UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BELLION SPIRITS, LLC, *et al.*, **Plaintiffs,** **v.** **UNITED STATES OF AMERICA, *et al.*,** **Defendants.**	**Civil Action No. 17-2538 (JEB)**

MEMORANDUM OPINION

Winston Churchill once said, "I have taken more out of alcohol than alcohol has taken out of me." Plaintiffs Bellion Spirits, LLC and Chigurupati Technologies Private Ltd. believe they can make such sentiment universal. They infuse their vodka with a compound called NTX, a proprietary blend of ingredients that they contend mitigates alcohol's damage to DNA. The Alcohol and Tobacco Tax and Trade Bureau (TTB), however, dashed their hopes of advertising NTX's health benefits when it found their claims to be unsubstantiated and misleading. Plaintiffs responded with this suit, and the parties have now cross-moved for summary judgment. Finding TTB's action consistent with both the Administrative Procedure Act and the Constitution, the Court will deny Plaintiffs' Motion for Summary Judgment and grant the Government's Cross-Motion.

I. Background

A. Legal Framework

While we may have come a long way since Prohibition, the Federal Alcohol Administration Act (FAAA) still regulates the production, sale, advertising, and labeling of alcoholic beverages. See 27 U.S.C. §§ 201–219a. Specifically, it requires that alcohol

advertising and labels accord with regulations issued by the Secretary of the Treasury. Id. § 205(e), (f). Those regulations must, among other things, "prohibit deception of the consumer" and ensure that products "provide the consumer with adequate information as to [their] identity and quality." Id. The Secretary has delegated responsibility for issuing these regulations to the Administrator of the TTB.

TTB's regulations thus 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) (labels on distilled spirits); see also 27 C.F.R. § 5.65(a)(1) (substantially identical regulation applying to advertising of distilled spirits). Although these provisions on labeling and advertising are essentially identical substantively, there is an important difference between the schemes governing the two: a regulated entity needs pre-approval from TTB to make any claims on an alcoholic-beverage label, but not for those in alcohol advertisements. See 27 U.S.C. § 205(e), (f).

In 2003, TTB also promulgated regulations dealing with statements about health in advertising or on labels. There are two types. The first is "health-related statements," which refers to — perhaps unsurprisingly — "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 distilled spirits, and health benefits or effects on health." 27 C.F.R. § 5.42(b)(8)(i)(A). Labels or advertisements "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." 27 C.F.R. § 5.42(b)(8)(ii)(A) (labels); 27 C.F.R. § 5.65(d)(2)(i) (advertisements).

The second — and narrower — category addressed by the 2003 regulations is "specific health claims." Those are "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." 27 C.F.R. § 5.42(b)(8)(i)(B). Specific health claims are "a type of health-related statement," 27 C.F.R. § 5.42(b)(8)(i)(B), and must therefore also comply with the more general regulations of "health-related statements." Plus, a specific health claim — whether appearing on a label or advertisement — must meet four additional conditions: The claim must (1) be "truthful and adequately substantiated by scientific or medical evidence"; (2) be "sufficiently detailed and qualified"; (3) "adequately disclose[] the heath risks associated with both moderate and heavier levels of alcohol consumption"; and (4) "outline[] the categories of individuals for whom any levels of alcohol consumption may cause health risks." 27 C.F.R. § 5.42(b)(8)(ii)(B)(2) (labels); 27 C.F.R. § 5.65(d)(2)(ii) (advertisements).

A regulated entity wishing to make a specific health claim can — but is not required to — ask TTB whether the claim is permitted under the regulations. See 27 C.F.R. § 70.471(a) (allowing "[a]ny person who is in doubt as to any matter arising in connection with the [FAAA]" to "request a ruling thereon by addressing a letter to the appropriate TTB officer"). There is an exception, however, for alcohol-beverage labels, which — as mentioned above — have a mandatory pre-approval process. Specifically, bottlers and importers are generally required to obtain from TTB a "certificate of label approval" (COLA) before circulating their products in interstate or foreign commerce. See 27 U.S.C. § 205(e). TTB, therefore, reviews all claims —

including those related to health — on labels in determining, as it must, whether a COLA "complies with applicable laws and regulations." 27 C.F.R. § 13.21(a).

B. Facts

On April 12, 2016, Plaintiffs Bellion Spirits, LLC and Chigurupati Technologies Private Ltd. — which the Court will refer to jointly as "Bellion" — filed a petition with TTB seeking permission to make eight advertising claims about the alleged positive health effects of NTX. See AR 2, 8. Only two of those claims are at issue here — namely, that "NTX helps protect DNA from alcohol-induced damage" and "NTX reduces alcohol-induced DNA damage." AR 8. Those are claims 7 and 8 from the original list. See AR 8. Bellion also included a proposed disclaimer to accompany the claims. It provides:

> 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.

AR 9. Bellion itself did not file any COLAs. See AR 15 ("Petitioners are not requesting the use of specific health-related statements on a specific label."). A separate entity, Frank-Lin Distillers Products, submitted nine COLAs for Bellion vodka labels less than a week after Bellion filed its petition. (The Court will discuss any link between Frank-Lin and Bellion and its legal

significance later.) Those proposed labels included the eight specific health claims relating to NTX and also a ninth iteration including all eight of the proposed claims. See AR 2080.

TTB acknowledged Bellion's petition in a letter dated May 26, 2016, and assigned the matter to its Regulations and Rulings Division. See AR 1495. It explained that it would treat the matter as a request that TTB rule on whether the use of the health claims would violate TTB regulations or, alternatively, that TTB initiate a rulemaking allowing Bellion to use the eight claims in labels and advertisements. Id. TTB also explained that it had forwarded the petition and exhibits to FDA, citing its regulatory authority to consult with that agency as to health claims on alcohol labels. Id. at 1497–98. Several months later, Bellion supplemented its petition. See AR 1375. TTB acknowledged receipt of the additional materials and notified Bellion that it would forward those to FDA for consideration as well. Id. at 1541–42.

Approximately a year after receiving the petition, TTB denied it with respect to each of the eight proposed health claims. See AR 1557–1603. It found that all of them fell both within the broader category of "health-related statements" and within the narrower category of "specific health claims." Id. at 1557. None, however, complied with the regulations governing either category. Id. at 1557–58. Summarizing its ruling, the agency explained that "the claims, including when viewed with the proposed disclaimer, do not comply with TTB regulations regarding the use of health-related statements or specific health claims" because they "are not adequately substantiated" and are "misleading . . . as to the serious health consequences of both moderate and heavy levels of consumption of alcohol beverages containing NTX." Id. at 1558. In addition, the agency found that the proposed claims implied that "drinking alcohol beverages infused with NTX" would "reduc[e] the risk of damage to the liver and . . . to the brain." AR 1575; see also AR 1576. It determined that such implication was — like the explicit claims

concerning DNA damage — misleading. See AR 1597. The 47-page letter went on to describe the agency's legal framework, the scope and nature of its consultation with FDA, the health risks of alcohol, its process for reviewing the eight claims, and its substantive analysis of them. See AR 1563–82. The parties do not deign to apprise the Court of the fate of Frank-Lin's COLAs, but the Court assumes they were likewise denied. See ECF No. 29 (Defendants' Cross-Motion for Summary Judgment) at 51 n.9 (noting that Frank-Lin Distillers did not "avail[] itself" of TTB's appeals process).

On November 27, 2017, Plaintiffs filed suit in this Court challenging TTB's decision. As mentioned, they take issue only with TTB's disposition as to two of the claims — those concerning the relationship between NTX and DNA damage. See ECF No. 16 (Amended Complaint), ¶ 1. They articulate four counts: first, that TTB's ruling on the two health claims at issue violates the First Amendment as an unconstitutional restriction on commercial speech; second, that TTB's regulatory scheme constitutes a prior restraint also in violation of the First Amendment; third, that TTB exceeded its statutory authority in consulting with FDA, thus running afoul of the Administrative Procedure Act; and, finally, that TTB's regulations are unconstitutionally vague. See ECF No. 16 (Am. Compl.), ¶¶ 71–110.

On June 12, 2018, Bellion moved to add extra-record evidence to the administrative record. See ECF No. 22 (Motion for Leave). Two months later, the Court denied the Motion. See Bellion Spirits, LLC v. United States, 335 F. Supp. 3d 32 (D.D.C. 2018). The parties have now cross-moved for summary judgment.

II. Legal Standard

The proper standard is the subject of dispute between the parties. They both agree, at least, that the Administrative Procedure Act provides the standard of review for Count III —

namely, the claim that TTB's consultation with FDA exceeded its statutory authority. See ECF No. 28 (Plaintiffs' Motion for Summary Judgment) at 15–16; Def. Cross-Motion at 16. Under the APA, courts must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, . . . contrary to constitutional right, . . . in excess of statutory jurisdiction, authority, or limitations, . . . [or] unsupported by substantial evidence[.]" 5 U.S.C. § 706(2). This is a "narrow" standard of review, under which "a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

The parties diverge, conversely, as to the proper standard of review for the constitutional claims — Counts I, II, and IV. As the Government points out, this Court has already weighed in on this issue, reasoning that, although "constitutional claims are typically reviewed *de novo*," that "does not mean the same thing in all contexts." Bellion Spirits, 335 F. Supp. 3d at 42. Rather, "'even in the First Amendment context,' a court must review certain agency 'factual finding[s] . . . under the ordinary (and deferential) substantial-evidence standard.'" Id. (quoting POM Wonderful, LLC v. FTC, 777 F.3d 478, 499 (D.C. Cir. 2015)); see also POM Wonderful, 777 F.3d at 499 ("Our precedents . . . call for reviewing the [agency's] factual finding of a deceptive claim under the ordinary (and deferential) substantial-evidence standard, even in the First Amendment context."). Looking forward, the Court concluded that "[w]hen the time comes, [it would] thus review *de novo* any question of constitutional law but . . . apply the substantial-evidence test and accord some deference to the agency's scientific and fact-bound determinations." Bellion Spirits, 335 F. Supp. 3d at 42.

That conclusion is compelled by D.C. Circuit precedent, and Bellion offers no rebuttal of that point here. Its standard-of-review arguments, in fact, pour old wine into new bottles.

Plaintiffs attempt to revisit this Court's prior decision, while scarcely acknowledging its existence or that of the controlling precedent on which it rests. Bellion's attachment of several exhibits to its summary-judgment Motion, moreover — some of which are not included in the record — appears to be a second, likewise unexplained effort to ignore the Court's past determinations. See Pl. Mot., Attachs. 2–17, 24–28, 36–40.

Plaintiffs resist all of these conclusions. They contend first that the Court "performs a *de novo* review of Bellion's constitutional claims." Pl. Mot. at 13 (citing Nat'l Oilseed Processors Ass'n v. Occupational Safety & Health Admin., 769 F.3d 1173, 1179 (D.C. Cir. 2014)). The decision Bellion cites, however, refers to questions of law and is one the Court considered in rendering its previous Opinion. See Bellion, 335 F. Supp. 3d at 42 (acknowledging that, "[a]s a general matter," constitutional claims are reviewed *de novo* but explaining that agencies nevertheless are afforded deference as to their factual findings) (citing Nat'l Oilseed Processors, 769 F.3d at 1179). Bellion's other citations are similarly unavailing because they, too, address when deference is appropriate to an agency's determinations about the law rather than as to its assessment of the facts. See Pl. Mot. at 13 (citing C-SPAN v. FCC, 545 F.3d 1051, 1054 (D.C. Cir. 2008); Cullman Regional Med. Ctr. v. Shalala, 945 F. Supp. 287, 293 (D.D.C. 1996)). It offers no rebuttal to the proposition that the Court — particularly when "face[d] [with] conflicting evidence at the frontiers of science" — rightly accords deference to the agency's factual findings. See Cellular Phone Task Force v. FCC, 205 F.3d 82, 90 (2d Cir. 2000); see also Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997) (reasoning that courts "review scientific judgments of the agency 'not as the chemist, biologist, or statistician that [they] are qualified neither by training nor experience to be, but as a reviewing court exercising [its]

narrowly defined duty of holding agencies to certain minimal standards of rationality'") (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976)).

Bellion protests further that *de novo* review is warranted here because "[d]eference is owed only for matters within the agency's expertise." Pl. Mot. at 14. TTB, Plaintiffs contend, has no such expertise here, since it disclaimed such knowledge on public-health issues in explaining its decision to consult with FDA. Id. at 15; see AR 1564, 1568. "Judicial deference to agency factfinding is inappropriate," Bellion concludes, "where the agency lacks expertise in the area." Pl. Mot. at 14.

As an initial matter, the cases Bellion cites on the significance of expertise again pertain to deference to agency legal interpretations, rather than factual determinations, which are at issue here. See Pl. Mot. at 14 (citing Pension Ben. Guar. Corp. v. LTV Corp., 496 U.S. 633, 651–52 (1990); Murphy Expl. & Prod. Co. v. Dep't of Interior, 252 F.3d 473, 479, op. modified on denial of reh'g sub nom. Murphy Expl. & Prod. Co. v. Dep't of Interior, 270 F.3d 957 (D.C. Cir. 2001); Springfield, Inc. v. Buckles, 116 F. Supp. 2d 85, 88 (D.D.C. 2000), aff'd, 292 F.3d 813 (D.C. Cir. 2002)). As to factual determinations, while agency expertise undoubtedly provides a basis for deference, see Troy Corp., 120 F.3d at 283, substantial-evidence review is not premised on its existence. Indeed, "even as to matters not requiring expertise[,] a court may [not] displace the [agency's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it *de novo*." Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951). The APA requires this standard of review, and it does not distinguish between situations where the agency has or lacks expertise. Bellion, likewise, has pointed to no authority making such a distinction. As a result, TTB's

acknowledgment — that, at least compared to FDA, it "is not an expert on public health issues," AR 1564 — does not alter the Court's analysis.

There is no need to rest there, however, as TTB did bring scientific expertise to bear on the questions before it. As discussed more below, see Section III.A, *infra*, TTB exercised its considered judgment in deciding how to characterize Bellion's petition, analyzing it given the particular health risks posed by alcohol, and reasoning — with FDA's assistance — about the credibility of scientific evidence. That TTB also availed itself of FDA's public-health expertise, moreover, does not suggest that FDA's findings and TTB's adoption of them are subject to *de novo* review. Rather, agencies are entitled to rely on the expertise of another agency without forgoing deferential review. See City of Boston Delegation v. FERC, 897 F.3d 241, 255 (D.C. Cir. 2018) ("Agencies can be expected to 'respect [the] views of such other agencies as to those problems' for which those 'other agencies are more directly responsible and more competent.'") (quoting City of Pittsburgh v. Fed. Power Comm'n, 237 F.2d 741, 754 (D.C. Cir. 1956)); id. at 254–55 (sustaining FERC's safety-related factual findings as supported by substantial evidence where it had consulted with Nuclear Regulatory Commission to conduct an "independent analysis"). Indeed, it would be strange if the fact of an agency's consultation with another expert body somehow divested TTB's opinion of expertise, thereby putting a court in the position of making complicated factual determinations in the first instance. This Court, consequently, has little trouble concluding that it will not review *de novo* either the factual findings of FDA — to the extent it reviews them — or, more to the point in this case, TTB's analysis and adoption of those findings.

III. Analysis

Bellion challenges TTB's decision on four fronts. They contend that it violates the First Amendment in two ways — as an unlawful restriction on commercial speech and as a prior restraint. See Pl. Mot. at 16, 31. It is also, they believe, unconstitutionally vague in violation of the Fifth Amendment. Id. at 41. Finally, Plaintiffs maintain that TTB exceeded its statutory authority — and violated the APA — in involving FDA in its evaluation of their petition. Id. at 35. The Court will begin with the statutory challenge. See POM Wonderful, LLC, 777 F.3d at 490 ("Per our usual practice, we first address petitioners' statutory challenges to the [agency's] order before turning to their constitutional claims.") (citation omitted). It will then address, in order, the two First Amendment issues before turning to the Fifth Amendment.

A. Statutory Authority to Involve FDA

Bellion argues, in sum, that "TTB's delegation of scientific fact-finding [to FDA] was *ultra vires* agency action in violation of the APA." Pl. Mot. at 35. They elaborate that, through the FAAA, "Congress delegated the regulation of alcohol beverage labeling exclusively to TTB." Id. Plaintiffs go on to suggest, seemingly, both that TTB could not involve FDA at all, id. at 35–37, and that, at the very least, TTB impermissibly rubber-stamped FDA's factual findings, "employ[ing] no procedures for review of [its] scientific conclusions." Id. at 38. Whichever way the Court tilts the wineglass, Bellion's vintage is wanting.

Plaintiffs are of course correct about the unremarkable proposition that agencies' power is circumscribed by statute. See La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986) ("[A]n agency . . . has no power to act . . . unless and until Congress confers power upon it."). The Secretary of Treasury has the authority to promulgate regulations to effect the FAAA's directives, including its prohibition on false and misleading advertising and labeling, and the

Court searches in vain here for the statutory command that TTB contravened or the limitation it exceeded in involving FDA in the evaluation of scientific evidence. The Act tasks the Secretary with prescribing certain regulations regarding advertising and labeling so that they comply with the Act's directives. See 27 U.S.C. §§ 202(f), 205(e), (f). Treasury has done so, and it issued the relevant decision here interpreting those regulations and their application to the instant petition. See AR 1603. In addition, TTB's regulations interpreting the FAAA explicitly contemplate consultation with FDA. See 27 CFR § 5.42(b)(8)(ii)(B)(1) ("TTB will consult with the [FDA], as needed, on the use of a specific health claim on a distilled spirits label.").

Bellion appears to hang its hat on the assertion that the regulation of alcohol has been delegated "exclusively to TTB," seemingly suggesting that the involvement of any other agency in any portion of TTB's decisionmaking is therefore contrary to the statute. See Pl. Mot. at 35 (emphasis added). They source this proposition, however, not in any statutory text, but rather in a single case from the Western District of Kentucky decided over fifty years ago. See Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976). That case held that FDA did not have "concurrent jurisdiction" with TTB — then the Bureau of Alcohol, Tobacco and Firearms — to regulate alcohol labeling. Id. at 12, 17. Yet, as noted, TTB issued the decision Bellion challenges here. See AR 1603. It did not cede concurrent jurisdiction to FDA to promulgate any ruling. Even if the Court were to follow the Brown-Forman decision as persuasive, therefore, its conclusion says little about whether TTB acted lawfully in submitting the issues it did to FDA before exercising its jurisdiction to make a final decision.

Not so fast, Plaintiffs say — the Court's methodology is corked. Rather than seek a statutory limitation that TTB exceeded in consulting FDA, the Court should assume TTB cannot engage FDA in its decisionmaking absent express statutory authority to do so. See Pl. Mot. at

36–37. In making this argument, Bellion relies on a series of cases that it contends stands for the proposition that "[a]fter Congress delegates authority to an agency, that agency is not permitted to subdelegate its decision-making power to an outside entity, unless the relevant statute so permits." Id. at 36–37 (citing U.S. Telecom Ass'n v. FCC, 359 F.3d 554, 566 (D.C. Cir. 2004); Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd., 29 F.3d 655, 671, amended, 38 F.3d 1224 (D.C. Cir. 1994); Assiniboine & Sioux Tribes of Fort Peck Indian Reservation v. Bd. of Oil & Gas Conservation of State of Montana, 792 F.2d 782, 795 (9th Cir. 1986); Nat'l Park & Conservation Ass'n v. Stanton, 54 F. Supp. 2d 7, 19 (D.D.C. 1999)).

Plaintiffs' argument on this score, however, suffers from a fundamental misunderstanding. Those cases address the permissibility of a delegation of final decisionmaking authority. That is not what occurred here. As discussed, TTB made the relevant decision, see AR 1572, 1579, 1603, following engagement with FDA. Bellion suggests that the Government's description of FDA's involvement as "consultation" is "semantic[s]." Pl. Mot. at 38; see also ECF No. 33 (Pl. Reply) at 38 ("TTB's delegation (however TTB semantically describes it) to FDA was *ultra vires*."). On the contrary, it rightly distinguishes TTB's seeking FDA's advice — what occurred here — from its entirely devolving final decisionmaking authority to FDA — an unlawful delegation, and what the cases Bellion cites discuss.

Review of the opinions on which Plaintiffs rely confirms the weakness of their challenge. For example, in U.S. Telecom, the D.C. Circuit held that the FCC had exceeded its statutory authority when it entirely outsourced the power to make certain "granular" determinations about market impairment to state commissions, without retaining the ability to review those decisions. See 359 F.3d at 564–66. By contrast, the court distinguished as permissible what TTB has done here — namely, agencies may "legitimate[ly]" seek "outside party input into the agency

decision-making process" in "fact gathering" and in "advice giving." Id. at 566; see also id. at 568 ("[A] federal agency may turn to an outside entity for advice and policy recommendations, provided the agency makes the final decisions itself."). Bellion's citation to Railway Labor Executives' Association is even further off the mark. There, the Circuit held that an agency could not assume that Congress had delegated authority to it not specifically enumerated by statute. Specifically, "the [agency's] position . . . amount[ed] to the bare suggestion that it possesses plenary authority to act within a given area simply because Congress ha[d] endowed it with some authority to act in that area" — believing that the statute authorized it to investigate certain labor disputes *sua sponte* because it was authorized to do so upon a party's petition. See Ry. Labor Executives' Ass'n, 29 F.3d at 670. TTB has done nothing of the kind in this case.

Plaintiffs' other two citations are equally inapplicable, since both involve the agency's abdication of a final decisionmaking prerogative. See Assiniboine & Sioux Tribes of Fort Peck Indian Reservation, 792 F.2d at 794 (invalidating scheme where "Secretary conduct[ed] no independent review of applications" in part because "it [was] impossible to reconcile this alleged rote approval of State Board orders with the strict standard of conduct expected of a trustee"); Nat'l Park & Conservation Ass'n, 54 F. Supp. 2d at 9–10, 19 (holding unlawful agency's "delegat[ion] [of] all its responsibilities for managing [a river] to an independent local counsel over which [the agency] ha[d] virtually no control" where agency was statutorily "responsible for overseeing the administration of the [river]").

The more coherent iteration of Plaintiffs' challenge to TTB's procedures is thus the second, less categorical one — *i.e.*, even if TTB's involvement of FDA was not an unlawful delegation, it at least retained impermissibly inadequate review procedures as to FDA's findings. In other words, the point appears to be that TTB was arbitrary and capricious in its adoption of

FDA's findings to the extent its decisions to do so were insufficiently reasoned. The Court, however, finds nothing irrational in TTB's treatment of FDA's findings.

Proceeding through Bellion's arguments makes this clear. They claim that TTB did not retain adequate procedures to review FDA's findings because TTB allowed FDA to apply its own food and dietary-supplement standards in evaluating the scientific evidence and because TTB adopted "without exception" all of FDA's conclusions. See Pl. Mot. at 38–40 (citing AR 1578, 1579, 1580, 1581, 1582, 1585, 1586, 1587–88, 1591–92); see also Pl. Reply at 40 (TTB approved "FDA's evaluation with only vague and inadequate assertions of final review authority" because "FDA's review was intended to be the only review of scientific evidence."). Plaintiffs contend that the latter point forecloses the argument that TTB made the final decision, since its "rubber-stamping" of FDA's work is "*prima facie* evidence" that it did nothing of the kind. See Pl. Mot. at 39–40.

As an initial matter, TTB's action in this case can hardly be described as rubber-stamping. It decided how to construe the petition and Bellion's claims. See AR 1557–1558; 1572–78 (classifying the proposed claims as health-related statements and as specific health claims). It elaborated and relied on its expertise regarding the risks of alcohol consumption. See AR 1567–71 (recounting the findings and regulatory background for TTB's treatment of alcohol and associated health risks). TTB made findings regarding misleadingness. See AR 1598. It assessed the sufficiency of the disclaimer that Bellion proposed. See AR 1598–99. And, of course, TTB ultimately rendered the 47-page decision, see AR 1603, in accordance with its regulatory framework, rather than FDA's. See AR 1572–1573; compare 27 CFR § 5.42(b)(8)(ii)(B)(2) (TTB regulation on specific health claims), with 21 CFR § 101.14(c) (FDA regulation regarding health claims).

As to TTB's treatment specifically of FDA's findings, it did adopt FDA's factual determinations about the reliability of Bellion's studies, the very issue on which it sought FDA's expertise. See AR 1588–1591; see also AR 1579 ("TTB requested a consultation from FDA on the scientific and medical evidence submitted by petitioners."); AR 1580 ("[TTB] ask[ed] for FDA's views on whether the scientific data submitted in the petition, including the exhibits in the Petition Supplement, adequately substantiate the proposed claims set forth in the petition."). It explained why those determinations were, in its view, apposite to the analysis of Bellion's petition, and it enumerated why it agreed with each finding it adopted. See AR 1581 ("The criteria articulated in FDA's guidance and regulations are relevant in determining whether a specific health claim is 'truthful and adequately substantiated by scientific or medical evidence,' within the meaning of the applicable TTB regulations, because those criteria provide a systematic and science-based approach to assess whether the evidence in support of a specific health claim actually substantiates it."); AR 1582–1598 (reviewing systematically FDA's analysis of each study and explaining TTB's agreement). In doing so, TTB did nothing more than permissibly "'respect [the] views of such other agencies as to those problems' for which those 'other agencies are more directly responsible and more competent.'" City of Boston, 897 F.3d at 255 (quoting City of Pittsburgh, 237 F.2d at 754). Bellion highlights no irrationality — and the Court finds none — in the reliance on FDA in this regard.

Plaintiffs' contention that TTB "may [not] rely on consultants in [this] manner" is also unavailing. See Pl. Mot. at 40 (citing State of Idaho By & Through Idaho Pub. Utilities Comm'n v. ICC, 35 F.3d 585, 596 (D.C. Cir. 1994)). Indeed, State of Idaho illustrates why TTB's consulting with FDA was permissible here. In that case, the D.C. Circuit invalidated the Interstate Commerce Commission's decision to forgo a required set of environmental-impact

determinations in favor of asking various other state and federal agencies to make their own. See State of Idaho, 35 F.3d at 595–96. By contrast, TTB — albeit while according significant weight to FDA's assessment of the particular studies — performed its own assessment of Plaintiffs' claims under its regulatory framework.

Bellion also protests that TTB adopted FDA's standards for assessing evidence, see Pl. Mot at 39 (citing AR 1581), although they do not suggest that the two agencies' standards are in conflict. Plaintiffs are not entirely correct that the agency adopted FDA's guidelines. In fact, TTB requested that FDA evaluate evidence that FDA otherwise would have excluded from consideration under its own standards. See AR 1584. More to the point, to the extent the FDA standards in question pertain to assessing the credibility of scientific evidence, reliance on those standards seems necessarily entailed in consulting FDA on whether the studies at issue are reliable. Cf. AR 1580 ("[TTB] ask[ed] for FDA's views on whether the scientific data submitted in the petition, including the exhibits in the Petition Supplement, adequately substantiate the proposed claims set forth in the petition."). As discussed, the consultation was permissible. The FDA's standards need not — nor could they obviously — be excised from that analysis.

Given that the Court finds that TTB's involvement of FDA was permissible and not *ultra vires*, it will grant the Government summary judgment on the APA count.

B. First Amendment: Restriction on Commercial Speech

Plaintiffs next assail TTB's decision as an unconstitutional restriction of commercial speech. See Pl. Mot. at 16. The parties do not dispute here that the speech at issue is properly regarded as commercial, nor that the agency's disposition suppressed Bellion's expression. Id. at 17; Def. Mot. at 30; cf. Rubin v. Coors Brewing Co., 514 U.S. 476, 481 (1995) ("[T]he information on beer labels constitutes commercial speech."). As a result — and both Plaintiffs

and Defendants agree on this as well — the Supreme Court's four-part framework for analyzing regulation of commercial speech governs here. See Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980). The Court there announced that, "[a]t the outset," "[it had to] determine whether the expression was protected by the First Amendment," since — to "come within" its protection at all — the speech "at least must concern lawful activity and not be misleading." Id. at 566; see also In re R.M.J., 455 U.S. 191, 203 & n.15 (1982) (holding that misleading commercial speech "may be prohibited entirely"). If the speech at issue passes the first hurdle of not being inherently misleading, a court moves to the second inquiry — namely, "whether the asserted governmental interest is substantial." Central Hudson, 447 U.S. at 566. The third and fourth parts of the inquiry are "whether the regulation directly advances the governmental interest asserted" and then "whether it is not more extensive than necessary to serve that interest." Id.

This test reflects the Court's conclusion that "[t]he Constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression," an outgrowth of "the commonsense distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech." Id. at 562–63 (internal quotation marks and citation omitted). Since Central Hudson, the Court has elaborated on its requirements. Where commercial speech is not inherently misleading, it has directed that requiring a disclaimer to cure potential confusion is generally less restrictive than banning the speech in question outright. As a result, mandating a disclaimer is more likely to comply with the fourth prong than is a blanket ban. See Pearson v. Shalala, 164 F.3d 650, 658 (D.C. Cir. 1999) ("It is clear, then, that when government chooses a policy of suppression over disclosure — at least where there is no showing that disclosure would not

suffice to cure misleadingness — government disregards a 'far less restrictive' means."); cf. 27 C.F.R. § 5.42(b)(8)(ii)(A) (explaining that "TTB will evaluate [health-related statements] on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement").

Bellion contends that both of its health claims are truthful and that TTB's suppression of them fails scrutiny under Central Hudson, particularly where permitting a disclaimer to cure potential misleadingness would have been less restrictive. See Pl. Mot. at 20, 27, 30–31. The Government rejoins that Bellion cannot even get the bottle opened because the proposed claims are inherently misleading and therefore can be banned outright with no constitutional problem. See Def. Mot. at 31. In the alternative, it argues that the restriction satisfies Central Hudson. Id. The Court agrees with TTB on both scores. The agency reasonably determined that Bellion's proposed claims are misleading; that alone is sufficient to render its decision lawful. Even were that not the case, however, its restrictions here pass constitutional scrutiny. Before moving through those two points in order, some framing is necessary.

In evaluating misleadingness, the Court does not start with a blank slate. As explained above, it accords deference to an agency's factual findings, even in the context of a constitutional challenge. To the extent TTB was permitted to rely on FDA's expertise, its treatment of those findings is likewise subject to deferential — rather than *de novo* — review. And the determinations here that Plaintiffs' proposed claims are misleading are indeed factual — not legal — ones. That is so even though their truth or falsity is dispositive in the first prong of the Central Hudson test. See POM Wonderful, 777 F.3d at 499–500 (treating similar agency determination challenged on First Amendment grounds as factual one entitled to deference); see

also Kraft, Inc. v. FTC, 970 F.2d 311, 317 (7th Cir. 1992) (observing that, in First Amendment challenge to restrictions on advertising agency found to be deceptive, "[w]hile it could be posited that it is counter-intuitive to grant more deference to the Commission than to courts, Commission findings are well-suited to deferential review because they may require resolution of exceedingly complex and technical factual issues") (internal quotation marks and citation omitted).

Plaintiffs' briefing puzzlingly reflects no recognition of this framework for review of TTB's decision. Its lack of acknowledgment makes especially little sense here since the Court has already explained precisely how it would evaluate these claims when they returned on summary judgment. See Bellion Spirits, 335 F. Supp. 3d at 42 ("When the time comes, the Court will thus review *de novo* any question of constitutional law but . . . apply the substantial-evidence test and accord some deference to the agency's scientific and fact-bound determinations.").

Bellion's argument rather invites the Court to take a fresh look at the evidence that they presented to the agency. They recount — in great detail — the features of several of their studies. See, e.g., Pl. Mot. at 20–25. They also cite a great deal of extra-record evidence in support, without noting either that it does not appear in the record or that the Court already held it would not allow supplementation or consider such material. Id. at 21; Bellion Spirits, 335 F. Supp. 3d at 36. Noticeably sparse in its analysis, however, is any defect identified with TTB's decision — for example, some contrary evidence in the record that the agency ignored, some irrationality in its analysis, or some reasoning it neglected to adequately explain. This understanding frames the discussion that follows.

1. *Misleadingness*

TTB found that "the proposed claims about alcohol beverages infused with NTX are explicit and implicit specific health claims that are not supported by credible evidence," which "create[d] a misleading impression that consumption of alcohol beverages infused with NTX will protect consumers from certain serious health risks associated with both moderate and heavy levels of alcohol consumption." AR 1557 (internal quotation marks omitted). In addition, the agency determined that the proposed claims also implied that "drinking alcohol beverages infused with NTX" would "reduc[e] the risk of damage to the liver and . . . to the brain." AR 1575; see also AR 1576. That implication was likewise determined to be misleading. In other words, the agency made essentially two findings in this respect: first, that the explicit claims Bellion sought to make were misleading; and second, that a set of implied claims arose from those explicit claims and was also misleading.

TTB reached those conclusions by examining — with involvement from FDA — the evidence Bellion submitted. It found Plaintiffs' studies offered in support of its explicit claims about DNA damage and regarding the health benefits of NTX not to be credible after systematically reviewing, analyzing, and adopting FDA's conclusions about that evidence. See AR 1582–1588. Between its original petition and supplement, Bellion submitted "a total of 112 articles or studies." Id. at 1582. Although FDA generally would have eliminated 106 of them from "further evaluation . . . for one or more reasons" relating to a credibility defect clear from the face of the study — for example, that "the studies were conducted on animals or *in vitro*," concerned only a component of NTX rather than the compound, or concerned neither NTX nor its components — TTB, "out of an abundance of caution, . . . asked FDA to review studies that included only a single ingredient of NTX, if those studies were not otherwise excluded by FDA's

criteria." AR 1582–84. Following that request, FDA included one additional study in its consideration but ultimately concluded it was not relevant. See AR 1584. (For the sake of brevity, the Court does not discuss in great detail the basis for this finding, which is set out in the decision letter and not specifically challenged by Bellion here.)

Six studies remain. The first, which both Plaintiffs and the Government refer to as the first Pandit study, did not include information about study design or its subjects. Agreeing that the study could not therefore "provide scientific or medical evidence that would adequately substantiate the proposed claims," TTB adopted FDA's findings to exclude it. See AR 1586–87. That leaves five — which really are four, since one set represented essentially a duplicate. See AR 1587. None of the four studies — including what Plaintiffs refer to as the first and second Chigurupati studies and describe as "the gold standard of the scientific community," Pl. Reply at 11 — "include[d] information about the dosage of NTX consumed by the study subjects, which would be necessary for TTB to evaluate whether the studies adequately substantiate the proposed claims." AR 1588. (The Government refers to the first and second Chigurupati studies as the Pandit study, not to be confused with "the first Pandit study," and the Nobel study, respectively.) The failure to include dosage information was a "shortcoming" that alone "[made] it impossible to draw any 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. The agency adopted a number of additional findings regarding the specific studies, including that the first Chigurupati (or Pandit) study "show[ed] a significant reduction in certain measures of DNA damage at some but not all time points after administration of NTX" and that the second Chigurupati (or Nobel) study "show[ed] no effect on protecting DNA." AR 1596.

In addition, TTB found the proposed claims misleading to the extent they make an implicit claim that NTX infusion will benefit brain and liver health. That implication is the product of the petition's linking of alcohol-induced DNA damage to brain damage and liver disorders. See AR 1575–76. But those implicit claims, TTB determined, were unsubstantiated. It adopted FDA's reasoning that the studies did not "purport to assess long-term effects" of consuming alcohol infused with NTX. See AR 1597. Because "alcohol-induced liver damage generally results from long-term, heavy consumption of alcohol," the unsupported "implication [was] that NTX will have the long-term effect of protecting DNA from alcohol-induced damage and reducing alcohol-induced DNA damage in a way that meaningfully protects consumers from alcohol-induced liver and brain damage." Id.

The foregoing analysis is adequately reasoned, and TTB did not neglect to account for contrary evidence in the record. Plaintiffs do not, however, agree with that assessment. Invoking Einstein, they "caution[]" that "[t]he scientific theorist is not to be envied" because "Nature . . . never says 'Yes' to a theory" but rather in "the most favorable cases says Maybe." Pl. Mot. at 29 (quoting Albert Einstein: The Human Side: New Glimpses from His Archives, Note Dates Nov. 11, 1922, at 18 (1979)). Given the agency's careful, nearly 50-page analysis, the Court is not willing to throw up its hands and suggest that the answer to the pertinent question — whether or not the proposed claims are substantiated and therefore comply with TTB regulations — is unknowable. For the same reason, it does not share Bellion's concern that affirming the agency's findings will "allow government to censor scientific speech simply because an agency disagrees with scientific conclusions," rendering "First Amendment speech . . . capped at the boundaries of state-sponsored orthodoxy." Pl. Reply at 17. TTB's

determinations were, as the foregoing analysis makes clear, measurably more considered than that.

Bellion also levels a number of additional attacks on the agency's work — facially more promising due to their specificity — which the Court will take in turn. None of them is, however, ultimately persuasive. First, Plaintiffs fault TTB for its treatment of various pieces of, or sets of, evidence. In their view, it did "not even attempt to explain" why some sets of studies "were outright ignored," Pl. Reply at 13, and they disagree with the agency's treatment of others. Specifically, Bellion highlights a set of studies it believes was unreasonably excluded because it did not have human data but did appear "in peer-reviewed literature." Id.; see also Pl. Mot. at 20, 29 (arguing that animal and *in vitro* studies were rejected for "circular" reasons). They contend that the exclusion is a product of TTB's arbitrary adoption of FDA's framework for assessing the evidence and its failure to instruct FDA on the differences between the two regulatory schemes, particularly where "alcohol-related studies raise different concerns than those of foods and dietary supplements." Pl. Reply at 13–15. Finally, Bellion argues that TTB improperly ignored dosage information in the first and second Chigurupati (Pandit and Nobel) studies. Id. at 16.

Taking the first of these first, the agency reasoned extensively about why animal and *in vitro* studies were not sufficiently reliable in this context to be considered. Although Bellion contends that they — or at least some of them — were peer reviewed, there is no reason to believe that is the only criterion for credibility here. Indeed, TTB's findings on this issue lay out an unrelated rationale for exclusion — one concerning not whether the studies themselves are reliable in some sense, but whether they can be used to make determinations about NTX's effect on humans. The agency concluded that reliance on FDA guidance on this subject was

reasonable. See AR1585. That guidance suggests that, while "animal and *in vitro* studies [can be used] as background information regarding mechanisms that might be involved in any relationship between the substance and the disease," the "physiology of animals is different from that of humans." Id. In addition, "[*i*]*n vitro* studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to consumption of foods and dietary substances." Id. As a result, while they may therefore be useful to "generate hypotheses, or to explore a mechanism," "these studies do not provide information from which scientific conclusions can be drawn regarding a relationship between the substance and disease in humans." Id.

Bellion does not dispute these conclusions directly, much less contend that they are not, at the very least, reasonable. In addition, the path of this analysis demonstrates that TTB did not — as Plaintiffs postulate — improperly rely on FDA's standards. None of the reasons that the studies lack credibility in this context is specific to food, as Bellion seems to suggest. Rather, the FDA guidance in question "provide[s] a systematic and science-based approach to assess whether the evidence in support of a specific health claim actually substantiates it." AR 1581. They have to do with the differences in biological mechanisms in humans, in animals, and *in vitro*. Bellion provides no rationale — and the Court can generate none — that would suggest that TTB was unreasonable in concluding that these concerns are appropriately applicable to the alcohol context as well.

Bellion's arguments regarding the dosage information in the first and second Chigurupati (Pandit and Nobel) studies require less ink. As to the first, they do not contend either that such material was in fact in the studies or that they could nevertheless be credible without it. See Pl.

Reply at 5 ("It is true . . . that [dosage] information was not included within the four corners of the study write-up."). Rather, they explain that "TTB had actual knowledge of Bellion's formula and the dosage of component ingredients because Bellion submitted its formula to TTB in connection with its [COLAs]" and attach to their reply brief those applications. Id. The Court has no way to evaluate whether the agency indeed could have reliably pieced together this information from the material it had or not. In addition, although there is no mention of this in the briefing, it appears to the Court that knowledge of Bellion's formula would not necessarily resolve the problem TTB highlighted in the studies — namely, that there was no information about the quantity of NTX consumed in the studies relative to "the quantities in which such an ingredient would be allowed in" Bellion's vodka. See AR 1588. More important here, however, is the fact that Plaintiffs do not locate the material they believe relevant anywhere in the record; that, presumably, is why they submit the COLAs with their reply brief. The Court will not consider information that was not in "[the record] before the agency." Bellion Spirits, 335 F. Supp. 3d at 42. Without that dosage information, TTB's determination that those studies were not reliable as a consequence makes eminent sense.

Plaintiffs' next salvo is simpler. They maintain that TTB's conclusion that the studies are not credible and the claims unsubstantiated is not the same as finding the claims misleading or false. They also argue that there is evidence supporting the proposed claims but that TTB has adduced no evidence to the contrary, so that the agency had no support for finding them false *per se*. See Pl. Reply at 18 ("It is literally true that peer-reviewed scientific publications have found that Bellion's product protects against alcohol-induced DNA damage, and it is literally true that no scientific evidence exists to contradict those studies.") (citing AR 77–81, 210–211). Neither iteration of the point carries the day.

The reason is similar as to both. In adjudicating whether a product generally threatening to human health confers some biological benefit, it is reasonable to conclude that absence of evidence supporting the existence of a benefit leaves only the background, well-supported assumption that the product is harmful. See AR 1567–1572 (recounting in decision letter TTB's extensive findings on the risks associated with alcohol consumption); see also Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 Fed. Reg. 10,076, 10,080, 10,084, 10,100 (2003) (recounting that alcohol accounts for "the deaths of more than 100,000 Americans each year" and in some cases is responsible for "social and psychological problems, cirrhosis of the liver, inflammation of the pancreas, and damage to the brain and heart"). In that context, insufficient evidence of a benefit is rationally related to the conclusion that any claims about salutary health effects are misleading.

Even in cases where the agency had not made findings that the product at issue generally threatened consumer health, the D.C. Circuit has upheld the determination that advertising claims were deceptive — *viz.*, misleading — because they were based on insufficient evidence of their credibility. See POM Wonderful, 777 F.3d at 500 ("At the time, there was insufficient support for an unqualified efficacy claim of a link between daily consumption of pomegranate juice and prevention of heart disease," and "[a]s a result, . . . the Commission sanctioned petitioners for misleading speech unprotected by the First Amendment."). In Pearson, too — a case on which Plaintiffs significantly rely — the Circuit reasoned that a claim could be prohibited as misleading "where [the] evidence in support . . . is outweighed by evidence against" or where a claim "rests on only one or two old studies." 164 F.3d at 659 & n.10; see also Alliance for Natural Health US v. Sebelius, 786 F. Supp. 2d 1, 14 (D.D.C. 2011) ("[T]he clear implication of the language of Pearson . . . is that unsupported or very weakly supported

claims may simply be banned outright."). TTB need not, similarly, adduce any evidence contrary to Bellion's claims to support its findings of misleadingness.

Finally, Plaintiffs argue that the agency did not reasonably conclude that the proposed claims created any implication about liver and brain health. Without surveys of consumers, TTB in their view was bereft of a "factual basis" besides "whim or caprice" to support a finding of claim implication. See Pl. Mot. at 26. Because no claim was implied at all, Plaintiffs argue, there cannot be any misleading one.

As an initial matter, the Court notes that it need not uphold TTB's findings as to the claim implication to hold that it reasonably ruled Bellion's proposed claims misleading. That is because the agency's determination that Bellion's studies do not substantiate its proposed explicit claims is an independent basis to conclude that they are misleading. While the APA mandates that an agency adequately and reasonably explain itself in every regard — not just those that might be necessary to its ultimate decision — the Court need only decide here whether the agency had a basis to reasonably conclude that the claims are not truthful. That much is clear from the agency's findings that Bellion's evidence in support of claims 7 and 8 is not credible. It is ultimately unimportant here, however, since the agency also reasonably explained the basis for its determination about claim implication.

Bellion mounts its challenge on this score without engaging with the agency's reasoning on this issue. TTB found that proposed claims 7 and 8 imply that NTX offers benefits for liver and brain health because of the link Plaintiffs sought to draw between damage to DNA and negative effects on the brain and liver. See AR 1575–76, 1597. Specifically, it referred to portions of Bellion's petition that sought to show that alcohol-induced DNA damage results in "brain damage" and a variety of "liver disorders." See AR 1575–76 (citing AR 19–20, 27).

While Bellion's framing of its petition may be dispositive of its intent to imply a link between NTX's DNA-related benefits and benefits to the liver and brain, it admittedly does not fully resolve whether consumers will so perceive the claim and be misled as a result. TTB was, nevertheless, entitled to rely on "common sense and administrative experience" in making the conclusion that observers would draw such a conclusion — drawing together the idea that NTX would counteract ill-health effects from well-known consequences of alcohol consumption. See Kraft, 970 F.2d at 320. While TTB could have been clearer in drawing the relevant set of connections, the Court can discern the rationale. That is all that is required to sustain the conclusion here. See State Farm, 463 U.S. at 43 (courts "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned") (quoting Bowman Transp. Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 286 (1974)).

Plaintiffs highlight no authority for the proposition that consumer-survey evidence is talismanic as they suggest. While some evidence of consumer perception may have been helpful or bolstered the agency's conclusion, TTB's decision on this score was not deficient for want of it. See Kraft, 970 F.2d at 319–20 ("[I]mplied claims fall on a continuum, ranging from the obvious to the barely discernible" and while the "Commission does not have license to go on a fishing expedition to pin liability on advertisers for barely imaginable claims falling at the end of this spectrum[,] . . . when confronted with claims that are implied, yet conspicuous, extrinsic evidence is unnecessary because common sense and administrative experience provide the Commission with adequate tools to makes its findings.").

* * *

In light of the foregoing, the Court finds there is no basis to disturb TTB's decision that the proposed claims are misleading. As a result, they may — consistent with the First

Amendment — be prohibited outright. No further analysis is necessary. See Central Hudson, 447 U.S. at 566; see also In re R.M.J., 455 U.S. at 203 & n.15. Nevertheless, in an abundance of caution, the Court will examine whether — if subjected to scrutiny under Central Hudson — TTB's prohibition is still constitutional. It has little trouble determining that it is.

2. *Central-Hudson Scrutiny*

Even if Bellion's proposed claims are not inherently misleading, they are at the very least potentially so. To remind the reader, commercial speech that is only potentially misleading cannot necessarily be prohibited outright consistent with the First Amendment. Rather, there remains a three-part inquiry. The first part is "whether the asserted governmental interest is substantial." Central Hudson, 447 U.S. at 566. The Court must next determine "whether the regulation directly advances the governmental interest asserted" and, finally, "whether it is not more extensive than is necessary to serve that interest." Id. Protection of health and prevention of consumer fraud are undoubtedly substantial government interests. See Pearson, 164 F.3d at 655–56 (reasoning that "protection of public health and prevention of consumer fraud" are "undeniabl[y]" substantial interests) (citing Rubin, 514 U.S. at 485; Edenfield v. Fane, 507 U.S. 761, 769 (1993)). This much Bellion does not take issue with. Indeed, Plaintiffs spend little time on Central-Hudson scrutiny in their briefing, directing their fire primarily at whether TTB permissibly found the proposed claims misleading. To the extent they mount challenges on this front, they do not quarrel with the substantiality of these interests. They do dispute whether TTB's decision directly advances the governmental interests and whether the prohibition is more extensive than necessary.

Starting with the former, Bellion contends that no interest is directly advanced here. Their reasoning is twofold. They believe that any harm to consumers is speculative so that there

is no material connection between denial of their petition and protection of public health. See Pl. Mot. at 30 (citing Rubin, 514 U.S. at 486–87). Rather, what is afoot is "TTB's censor[ship] [of] Bellion's health claims out of paternalistic speculation." Id. at 31. In addition, Plaintiffs argue that because alcohol is a large industry in the U.S. and because Bellion could sell alcohol even without attaching health claims to its products, consumers could still purchase and consume the same amount of alcohol no matter the disposition of its petition. That means, in their view, TTB's denial will not advance public health. See Pl. Reply at 21–22.

As a preliminary matter, all of these contentions dispute the link between TTB's action and the advancement of consumer health. But prevention of consumer fraud is a substantial interest in its own right, see Pearson, 164 F.3d at 655–56, and there is no question that the denial of Bellion's petition directly advances that interest here. Denying the petition is directly linked to the prevention of potential consumer deception. The advancement of more than one interest is not necessary.

The agency's action does, nevertheless, also directly promote its interest in health. The arguments to the contrary are small beer. The potential harm to consumers at issue here is not notional or based on some paternalistic speculation. Rather, TTB has extensively documented the health risks of alcohol consumption. See AR 1567–1572; Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 Fed. Reg. 10,076, 10,084, 10,100 (2003). It is no unsubstantiated leap to believe that if consumers come to think that a certain alcoholic beverage has health benefits, they may consume more without regard to the risk. For the same reason, preventing Bellion from labeling and advertising its product to promote its biological benefits is directly connected to the Government's interest in promoting health, even where consumers will undoubtedly continue to consume alcohol.

Rubin is not to the contrary. There, the Court reasoned that the government may not simply "speculat[e]" that its restriction of speech will advance its interest and struck down an "overall irrational[] . . . scheme" requiring disclosure of alcohol content on labels. See 514 U.S. at 487–88. The interest there was in "suppress[ion] [of the]" so-called "strength wars" — competition between alcohol producers to put the most potent beverages on the market. Id. at 487–88. The Court found obvious potholes in the road between the interest asserted and the regulation to achieve it because, among other things, the regulatory scheme allowed purveyors to still convey alcohol content in advertising — if not on labels — and to describe on labels the beverage strength in descriptive — if not percentage-based — terms. Id. at 488–89. There is no such defect in the directness of reasoning here.

Bellion makes one final — though brief — argument about why TTB has not directly advanced any interest here. It has, in Plaintiffs' view, a discriminatory enforcement problem. See Pl. Reply at 23 & n.12. Bellion believes that because TTB has allowed other health-related claims on vodka — for example, advertisement of protein content on one brand — it cannot be the case that inclusion in advertising or labeling of "alcohol-related health claims will encourage greater consumption of alcohol." Id. at 23. Plaintiffs cite no evidence to support their claim of discriminatory enforcement except a website titled, perhaps appropriately, "Questionable Health Claims by Alcohol Companies." Id. at 23 n.12. The Court cannot assess the appropriateness or consistency of TTB's other enforcement decisions based on Bellion's representation of a claim another company sought to make — which may or may not be analogous to its own claims — while lacking the agency's reasoning for its disposition there.

Plaintiffs reserve some energy for the second question of whether the agency's prohibition is more extensive than necessary. Here, they make two related points. They rely on

Pearson, contending that requiring a disclaimer would have been a less restrictive alternative course of action. Next, to the extent TTB considered and rejected Bellion's proposed disclaimer here, they maintain that Pearson requires the agency to consider any possible disclaimers, generating and rejecting many — if not every — potential iteration to demonstrate that such a course would not be possible at all. See Pl. Mot. at 18, 28–29; Pl. Reply at 28.

Pearson offers little. There, the agency had "unequivocally rejected the notion of requiring disclaimers to cure misleading health claims for dietary supplements" and "refuse[d] to entertain a disclaimer requirement for the proposed health claims." 164 F.3d at 655 (internal quotation marks omitted). TTB has done nothing of the sort here. It routinely considers whether disclaimers can cure misleadingness and, in contrast to the FDA in Pearson, has memorialized that practice in its regulations. See 27 C.F.R. § 5.42(b)(8)(ii)(A) (explaining that "TTB will evaluate [health-related statements] on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement").

In this case, TTB reasonably rejected Bellion's proposed disclaimer as failing to cure the potential for its claims to mislead. Specifically, it explained that "the disclaimer that the petitioners have put forward does not cure the misleading nature of the proposed claims or adequately address the requirements for qualifying language that must be present for specific health claims" because it promotes the conception that "infusion of NTX in alcohol beverages . . . protects consumers from the numerous and real health risks associated with alcohol consumption" rather than conveying any "qualif[ication] [of] the proposed claims." AR 1599.

The agency need not have generated and rejected many possible disclaimers, let alone every one. Pearson does not, as Bellion contends, stand for that proposition. It instead makes the more limited point that an agency cannot, consistent with the First Amendment, refuse to consider disclaimers at all as possible less restrictive alternatives to prohibitions on speech. But to go further and require that an agency necessarily generate and systematically review any possible disclaimer runs afoul of the principle that there need only be a reasonable fit between the Government's interest and its regulation. The agency need not adopt the "least restrictive means" of advancing its goal. See Bd. of Trustees of the State Univ. of New York v. Fox, 492 U.S. 469, 480 (1989); see also Spirit Airlines, Inc. v. Dep't of Transp., 687 F.3d 403, 415 (D.C. Cir. 2012) (explaining court need only determine "whether the fit between the government's ends and the means chosen to accomplish those ends 'is not necessarily perfect, but reasonable'") (quoting Pearson, 164 F.3d at 656). In the absence of a disclaimer that would sufficiently qualify Bellion's claims, TTB reasonably chose to prohibit them. Pearson does not require more legwork. This Court, too, thus can proceed no further.

C. First Amendment: Prior Restraint

Bellion next contends that TTB's regulatory scheme constitutes an unconstitutional prior restraint. See Pl. Mot. at 31. A law acts as a prior restraint when it mandates that a speaker seek government permission before engaging in protected expression. See City of Lakewood v. Plain Dealer Pub. Co., 486 U.S. 750, 757 (1988); Near v. State of Minnesota ex rel. Oregon, 283 U.S. 697, 713 (1931). Prior restraints are suspect as a First Amendment matter because they involve "the danger of censorship and abridgment of . . . precious . . . freedoms" of speech and expression in contexts "where officials have unbridled discretion over a forum's use." Se. Promotions, Ltd. v. Conrad, 420 U.S. 546, 553 (1975); see also id. at 558–59 ("The presumption

against prior restraints is heavier — and the degree of protection broader — than that against limits on expression imposed by criminal penalties" because "a free society prefers to punish the few who abuse rights of speech after they break the law than to throttle them and all others beforehand."); City of Lakewood, 486 U.S. at 772 ("We hold those portions of the Lakewood ordinance giving the mayor unfettered discretion to deny a permit application and unbounded authority to condition the permit on any additional terms he deems 'necessary and reasonable,' to be unconstitutional."). Any prior restraint, therefore, bears "a heavy presumption against its constitutional validity." Se. Promotions, 420 U.S. at 558 (citations omitted). It will "avoid[] constitutional infirmity only if it takes place under procedural safeguards designed to obviate the dangers of a censorship system." Id. at 559 (internal quotation marks and citation omitted). Specifically, only "narrow, objective, and definite standards" can cure the problem of unfettered discretion that characterizes prior restraints. See Shuttlesworth v. City of Birmingham, Ala., 394 U.S. 147, 151 (1969); see also Se. Promotions, 420 U.S. at 553.

Although Bellion is not particularly specific about the aspects of TTB's regulatory scheme it believes impermissible, the Court assumes that they must be challenging the COLA process — the procedure requiring pre-approval for, *inter alia*, health-related claims on alcohol labels. See 27 U.S.C. § 205(e); 27 C.F.R. § 13.21(a); 27 C.F.R. § 5.55(a). No other aspect of TTB's procedures requires any kind of advance permission; claims in alcohol advertising, for instance, are not subject to any kind of pre-approval. See 27 U.S.C. § 205(f); 27 C.F.R. § 70.471(a) (allowing, but not requiring, "[a]ny person who is in doubt as to any matter arising in connection with the [FAAA]" to "request a ruling thereon by addressing a letter to the appropriate TTB officer").

At the outset, the Government disputes that Bellion "can bring a prior restraint challenge here" at all since they "did not actually go through [the COLA] process." Def. Mot. at 45–46. Rather, "a separate entity, Frank-Lin Distillers, did." Id. at 45. That appears to be true. See AR 6 (describing Frank-Lin Distillers as the COLA "applicant"). Neither the Government nor Plaintiffs clarify what relationship, if any, exists between Frank-Lin Distillers and any party in this case. Indeed, Bellion never mentions Frank-Lin Distillers in any of its briefing. Defendants, likewise, do not explain what consequences they believe follow from this fact. The Court assumes that they are gesturing at a standing defect.

If that is so, it is not an obstacle to Plaintiffs' raising a prior-restraint challenge here. The Government appears to recognize that, since it devotes only half a paragraph to this issue. See Def. Mot. at 45. Bellion's position — both in its petition to TTB and in its Complaint in this Court — is that the COLA process is inadequate to ensure meaningful review of proposed health-related claims. See AR 14–16; Am. Compl., ¶ 83; see also Pl. Mot. at 33 (pressing this contention). Perhaps as a result, Bellion submitted additional evidence with its petition to TTB that it intended would supplement Frank-Lin's COLA; the agency apparently considered it a supplement. See Def. Mot. at 50 (citing AR 2126, 2128–29). Assuming the merit of Plaintiffs' allegations that the inadequacy of the COLA process required them to submit additional materials in conjunction with Frank-Lin to ensure meaningful review of applications that were ultimately rejected to Bellion's detriment, see Muir v. Navy Fed. Credit Union, 529 F.3d 1100, 1105 (D.C. Cir. 2008), there is no standing defect to prevent them from challenging a feature of the COLA process.

Moving past standing, Bellion levels challenges to the relevant process principally on two fronts. They contend, first, that the regulatory requirement that specific health claims on labels

be "adequately substantiated by scientific or medical evidence" is so vague and unconstrained by objective criteria that it confers upon the agency limitless discretion to censor. See Pl. Reply at 33, 35 (citing 27 C.F.R. § 5.42(b)(8)(ii)(B)(2)). Second, Plaintiffs argue that there is no timeframe by which the agency must respond to petitions for pre-approval — or indeed any requirement that it respond to a petition at all — an additional dimension on which TTB has an impermissible amount of discretion. Id. at 31, 34. These arguments overlap significantly with Plaintiffs' Fifth Amendment vagueness claim. Although the D.C. Circuit has, in the past, declined to analyze as not properly presented a prior-restraint argument where it amounted to a reiteration of a vagueness claim, see Pearson, 164 F.3d at 660, this Court will — in the interest of caution — address it as a distinct challenge to TTB's action here.

As an initial matter, it seems reasonably clear that the prior-restraint doctrine does not even apply to commercial speech. The D.C. Circuit has not yet weighed in on this issue. See Pearson, 164 F.3d at 660 & n.11 (declining to "decide whether prior restraint analysis applies to commercial speech"). But it has acknowledged that the Supreme Court has plainly "suggest[ed]" that it would not have any application in that context. Id. at n.11 (citing Central Hudson, 447 U.S. at 571 n.13).

The Court in Central Hudson reasoned that a "system of prereviewing advertising campaigns to insure that they" accorded with government policy would be a possible constitutional alternative to the restrictions on advertising challenged in that case. See Central Hudson, 447 U.S. at 571 & n.13. It explained further that such a scheme could be permissible because "commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it." Id. at 571 n.13 (citing Va. Pharmacy Bd. v. Va. Citizens Consumer Council, 425 U.S. 748, 771–72 n.24 (1976)); see also Zauderer v. Office of

Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 668 n.13 (1985) ("The Court previously has noted that, because traditional prior restraint principles do not fully apply to commercial speech, a State may require a system of previewing advertising campaigns to insure that they will not defeat state restrictions.") (citation and internal quotation marks omitted). In considering this language, the Sixth Circuit has observed that the Supreme Court has consistently declined to apply prior-restraint analysis to commercial speech and that there is "no authority" for the proposition that "regulation of commercial speech requires the strict scrutiny and presumption of constitutional invalidity afforded to laws effecting a prior restraint on protected non-commercial speech." Discount Tobacco & City Lottery, Inc. v. United States, 674 F.3d 509, 532 & n.7 (6th Cir. 2012).

The rationale for the reluctance to apply prior-restraint analysis to commercial speech is clear. The logic animating the doctrine applies with significantly less force, if at all, in this context for at least two reasons. First, commercial speech is "sturd[ier]" than other kinds of protected expression. See Central Hudson, 447 U.S. at 571 n.13. That is because it is typically motivated by profit or some other economic impetus. Second, the paradigmatic standards characterizing prior restraints generally involve amorphous benchmarks about public welfare or morality. See Se. Promotions, Ltd., 420 U.S. at 548 (theatrical production denied permission to go forward because it "would not be 'in the best interest of the community'"); Shuttlesworth, 394 U.S. at 149–50 (civil-rights demonstrators denied permit to march because, "in [the] judgment" of Birmingham's City Commission, "the public welfare, peace, safety, health, decency, good order, morals or convenience require that it be refused"). The standards regulators apply to commercial speech, conversely, are typically susceptible to clearer enforcement criteria. Here, for example, whether a claim is "adequately substantiated," 27 C.F.R. § 5.42(b)(8)(ii)(B)(2), is

subject to relatively objective administration. See Nutritional Health Alliance v. Shalala, 144 F.3d 220, 228 (2d Cir. 1998) (observing that the "evil" of "unbridled discretion" with which prior-restraint analysis is typically concerned was not present, since the "significant scientific agreement standard for evaluating claims" in FDA's regulations was "sufficiently definite to constrain the [agency] within reasonable bounds").

For those two reasons, laws that might otherwise be prior restraints applied in the commercial-speech context present less of a risk of chilling protected expression — the concern that undergirds the robustness of the analysis when non-commercial speech is at issue. See Se. Promotions, Ltd., 420 U.S. at 558–59 (discussing concern that prior restraints will "throttle" both those "who abuse rights of speech after they break the law" and also "all others beforehand"). Plaintiffs retort that speech has plainly been chilled by TTB's regulatory regime, since health claims are not very common on alcohol labels. See Pl. Reply at 34. Of course, that might well be because alcohol — as TTB has documented extensively and Churchill well understood — is not exactly a beverage produced for salubriousness. Indeed, when TTB promulgated the relevant regulations in 2003, it observed that the "extensive rulemaking record . . . revealed little, if any, interest on the part of industry members in using substantive health claims on alcohol beverage labels. In fact, . . . in many cases, [industry members] specifically disavowed any interest in using substantive health claims." Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 Fed. Reg. 10,076, 10,090 (2003). In any case, the relevant question is whether commercial speech as a category is generally susceptible to the risks that animate prior-restraint doctrine. It seems clear that it is not.

Plaintiffs point out that two Circuits — the Tenth and the Second — have held that conventional prior-restraint analysis does apply to commercial speech. See Pl. Mot. at 32 & n.16

(citing N.Y. Magazine v. Metro. Transp. Auth., 136 F.3d 123, 131 (2d Cir. 1998); In re Search of Kitty's East, 905 F.2d 1367, 1371–72 & n.4 (10th Cir. 1990)). Bellion also cites an unpublished Sixth Circuit decision that was plainly abrogated by the subsequent, published decision in Discount Tobacco, 674 F.3d 509, although it surprisingly neglects to point out that the former decision is no longer good authority. See Pl. Mot. at 32 n.16 (citing Bosley v. WildWetT.com, 2004 WL 1093037, at *1 (6th Cir. Apr. 21, 2004)). The Tenth Circuit's holding, however, seems to be based on the erroneous observation that "the Supreme Court has not distinguished between political and commercial speech when it has held that any prior restraint must be followed by prompt judicial review." Kitty's East, 905 F.2d at 1371 n.4. It also offers no reason that the doctrine ought to apply to commercial speech, even after observing that "the interests of the commercial speech at issue here may not equate with those of political speech," id. at 1371, so it is difficult to discern the rationale undergirding that decision.

The Second Circuit likewise held that prior-restraint analysis applies to commercial speech, but it did so in a case where it was animated significantly by "the difficulty of the question" of "whether the [speech in question was] actually commercial speech or core-protected [political speech]." See N.Y. Mag., 136 F.3d at 131. It explained that the case in question, involving proposed advertising for a transit system, "aptly demonstrate[d] that where there are both commercial and political elements present in speech, even the determination whether speech is commercial or not may be fraught with ambiguity and should not be vested in an agency." Id. It held that it "need not decide whether the [a]dvertisement [was] actually commercial speech or core-protected speech; the difficulty of the question alone convince[d] [it] that the requirement of procedural safeguards in a system of prior restraints should not be loosened even in the context of commercial speech." Id. That reasoning does not apply with

much force here. Although the Second Circuit also observed more generally that the "requirement of procedural safeguards" should be applied equally to commercial speech, id., the concern about ceding authority to an agency to make a difficult distinction between commercial and political speech is not present in this case.

Even if the D.C. Circuit were, moreover, to follow the Second Circuit in determining prior-restraint analysis applies to commercial speech, TTB's scheme would pass muster. Indeed, the Second Circuit itself upheld an extremely similar regulatory program — involving FDA pre-approval of health claims on dietary supplements — following its decision to apply prior-restraint analysis to commercial speech. See Nutritional Health Alliance, 144 F.3d at 227–28 (considering and upholding an "FDA requirement for prior approval of all health claims appearing on dietary supplement labels" where regulations stipulated that there be "significant scientific agreement" regarding any proposed claim). It reasoned that "the speech involved [was] indisputably" only commercial speech, and "the regulation pertains to health and safety," where there was a "need to protect consumers before any harm occur[red]." Id. at 228. In addition, it observed that the "evil" of "unbridled discretion" with which prior-restraint analysis is typically concerned was not present, since the "significant scientific agreement standard for evaluating claims" in FDA's regulations was "sufficiently definite to constrain the [agency] within reasonable bounds." Id. As a result, the Second Circuit concluded that the "critical question" in scrutinizing a prior restraint of commercial speech was the same as the fourth prong of Central Hudson — namely, whether the regulation in question is "more extensive than necessary." Id. at 225 n.10, 228. Because of the public-health equities involved, the FDA's scheme was permissible. Id. at 228.

All of that analysis applies with equal force here. TTB's requirement that health claims be "adequately substantiated" is as objective as FDA's criteria in that case mandating significant scientific agreement. See 27 C.F.R. § 5.42(b)(8)(ii)(B)(2). Both are different from the open-ended guideposts that the Supreme Court has found suspect. See, e.g., Se. Promotions, 420 U.S. at 558–59; Shuttlesworth, 394 U.S. at 150–51. They are rather examples of "narrow, objective, and definite standards" that can cure the problem of unbridled discretion characterizing prior restraints. See Shuttlesworth, 394 U.S. at 150–51; see also Se. Promotions, 420 U.S. at 553.

Bellion has no response to the reasoning of Nutritional Health or its clear application here, except to contend that the D.C. Circuit invalidated the same regulatory standard in Pearson. See Pl. Reply at 34 n.19 (citing Pearson, 164 F.3d at 660–61). This Circuit did so, however, on grounds unrelated to prior restraint. Indeed, as mentioned, it explicitly declined to reach that question. See Pearson, 164 F.3d at 660 & n.11 (indicating it would not "decide whether prior restraint analysis applies to commercial speech"). This Court, therefore, finds the Second Circuit's analysis to a very similar regulation persuasive in determining that — to the extent restrictions on commercial speech can be characterized as prior restraints in the first instance — it is the kind of objective regime that overcomes the constitutional concerns they otherwise raise.

Bellion has one final vintage in its cellar. Recall that, apart from the objectivity of TTB's standard, Plaintiffs maintain that TTB retains an unconstitutional level of discretion because there is no prescribed timeframe by which it must respond to any petition. See Pl. Mot. at 31–32. Although it does not cite any authority for the proposition that the lack of a time limit applied to an otherwise appropriately objective permitting scheme can independently render that regime unconstitutional, the Court will separately address this final wrinkle.

The COLA process — the only aspect of TTB's regulatory scheme that subjects any party to a pre-approval scheme — does in fact have a defined timeframe. The agency must respond within 90 days, subject to one possible 90-day extension. See 27 C.F.R. § 13.21(b). That is shorter than the 540-day timeline approved in Nutritional Health Alliance. See 144 F.3d at 228. Rather than contend that the 90-day — or possibly 180-day — timeline renders the COLA process unconstitutional, Bellion maintains instead that it is deficient because it does not permit applicants to submit adequate scientific evidence in support of their petitions. See Pl. Mot. at 33; Pl. Reply at 31. As a result, Plaintiffs contend that applicants are forced to avail themselves of the more generalized process for seeking the agency's advice as to whether a proposed claim would violate any of its regulations. See Pl. Mot. at 33; Pl. Reply at 31; see also 27 C.F.R. § 70.471(a) (allowing, but not requiring, "[a]ny person who is in doubt as to any matter arising in connection with the [FAAA]" to "request a ruling thereon by addressing a letter to the appropriate TTB officer"). The latter process has no time limit, and Bellion appears to believe that if a party supplements its COLA application that way, it will strip the time limit from the COLA process.

That argument does not get Bellion over the line. The Court does not see why — and Bellion does not suggest a reason that — the submission of supplemental materials through an alternate process would nullify the constraints on the COLA system. If TTB took that view, the Court assumes Plaintiffs could bring a deadline suit to compel action. Perhaps Bellion worries that TTB might well rule on a COLA application within the requisite timeframe but ignore anything submitted via the other regulatory avenue. If an agency rendered a decision on a COLA application but chose to ignore supplemental material submitted via the other channel, perhaps its decision to ignore the additional materials would be arbitrary and capricious. In any

case, if the COLA process does generally permit TTB not to consider additional types of material that Plaintiffs believe essential, that could be a defect characterizing that process, but it is not a reason that the COLA process or any other TTB regulation is an unconstitutional prior restraint. Finally, to the extent Bellion complains about the lack of a timeframe generally characterizing TTB's other regulations, no other scheme besides the COLA one requires any form of pre-approval. This last First Amendment challenge thus falls by the wayside.

D. Fifth Amendment

Plaintiffs have one remaining shot to take at TTB's decision: They contend its regulations are unconstitutionally vague. See Pl. Mot. at 41 (citing 27 CFR § 5.42(b)(8)). Specifically, they appear to challenge only — or at least primarily — the phrase "adequately substantiated" as failing to give regulated parties adequate notice of what conduct is permitted or prohibited. See Pl. Reply at 41–42. Before the Court digs into the substance of this argument, it must first address a threshold objection by the Government.

Defendants contend that no fair-notice concerns are implicated here because TTB did not impose any penalty on Plaintiffs' conduct. Rather, because they sought TTB's guidance before acting, Bellion received notice of exactly what was prohibited. See Def. Mot. at 26. The Government appears to argue both that this advice-seeking process itself provided adequate notice to Plaintiffs and that no notice was required at all in this situation because no sanction was imposed on Bellion. Id. at 25–26. As a result, in the agency's view, Bellion is wholly barred from bringing a fair-notice challenge here. Id. at 25–27.

The Court is not persuaded. Because Plaintiffs' challenge seems best characterized as a facial one, see U.S. Telecom Ass'n v. FCC, 825 F.3d 674, 735–36 (D.C. Cir. 2016), whether they themselves sought specific guidance here does not suggest that the regulations in general

give adequate notice of prohibited conduct. In addition, Plaintiffs did receive a sanction — one that was not insignificant. They have an interest in disseminating their advertising, and TTB has prevented them from doing so. The D.C. Circuit has held that "[t]he dismissal of an application . . . is a sufficiently grave sanction to trigger [the] duty to provide clear notice." Satellite Broad. Co., Inc. v. FCC, 824 F.2d 1, 3 (D.C. Cir. 1987) (citations omitted). Defendants protest that Satellite Broadcasting is distinguishable because it involved the application for a scarce resource — namely, the right to operate limited radio channels. See Def. Mot. at 26–28. There is no indication, however, that such scarcity was dispositive, or even relevant, there. Rather, the Circuit held, there in unqualified fashion, that dismissal of an application is significant enough to at least implicate fair-notice concerns.

Although the Court finds, therefore, that Bellion can make a fair-notice argument here, it does not ultimately carry the day. A law is impermissibly vague only where it "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012) (citation omitted). TTB's framework both provides adequate warning as to how applications will be treated by the agency— regarding both substantive criteria and process — and conforms to a standard sufficiently objective to vitiate any concern about arbitrary enforcement.

TTB's regulations enumerate the substantive criteria for approval of health claims and also explain that it may consult with FDA. See 27 CFR § 5.42(b)(8)(ii)(B)(1) (consultation with FDA); 27 C.F.R. § 5.42(b)(8)(ii)(A) (health-related statements on labels); 27 C.F.R. § 5.65(d)(2)(i) (health-related statements in advertising); 27 C.F.R. § 5.42(b)(8)(ii)(B)(2) (specific health claims on labels); 27 C.F.R. § 5.65(d)(2)(ii) (specific health claims in

advertising). To the extent Bellion's challenge focuses on the requirement that claims be "adequately substantiated," that standard likewise is specific enough that 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).

Of course, that language permits the agency some flexibility, as many regulations administered on a case-by-case basis properly do. See Alliance for Natural Health US v. Sebelius, 775 F. Supp. 2d 114, 131 (D.D.C. 2011) ("Regulations need not achieve 'mathematical certainty' or 'meticulous specificity,' and may instead embody 'flexibility and reasonable breadth.'") (quoting Freeman United Coal, 108 F.3d at 362). "[T]he use of terms like 'adequate,' 'appropriate,' 'suitable,' and 'qualified,'" however, does not necessarily render a regulation "impermissibly vague." Id. at 132. Rather, because "specific regulations cannot begin to cover all of the infinite variety of conditions which [regulated parties] must face," "requiring regulations to be too specific . . . would be opening up large loopholes allowing conduct which should be regulated to escape regulation." Id. (quoting Freeman United Coal, 108 F.3d at 362).

In addition, while it does not, as the Government contends, act as a *per se* bar to bringing a vagueness challenge, the agency's "clear process" for issuing advice about compliance with its regulatory scheme, see 27 C.F.R. § 70.471(a), substantially diminishes a "due process risk of prosecution for conduct it could not have known to be illegal." Trans Union Corp. v. FTC, 245 F.3d 809, 818 (D.C. Cir. 2001); see also U.S. Telecom Ass'n, 825 F.3d at 738–39 (ruling that "[t]he opportunity to obtain prospective guidance" via an "advisory-opinion procedure" disposed of "any remaining concerns about [a rule's] allegedly unconstitutional vagueness").

Bellion lobs a final challenge against the regulation on vagueness grounds. It contends that TTB's "adequately substantiated" standard is very similar to FDA's "significant-scientific-agreement" benchmark that the D.C. Circuit invalidated in Pearson. See Pl. Mot. at 44 (citing Pearson, 164 F.3d at 661). In Pearson, however, the D.C. Circuit declined to reach the constitutional-vagueness question and instead held that the FDA had acted unlawfully because it had violated the APA's "require[ment] [that] the agency . . . explain why it reject[ed] their proposed health claims," which would have "necessarily" entailed "giving some definitional content to the phrase 'significant scientific agreement.'" 164 F.3d at 660. The Pearson court nevertheless warned that it did "not . . . say that the agency was necessarily required to define the term in its initial general regulation — or indeed that it is obliged to issue a comprehensive definition all at once"; rather, it could "proceed case by case." Id. at 661. Although that principle follows from courts' interpretation of the APA, it has some application here in clarifying that the D.C. Circuit did not intend to suggest in Pearson that the standard at issue necessarily was impermissibly vague, but rather that the FDA had not adequately explained its action, as it was required to do.

Here, by contrast to the agency in Pearson, TTB elaborated at length about why the proposed claims were not adequately substantiated and therefore not credible. See AR 1572 ("[T]he claims must be supported by credible scientific or medical evidence."); AR 1582–1583, 1585 (adopting findings that studies were not credible where they, *inter alia*, concerned individual components of NTX rather than the compound, were conducted on animals or *in vitro*, or were published in a foreign language). That is all that is required.

IV. Conclusion

For the foregoing reasons, the Court will deny Plaintiffs' Motion for Summary Judgment and grant Defendants' Cross-Motion. A separate Order consistent with this Opinion will issue this day.

/s/ *James E. Boasberg*
JAMES E. BOASBERG
United States District Judge

Date: August 1, 2019