed disclaimer does not characterize the level of evidence to support the claims, and it reinforces the most misleading aspects of the claims." *Id.* at 1097. And TTB explained that it had "considered but rejected use of a different disclaimer to accompany the proposed claims," because any disclaimer would need to "effectively characterize[] the claim as baseless." *Id.*

Bellion then filed suit in the district court. Bellion challenged TTB's ruling letter on a number of grounds, bringing both statutory and constitutional claims. Bellion later moved to add evidence outside the administrative record, including testimony from expert witnesses that was not before TTB when it made its decision. The court denied that motion. *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 36 (D.D.C. 2018).

The parties both moved for summary judgment, and the court granted the government's motion. *Bellion Spirits, LLC v. United States*, 393 F. Supp. 3d 5, 9 (D.D.C. 2019). With regard to Bellion's statutory challenge, the court concluded that TTB permissibly consulted with FDA. *Id.* at 17. The court then determined that TTB's ruling letter did not impermissibly proscribe commercial speech under the First Amendment. *Id.* at 24. The court next held that TTB's regulations did not impose an unconstitutional prior restraint. *Id.* at 32. Last, the

court concluded that TTB's regulations were not unconstitutionally vague. *Id.* at 34.

II.

Before addressing the merits of Bellion's challenges, we consider as a threshold matter whether the dispute is ripe for our review, and, relatedly, whether TTB's ruling letter constituted final agency action. Under the Administrative Procedure Act (APA), an agency's challenged decision is subject to judicial review if it constitutes final agency action. 5 U.S.C. § 704. While TTB has not argued that its ruling letter fails to qualify as final agency action, satisfaction of that requirement is a prerequisite to ripeness in an APA case: "a dispute is not ripe if it is not fit, and (at least in an APA case) it is not fit if it does not involve final agency action." *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 n.4 (D.C. Cir. 2012) (citations omitted). We take up the question of ripeness on our "own motion," *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003), which, in the context of this case, necessarily requires us to examine whether the ruling letter amounted to final agency action.

Agency action is final "if two independent conditions are met: (1) the action mark[s] the consummation of the agency's decisionmaking process and is not of a merely tentative or interlocutory nature; and (2) it is an action by which rights or obligations have been determined, or from which legal consequences will flow." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018) (internal quotation marks omitted). TTB's ruling letter satisfies both conditions.

First, the ruling letter marks the consummation of TTB's decisionmaking process with respect to Bellion's petition. The letter puts forth the agency's official position about how the

Act and its regulations apply to the facts described in the petition. The letter was not "informal, or only the ruling of a subordinate official, or tentative." *Abbott Labs. v. Gardner*, 387 U.S. 136, 151 (1967) (citations omitted). In addition, the letter did not provide any other "avenue for [Bellion] to affirmatively seek relief" through additional procedures. *See Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 958 (D.C. Cir. 2019). Regardless of whether Bellion could submit a COLA application or additional petitions for review, the ruling letter concluded the agency's decisionmaking process with regard to the petition Bellion filed.

Second, the ruling letter is an agency action from which legal consequences will flow. It is true that the ruling letter is an advisory guidance and does not itself expose Bellion to additional civil or criminal liability above what it would already face for violating the Act or TTB's regulations. But legal consequences nonetheless attach to the letter because it has the effect of extinguishing any willfulness defense Bellion otherwise might assert in an administrative proceeding involving its basic permit.

Under the Act, the Secretary of the Treasury must suspend or revoke an alcoholic beverage distributor's basic permit for violating the permit's conditions. 27 U.S.C. § 204(d), (e). Those conditions include compliance with the Act's labeling and advertising requirements. *See id.* § 204(d). But the Secretary can suspend or revoke a permit only upon finding "that the permittee has *wilfully* violated any of the conditions thereof." *Id.* § 204(e) (emphasis added). When, as here, a ruling letter concludes that the regulated entity's proposed statements would contravene the governing regulations, TTB could use that letter as evidence of willfulness to suspend a basic permit. TTB's ruling letter thus had a concrete legal effect on Bellion's ability to make the challenged statements

without jeopardizing its basic permit. *See Ipsen*, 943 F.3d at 957 (letter expressing agency's position was final because it "refute[d] any colorable argument [the plaintiff] might have in an enforcement action that it was acting without knowledge of [the agency's] position"); *accord Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1028–30 (D.C. Cir. 2016); *Unity08 v. FEC*, 596 F.3d 861, 865 (D.C. Cir. 2010).

Having concluded that the ruling letter constituted final agency action, we also hold that the dispute is ripe. The ripeness inquiry encompasses "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Marcum v. Salazar*, 694 F.3d 123, 129 (D.C. Cir. 2012) (quoting *Abbott Labs.*, 387 U.S. at 149). Bellion's challenges are fit for judicial decision because they involve final agency action and because "judicial intervention" would not "inappropriately interfere with further administrative action." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998). As for hardship to the parties, if we were to withhold review, then Bellion could obtain judicial review of TTB's position only by flouting the ruling letter and publishing the statements, thereby risking the imposition of civil and potentially criminal penalties. *See* 27 U.S.C. § 207. The ripeness requirement does not require parties to subject themselves to that kind of jeopardy. *See Unity08*, 596 F.3d at 866.

III.

Proceeding to the merits of Bellion's challenges, we first address Bellion's non-constitutional arguments before turning to its constitutional claims. *See POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015).

A.

Bellion first contends that the district court abused its discretion by declining to supplement the administrative record with additional evidence. We disagree.

It is "black-letter administrative law that in an APA case, a reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.'" *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) (quoting *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984)). "We do not allow parties to supplement the record 'unless they can demonstrate unusual circumstances justifying a departure from this general rule.'" *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (quoting *Tex. Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685, 698 (D.C. Cir. 1991)).

Bellion challenges administrative action in the form of TTB's ruling letter. And Bellion identifies no circumstances that would warrant departing from the ordinary rule against admitting evidence not before the agency when it made its challenged decision. For instance, there is no reason to think that TTB deliberately excluded evidence from the record. *See City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010). Rather, Bellion simply did not submit the additional evidence to TTB and then sought to have the district court consider it in the first instance. The district court appropriately exercised its discretion in declining to supplement the administrative record. *See Bellion Spirits, LLC*, 335 F. Supp. 3d at 45.

B.

Bellion next argues that TTB improperly delegated its statutory authority to FDA. We again disagree.

The Federal Alcohol Administration Act does not preclude TTB from involving FDA in TTB's evaluation of scientific evidence. To the contrary, the Act empowers the Secretary of the Treasury to "utilize the services of any department or other agency of the Government to the extent necessary to carry out his powers and duties under this chapter." 27 U.S.C. § 202(f). And TTB's regulations expressly authorize TTB to "consult with [FDA], as needed, on the use of a specific health claim on a distilled spirits label." 27 C.F.R. § 5.42(b)(8)(ii)(B)(1).

TTB acted in accordance with that scheme. TTB explained in the ruling letter that it "consulted with FDA and [drew] on that agency's substantial expertise in assessing scientific studies" to determine whether the petition satisfied TTB's requirements for specific health claims. TTB Ruling Letter at 16, J.A. 1070. But "FDA did not recommend any decision with regard to the ultimate issue of whether to approve the eight claims in the petition." *Id.* at 1077. Based on its examination of FDA's analysis, TTB "determined that none of the eight claims is supported by credible scientific or medical evidence" and that the claims thus did not satisfy TTB's standards for specific health claims or health-related statements. *Id.* at 1070.

TTB did not rubberstamp FDA's analysis of the scientific evidence or delegate final decisionmaking authority to FDA. Rather, TTB systematically evaluated and explained its reasons for agreeing with FDA's analysis of each scientific study. TTB then made its own determinations about whether the proposed claims complied with its standards for health-related

statements and specific health claims. In short, TTB consulted with FDA on a matter implicating FDA's expertise and then considered that expertise in reaching its own final decision.

IV.

We next turn to Bellion's constitutional arguments. Bellion challenges TTB's ruling letter on both First Amendment grounds and Fifth Amendment vagueness grounds. We reject those challenges.

A.

Bellion first contends that TTB's position on the proposed claims about NTX is inconsistent with the First Amendment. We conclude that Bellion's claims are unprotected by the First Amendment because they constitute inherently misleading commercial speech.

Bellion seeks to include its proposed claims about the alleged health benefits of NTX on vodka labels and in vodka advertisements. The speech at issue, then, amounts to commercial speech. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) ("Both parties agree that the information on beer labels constitutes commercial speech.").

"For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Consequently, "[m]isleading advertising may be prohibited entirely." *In re R.M.J.*, 455 U.S. 191, 203 (1982).

In its ruling letter, TTB found that Bellion's proposed statements about NTX may be barred consistent with the First

Amendment because they are inherently misleading. The parties debate the standard of review under which we should examine that determination. TTB, relying on our decision in *POM Wonderful*, 777 F.3d at 499, contends that we should apply deferential, substantial-evidence review to the agency's determination that the proposed speech is misleading. Bellion submits that we must apply de-novo review to TTB's conclusion that the proposed speech is misleading. *See Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 108 (1990) (plurality opinion).

We need not resolve whether de-novo review or substantial-evidence review applies in the circumstances of this case. Even assuming that de-novo review governs, and applying that standard, we agree with TTB that Bellion's proposed claims are misleading and thus can be proscribed consistent with the First Amendment.

Consider the scientific studies Bellion submitted to TTB. In total, Bellion submitted 112 scientific articles or studies in support of its petition. Aided by FDA's analysis, TTB systematically considered and assessed the probative value of those materials. And based on its review, TTB concluded that the studies provided no credible evidence supporting the proposed claims.

Our independent review yields a similar assessment of the evidence. Of the 112 articles or studies, we see no basis to disagree with TTB's conclusion that 106 of them do "not allow scientific conclusions to be drawn about the claims." TTB Ruling Letter at 30, J.A. 1084. For example, many of the studies were conducted only on animals or in vitro, while others included only one component of NTX rather than the full compound. Additionally, some of the submitted materials were written in foreign languages or were simply book chapters

or review articles that discussed a number of studies at a high level of generality. Like TTB, we are "unable to evaluate data provided in articles published in a foreign language unless an accurate and complete English translation is provided." *Id.* at 1081. And we agree with TTB that the book chapters and review articles do not provide sufficient information about individual studies to evaluate Bellion's claims.

Nonetheless, out of an abundance of caution, TTB asked FDA to review studies that included only a single ingredient of NTX and were not otherwise excluded for one of the above reasons. But FDA and TTB still correctly determined that "scientific conclusions cannot be drawn" from those studies because they did not address how NTX interacts with alcohol. *Id.* at 1082.

With regard to the six remaining articles or studies submitted by Bellion, we agree with TTB's conclusion that Bellion's proposed claims "are not adequately substantiated by the evidence presented" because the materials "do not provide credible evidence to support" the claims. *Id.* at 1095–96. For example, one of the studies (referred to as the first Pandit study) "did not include information on the study, such as study subjects (e.g., health status) and study design (e.g., provision of the control and test (NTX Products), dose of NTX provided, appropriateness of control group)." *Id.* at 1084. Two of the studies were merely "the findings of the same study with one being a published version of the other." *Id.* at 1085. And neither that study nor the three remaining studies provided credible support for Bellion's proposed claims. For instance, none of those four studies "includes information about the dosage of NTX consumed by the study subjects." *Id.* at 1086. We concur with TTB's assessment that studies lacking dosage information cannot support valid scientific conclusions.

Despite the facially evident shortcomings of those four studies, TTB analyzed their findings in greater depth. Our review confirms that the studies provide no credible evidence supporting Bellion's proposed claims. For example, one of the studies "show[ed] no effect on protecting DNA." *Id.* at 1094. And the study that came the closest to providing a modicum of support for Bellion's claims was the second Pandit study, which provided, at best, "weak evidence tangentially related to" to Bellion's DNA protection claims. *Id.* at 1092. The study showed a "reduction in certain measures of DNA damage at some but not all time points after administration of NTX." *Id.* at 1094. Meanwhile, none of the four studies purported to assess the long-term effects of NTX on DNA. For those reasons—and because the studies, as noted, lack information about the dosages of NTX administered—we agree with TTB that the studies do not permit "valid scientific conclusions regarding the health effects of consumption of alcohol beverages containing NTX in the quantities in which such an ingredient would be allowed in alcohol beverages." *Id.* at 1086.

In light of the absence of scientific support for Bellion's proposed claims concerning NTX's effect on DNA, we conclude that the claims are inherently misleading. Specifically, Bellion's claims that "NTX helps protect DNA from alcohol-induced damage" and that "NTX reduces alcohol-induced DNA damage," Bellion Petition for Health Claims, J.A. 426, are misleading because none of the studies reliably support those assertions.

Our precedents confirm that commercial speech lacking any reliable support is properly characterized as misleading and thus may be proscribed consistent with the First Amendment. In *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999), we explained that, "where evidence in support of a claim is

outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." Similarly, there would be "no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim—for example, where the claim rests on only one or two old studies." *Id.* at 659 n.10. And in *POM Wonderful*, we described claims as "misleading speech unprotected by the First Amendment" because they had "insufficient support." 777 F.3d at 500.

The same is true here. At best, one study provided "weak evidence tangentially related" to the proposed claims. TTB Ruling Letter at 38, J.A. 1092. And the remaining studies either provided no evidence about the proposed claims or tended to undercut them. In those circumstances, the proposed claims are misleading because they are not backed by credible scientific findings.

B.

Bellion next contends that TTB subjected it to an unconstitutional prior restraint on speech. We have previously left open whether the prior-restraint doctrine applies in the context of commercial speech, *see Pearson*, 164 F.3d at 660 & n.11, and we do so again here. Even assuming the applicability of prior-restraint principles, Bellion fails to demonstrate an unconstitutional prior restraint.

Under the Act, regulated entities do not need TTB's preapproval to make health claims in alcohol-related advertising. *See* 27 U.S.C § 205(f). Insofar as Bellion wishes to make its health claims in advertisements, then, there is no prior restraint limiting its ability to do so. Preapproval is required only when entities seek to put health claims on

alcoholic beverage labels. *See id.* § 205(e). That preapproval, as explained, is obtained through a COLA, and TTB regulations spell out the procedural requirements for applying for a COLA. *See* 27 C.F.R. § 5.55. For its part, Bellion did not make use of the procedures for obtaining a COLA, and instead opted to pursue non-mandatory, advisory guidance under 27 C.F.R. § 70.471(a). In fact, Bellion's petition to TTB expressly disavowed that it was seeking authorization for the "use of specific health-related statements on a specific label." Bellion Petition for Health Claims, J.A. 433.

Notwithstanding Bellion's disavowal of the COLA process, we assume Bellion can bring a facial challenge to the COLA scheme on the basis that it vests undue discretion in the licensor. *See City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 755 (1988). That challenge fails.

By imposing sufficiently "narrow, objective, and definite standards," *Shuttlesworth v. City of Birmingham*, 394 U.S. 147, 151 (1969), the COLA scheme adequately channels TTB's discretion. The COLA regulation provides that TTB "will approve" specific health claims "only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks." *See* 27 C.F.R. § 5.42(b)(8)(ii)(B)(2). Those conditions of approval are "sufficiently definite to constrain [TTB] within reasonable bounds." *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 228 (2d Cir. 1998).

In addition, the COLA process, contrary to Bellion's contention, channels TTB's decisionmaking through

adequately strict deadlines. *See Freedman v. Maryland*, 380 U.S. 51, 58 (1965). The regulation states that TTB must respond to an application within 90 days, unless it elects to use one 90-day extension. *See* 27 C.F.R. § 13.21(b). Indeed, applicants who do not receive a decision from TTB within the specified time period may file an administrative appeal. *Id.* We find no "unbridled" discretion in that scheme. *See City of Lakewood*, 486 U.S. at 757.

We note that, before the district court, Bellion contended that the COLA process unduly restricts the kinds of evidence that can be submitted in support of an application. *See Bellion Spirits, LLC*, 393 F. Supp. 3d at 31. But Bellion has forfeited any such argument in our court by suggesting it only in its reply brief (and even then, only in passing). *See Am. Wildlands*, 530 F.3d at 1001.

C.

Finally, Bellion contends that TTB's regulations addressing specific health claims are unconstitutionally vague in violation of the Fifth Amendment's guarantee of due process. That challenge is similarly without merit.

As noted, the primary regulations at issue state that a specific health claim will be approved only if it is, among other things, "truthful and adequately substantiated by scientific or medical evidence" and "sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies." 27 C.F.R. §§ 5.42(b)(8)(ii)(B)(2); 5.65(d)(2)(ii). Because Bellion received a clear response from TTB about why its proposed claims were denied, Bellion cannot—and does not purport to—bring an as-applied vagueness challenge to the regulation. And Bellion's facial challenge to the regulation is without merit.

"[A] regulation is not impermissibly vague because it is 'marked by flexibility and reasonable breadth, rather than meticulous specificity.'" *U.S. Telecom Ass'n v. FCC*, 825 F.3d 674, 737 (D.C. Cir. 2016) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972)). Instead, regulations withstand a vagueness challenge as long as a "reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require." *Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Review Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997). TTB's regulation satisfies that standard by giving regulated entities sufficient notice of what kind of evidence they must present to obtain approval of specific health claims.

Moreover, vagueness concerns are mitigated when regulated entities "have the ability to clarify the meaning of the regulation by [their] own inquiry, or by resort to an administrative process." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). TTB permits regulated entities to ask for a ruling about whether statements made on labels would violate its regulations. *See* 27 C.F.R. § 70.471. Bellion, as noted, made use of that option here. TTB's regulations thus provide "[t]he opportunity to obtain prospective guidance," which allays "any remaining concerns about [the regulation's] allegedly unconstitutional vagueness." *U.S. Telecom Ass'n*, 825 F.3d at 738–39.

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For the foregoing reasons, we affirm the district court's grant of summary judgment in favor of TTB.

So ordered.