BEFORE THE DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C.

In re: BELLION SPIRITS, LLC'S PETITION FOR HEALTH CLAIMS UNDER 27 C.F.R. §§ 70.701, 7.54(e)	)	**TTB DOCKET No. _____** **PETITION FOR HEALTH CLAIMS**

PETITION FOR HEALTH CLAIMS UNDER 27 C.F.R. § 70.701 & 7.54(e)

Bellion Spirits, LLC and Chigurupati Technologies (collectively "Bellion" or "Petitioners"), by counsel and pursuant to 27 CFR §§ 70.701 and 7.54(e), hereby submit this petition for health-related statements concerning the effect of NTX® in distilled spirits or beverages. NTX® is a proprietary blend of glycyrrhizin,[1] mannitol,[2] and potassium sorbate.[3] As discussed below and in the materials attached, when NTX® is infused into alcoholic beverages, it renders them safer, i.e., less toxic, than counterparts that do not contain NTX®. NTX® reduces the adverse effects of alcohol on the liver and on DNA. Thus, NTX® lessens certain deleterious effects caused from consumption of alcohol. Accordingly, Petitioners hereby request that the Alcohol and Tobacco Tax and Trade Bureau ("TTB") declare, via rulemaking or through the exercise of enforcement discretion, that the use of the Petitioners' proposed health-related statements concerning the hepatoprotective and DNA-protective effects of NTX® in the labeling and advertising of wines, distilled spirits, and malt beverages is permissible. The health claims

[1] Glycyrrhizin is an extract of licorice root.
[2] Mannitol is a sugar alcohol.
[3] Potassium sorbate is commonly used as a food preservative.

requested through this petition facilitate informed decisions concerning consumer health when purchasing and/or consuming alcoholic beverages. The health claims identified in this petition are truthful and non-misleading, supported by peer-reviewed scientific literature and human clinical studies. By giving consumers an ability to distinguish between alcoholic beverages that are less toxic than traditional counterparts, consumers may choose the healthier alcoholic beverage and, as a result, experience greater health and wellness than would otherwise be the case.

Petitioners' proposed health-related statements appear in section III below. Attached hereto, and incorporated in this petition, are the following supportive materials: (1) Expert Report of Dr. Sidney Stohs, Ph.D., FACN, CNS, ATS, FAPhA; (2) Expert Report of Dr. Harry G. Preuss, MD, MACN, CNS; (3) Stohs Curriculum Vitae; (4) Preuss Curriculum Vitae; and (5) scientific literature and studies supportive of the NTX technology.[4]

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[4] Bellion submits its confidential and proprietary scientific data "Confidential" under 5 U.S.C. § 552(B)(4).

I. Interests of the Petitioners

Bellion Spirits, LLC is the independent bottler and distributor of Bellion brand Vodka. Its principal place of business is Bellion Spirits LLC, One Harmon Plaza, Suite 805, Secaucus,

NJ 07094. Bellion Spirits was founded to pioneer innovation in the alcohol beverage industry, through the introduction of functional alcoholic beverages, which generally retain the customary characteristics of alcoholic beverages, while reducing or mitigating the unwanted negative effects, like damage to the liver, genetic injuries, and oxidative stress. Bellion's scientific and commercial goals focus on the education of consumers concerning the detrimental effects of alcohol consumption, along with the advantages of functional beverages or spirits that aid consumers in making smarter, safer, and healthier choices. Bellion's objectives include the distribution of products and technologies that help to educate consumers about the chemical interactions of alcohol in the body (both positive and negative). Bellion has coined the phrase "Functional Spirits" as a description of the benefits or protective properties conveyed through its technology, as described more fully below in this petition.

Chigurupati Technologies Private Ltd. is solely a Research & Development institution founded with the objective to "aid in the evolution of mankind." Its principal place of business is Plot No. 512/m/1. Road No. 31 Jubilee Hills, Hyderabad, 500033, Andhra Pradesh, India. By focusing on research and development, Chigurupati Technologies develops and leverages innovations that later provide beneficial health products for consumers globally, thus encouraging a physical and philosophical consumer evolution. Chigurupati Technologies depends on its ability to convey scientific literature and facts to consumers and businesses in association with its technologies.

Chigurupati Technologies Private Ltd. developed and owns a proprietary blend of three generally recognized as safe ingredients combined through a proprietary process and sold under the name "NTX." Those three ingredients are Glycyrrhizin Acid, D-Mannitol, and Potassium Sorbate. "NTX" is thus an ingredient in Bellion Vodka that Bellion purchases from Chigurupati

Technologies. Studies commissioned by Chigurupati Technologies reveal that "NTX," when infused into liquor, yields a protective effect on the human liver during alcohol consumption, lessening the adverse effect of alcohol on the liver. Heretofore that information has not appeared on the label, in the labeling, or in the advertising for alcohol containing products sold in the United States. NTX® also adds flavor and smoothness to the vodka drink. Bellion Vodka has not promoted the use of NTX for health purposes, but seeks to convey the liver and DNA protective effects of alcohol containing NTX® through this instant petition.

II. Procedural Background

In 2014, Bellion petitioned the TTB through the COLA process and requested approval for the use of Bellion's "NTX" designation on labeling. That designation reveals the presence of Bellion's proprietary blend in vodkas. In a letter dated December 17, 2014, the TTB informed Bellion it would send two pending COLAs[5] for Bellion Vodka back to the applicant, Frank-Lin Distillers Products, Ltd. ("Frank-Lin"), with a "Needs Correction" notification because the labels' referenced "NTX." According to the TTB, the acronym "NTX" was a misleading health claim.

At the time, Bellion's labeling included the following descriptive phrase as the statement of composition: "Vodka Infused With Natural Flavors." The label included the following statements:

For over 600 years, vodka has been made the same way.
No longer. Infused with NTX, Bellion changes vodka forever.

• Vodka Evolved • Infused With Natural Flavors • Created With NTX •

[5] The labels' TTB ID numbers are 1425001000403 and 14227001000056.

Bellion's labels did not explain or define the acronym "NTX." Both of Bellion's label applications, however, identified "NTX" as a fanciful name. One COLA submission provided the following explanation:

> NTX = NEW TECHNIX (OR NEW TECHNIQUES). THIS IS A BREAKTHROUGH COMBINATION OF INGREDIENTS AND PROPRIETARY TECHNIQUES THAT REMOVES THE UNDESIRABLE ATTRIBUTES [TASTES] COMMON IN MANY VODKAS AND PROMOTES SMOOTHNESS AND ROUNDNESS AND MOUTHFEEL BEYOND WHAT NORMAL FILTRATION AND MULTIPLE DISTILLATIONS CAN DO. WORLDWIDE PATENT AND TRADEMARK PROTECTION IS IN PROCESS. BRAND NAME, LOGO AND GRAPHICS MAY REPEAT; LOT NUMBER(S) MAY APPEAR/CHANGE.

According to the TTB, reference to "NTX" was an implied specific health claim in violation of 27 C.F.R. § 5.42(b)(8). The TTB determined that extraneous information not present on the Bellion label (e.g., in scientific publications elsewhere) touted the health benefits of "NTX." TTB asserted that "NTX" was an implied claim relating to Naltrexone, a prescription drug that was approved for the treatment of alcohol dependence, and "[t]he use of the drug NTX to treat alcohol dependency, as well as publicly available studies claiming that NTX has beneficial effects for patients with elevated liver enzymes, would be likely to reinforce the health claim . . . and cause further confusion about the term 'NTX.'" The TTB produced no consumer perception or survey data in support of its COLA denials.

On January 15, 2015, Bellion Spirits, L.L.C. appealed the TTB COLA denial through 27 CFR § 13.25. That appeal asserted that the TTB's censorship of the "NTX" labeling information violated the First Amendment of the U.S. Constitution because, inter alia, the TTB had no factual or legal bases to censor basic information related to product composition and ingredients. The

parties informally resolved the COLA disputes and, in April 2015, the TTB approved separate COLA applications for Bellion Vodka labels that referenced "NTX."[6]

Now, through this instant submission, Bellion petitions the TTB for use of nine (9) specific health claims under 27 CFR § 7.54(e) related to the NTX® ingredients contained in Bellion Vodka.

III. Requested Action

Petitioners hereby request that the TTB rule that alcoholic spirit beverages that contain NTX® may bear one or more the following health-related statements in its labeling, advertising, or promotional speech:

- NTX® provides antioxidant and anti-inflammatory support;
- NTX® helps protect against, i.e., reduces, alcohol-induced oxidative damage to the liver;
- NTX® helps maintain normal liver enzyme production and function;
- NTX® supports normal liver defenses and regenerative mechanisms;
- NTX® reduces the risk of alcohol-induced liver diseases, including fibrosis and cirrhosis;
- NTX® helps maintain normal liver functions;
- NTX® helps protect DNA from alcohol-induced damage; and
- NTX® reduces alcohol-induced DNA damage.

[6] The labels' TTB ID numbers are 15091001000076 (approved) and 15091001000077 (expired). Previously, the TTB had approved a label that was identical to the labels at issue in the appeal (TTB ID number 13294001000173). Frank-Lin voluntarily surrendered that label on July 31, 2014, however, at the request of the TTB. Two other labels (TTB ID numbers 13052001000468 and 13051001000241) were surrendered in 2014 because the applicant, Covington Spirits, L.L.C., no longer bottled Bellion Vodka.

Those health-related statements are accompanied by the following, prominently placed disclaimer:

> 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.

The above-listed health-related statements are truthful and non-misleading. The disclaimer language is reasonable and adequate to properly identify the remaining risks inherent in alcohol consumption. As discussed below, the above-listed health claims are protected speech under the First Amendment to the United States Constitution.

IV. Legal and Statutory Framework

The provision of truthful and non-misleading health information is indispensable to informed consumer choice. The need for accurate health information at the point of sale is no less important in the alcoholic beverage context as it is in the food and dietary supplement context. *See, e.g., Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). Unlike the Federal Food and Drug Administration, the TTB has yet to adopt a cogent and workable regulatory regime for the evaluation of health-related statements. *C.f.* 21 CFR § 101.70 (articulating procedure and elements required for health claim petition). To determine whether a health claim satisfies Section 27 CFR 7.54, petitioners must have a full and fair opportunity to present all supportive science. The adequacy of that science must be evaluated in context with the benefit sought to be achieved.

Bellion submits this instant petition for agency action in lieu of (or in conjunction with) the COLA process, in part, because the TTB's existing regulatory framework concerning health claim petitions is inadequate and insufficient to provide constitutionally required protection for truthful and non-misleading health information on the label, in the labeling, and in the advertising of alcoholic beverages.

A. TTB's Extant Framework Involving Health-Related Statements

The Federal Alcohol Administration Act authorizes the Secretary of the Treasury to promulgate regulations concerning the labeling and advertising of alcoholic beverages, including regulations that are intended to prevent consumer deception and prohibit the use of misleading statements, irrespective of falsity. *See* 27 U.S.C. § 205(e)-(f).

In 2003, the TTB issued regulations for the use of health claims and health-related statements in the labeling and advertising of wines, distilled spirits, and malt beverages. *See* 68 Fed. Reg. 10076 (Mar. 3, 2003) (Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages); 27 C.F.R. § 4.39(i) (labeling of wine); *id*. at § 4.64(i) (advertising of wine); *id*. at § 5.42(b)(8) (labeling of distilled spirits); *id*. at § 5.65(d) (advertising of distilled spirits); *id*. at § 7.29(e) (labeling of malt beverages); and *id*. at § 7.54(e) (advertising of malt beverages). Those regulations attempted to balance the speaker's First Amendment right to label and advertise products through truthful and non-misleading scientific information and the public's right to be informed of the significant health risks associated with alcohol consumption.[7]

[7] The agency was motivated apparently by the well-established scientific link between moderate alcohol consumption (notably red wine consumption) and a reduced risk of coronary heart disease. *See, e.g.*, 68 Fed. Reg. 10076, 10082-83 (Mar. 3, 2003). The TTB had refused to permit health claims associated with red wine, despite the general agreement in support of that claim by the scientific and medical fields.

Under TTB's health claim regulations, alcoholic beverage labels and 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. *See id.* at §§ 4.39(h)(2), 4.64(i)(2), 5.42(b)(8)(ii), 5.65(d)(2), 7.29(e)(2), 7.54(e)(2). For purposes of the TTB's regulations, a "health-related statement," means:

> [A]ny statement related to health . . . and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, as well as health-related directional statements. The term also includes statements and claims that imply that a physical or psychological sensation results from consuming the distilled spirits, as well as statements and claims of nutritional value (*e.g.,* statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

Id. at §§ 4.39(h)(1)(i), 4.64(i)(1)(i), 5.42(b)(8)(i)(A), 5.65(d)(1)(i), 7.29(e)(1)(i), 7.54(e)(1)(i). Additionally, a "specific health claim," is "a type of health-related statement that expressly or by implication, characterizes the relationship of the distilled spirits, alcohol, or any substance found within the distilled spirits, to a disease or health-related condition." *Id*. at §§ 4.39(h)(1)(ii), 4.64(i)(1)(ii), 5.42(b)(8)(i)(B), 5.65(d)(1)(ii), 7.29(e)(1)(ii), 7.54(e)(1)(ii). Examples of implied specific health claims include the following: "statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between distilled spirits, alcohol, or any substance found within the distilled spirits, and a disease or health-related condition." *Id*.

Thus, the TTB has extended its definition of "health claims" to encompass nearly any statement that suggests a positive benefit for the human body from consumption of alcohol. The

TTB's definition of "health claim" is more expansive than similar interpretations by sister agencies like the FDA. *See* 21 U.S.C. §343(r)(1)(B) (defining a health claim, for purposes of the FDCA, to mean a claim that "characterizes the relationship of any nutrient . . . to a disease or a health-related condition . . .").

If the health-related statement conveys a misleading impression, the TTB may require a prominent disclaimer or other qualifying statement for the purpose of dispelling the misleading impression. *See, e.g.*, 27 C.F.R. § 5.42(b)(8)(ii)(A). Under the TTB's regulations, a specific health claim is misleading unless it: (1) is truthful and adequately substantiated by scientific or medical evidence; (2) is sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; (3) adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and (4) outlines the categories of individuals for whom any alcohol consumption poses risks. *See, e.g., id*. at § 5.42(b)(8)(ii)(B)(2). That information must appear as part of the specific health claim on a label, and, in advertising, as prominent as the specific health claim. *See id*. The TTB has never produced a consumer survey or impact study that determined consumers' level of understanding concerning health-related claims and alcohol consumption.

B. The TTB Must Implement a Constitutional Regulatory Framework for Evaluation of Health Claim Petitions

Unlike the Federal Food and Drug Administration, the TTB has yet to issue workable regulatory procedures and criteria for the evaluation of health-related statements. That regulatory deficiency creates hardship for petitioners, like Bellion, by denying them a well-defined regulatory avenue within TTB jurisdiction that will ensure allowance of constitutionally protected speech on the labels, in the labeling, and in advertising of alcoholic beverages. The limited scope and applicability of extant TTB labeling and advertising regulations precludes the

sponsorship of health claim petitions that could satisfy the elements of the TTB's regulations in, for example, Section 5.42(b)(8). As discussed below the process available to advertisers and labelers fails under the First Amendment.

In prior meetings between Bellion and TTB staff members in July 2014, the TTB conceded that its health claim procedures were inadequate and regulations concerning same were dead letters. Rather than perform its administrative review, the TTB expressed its intent to transfer health claim petitions to the FDA for review—a procedure that would violate administrative procedure. "Agency action taken without statutory authorization, or which frustrates the congressional policy which underlies a statute, is invalid." *See Yankton Sioux Tribe v. Kempthorne*, 442 F.Supp.2d 774, 784 (D.S.D. 2006). The FDA lacks jurisdiction or authority to interpret the TTB's regulations. *See Am. Library Assn. v. FCC*, 406 F.3d 689, 702 (D.C. Cir. 2005) (an agency does not possess plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area); *see also* 5 U.S.C. § 706(2)(C) (under the APA, agency action must be set aside and deemed unlawful where the agency acts "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right").

Congress tasked the TTB with the regulation of spirit products, which includes exclusive authority to regulate their labeling and advertising. *See* 27 U.S.C. §§ 201, *et seq.* The FDA lacks statutory authority to regulate alcoholic spirits that are within the TTB's purview. *See Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 8 (W.D. Ky. 1976) ("it was Congress' intention to place exclusive jurisdiction in BATF with respect to regulating labeling of alcoholic beverages."). Nothing in the FAA Act grants the TTB authority to delegate its

administrative functions or responsibilities to the FDA, and the FDA similarly lacks primary authority to regulate the labels and advertising of alcoholic spirits. *Id.* at 12.

i. TTB's Mandatory Label Reviews (COLAs) Are Inadequate

Regardless of whether a label bears a health-related statement, the TTB must generally preapprove wine, distilled spirit, and malt beverage labels.[8] *See* 27 C.F.R. §§ 4.50-4.52 (wine); *id*. at §§ 5.55-5.56 (distilled spirits); *id*. at §§ 7.40-7.42 (malt beverages). To obtain the TTB's approval, alcohol producers may apply for a Certification/Exemption of Label/Bottle Approval ("COLA"). The TTB will reject the application if the label fails to comply with applicable regulations or is otherwise deficient. For instance, the TTB will decline to approve an application if the label bears a misleading health-related statement in violation of the regulations discussed above. The TTB evaluates health-related statements on a case-by-case basis during its label reviews. *See id*.

Although the TTB will examine health-related statements that appear on labels of alcoholic beverages during its standard review, the "COLAs Online" process is not equipped to receive information necessary to demonstrate that a particular-health related claim is substantiated (to wit, that the claim is truthful and non-misleading, and supported by reliable scientific evidence). For instance, the only type of label attachments included within a filed COLA application include JPEG and TIFF file formats that use only RGB color mode. *See* TTB, COLAs and Formulas Online FAQs.[9] Moreover, the paper COLA application, TTB F 5100.31,

[8] Certain changes to labels that the TTB has previously approved may be made without obtaining a new certification/exemption of label/bottle approval ("COLA") from the TTB. *See*, TTB, *List of Allowable Changes to Approved Labels*, *available at* http://www.ttb.gov/labeling/allowable_revisions.shtml#completeList (last accessed Mar. 31, 2016).

[9] *Available at* http://www.ttb.gov/faqs/colasonline.shtml (last accessed April 5, 2015).

which can be submitted in lieu of an electronic application, includes no exceptions or provisions that allow submission of detailed scientific information related to health statements on labels or labeling.

Even if the COLA process permitted the submission of information regarding a health-related statement that appears on the label of an alcoholic beverage, the TTB could, theoretically, leave applicants buried within "corrective" processes inherent to the COLA review process. The system of administrative appeals is not designed (nor efficient enough) to prevent significant constitutional injury or alleviate the burdens of the TTB's prior restraint of health claim language. As explained below, a deprivation of First Amendment rights, even for minimal periods of time, constitutes an irreparable constitutional injury. *Elrod v. Burns*, 427 U.S. 347, 373–74 (1976). To the extent Bellion is precluded from communicating its truthful scientific information, it suffers an irreparable constitutional injury.

The COLA process is also too narrow to achieve the proper review of claims that would be used beyond labels or labeling. The COLA process pertains solely and exclusively to content appearing on spirit labels or labeling. That approval process has no relationship to advertising statements, or promotional content that may appear beyond the "label" of an alcoholic product. Thus, the COLA process would provide inadequate and inefficient relief for Bellion here. Petitioners are not requesting the use of specific health-related statements on a specific label, but, rather, they seek permission to include the proposed health-related statements throughout their labels, advertising, and promotional content. Moreover, Bellion would choose from among the various health claims subject to approval when designing or implementing labeling changes. Bellion should not be required to independently clear health claims through the COLA process

when such approval can most efficiently and pragmatically proceed through one health claim petition, the instant petition.

ii. TTB Advanced Review of Advertisements Is Inadequate

Although the TTB must preapprove alcoholic beverage labels, its regulations do not require preapproval of alcoholic beverage advertisements, including those that contain health-related statements.[10] The TTB, however, may review advertisements that appear in various media (e.g., online, print, or broadcast) on a case-by-case basis, either on its own accord or in response to complaints it receives about specific advertisements. Like labels, the TTB reviews alcoholic beverage advertisements on a case-by-case basis. *See id*. at § 7.54(a), (e)(2)(i) (malt beverages); *id*. at § 5.65(a)(1), (d)(2)(i) (distilled spirits); and *id*. at §4.64(a)(1), (i)(2)(i) (wine).

An alcoholic beverage advertiser faces serious risk when it includes a health-related statement in advertisements. For instance, several years prior, the TTB targeted an advertisement for alcoholic beverages that contained ingredients associated with non-alcohol energy drinks on the grounds that they implied that ingestion of the extra ingredients would result in a stimulating or energizing effect or enable consumers to drink more of a product without feeling the effects of alcohol in violation of the TTB's advertising regulations. Rather than have an advertiser bear the risk that the TTB will initiate enforcement action for use of a health-related statement in an advertisement, the TTB must provide a clear pathway for premarket claims approval.

[10] Alcoholic beverage industry member may, voluntarily, pre-clear advertising with the TTB.

iii. Bellion Has the Right to Petition the TTB for Health Claims

The First Amendment guarantees the right to petition government for redress. *Am. Bus. Ass'n v. Rogoff*, 649 F.3d 734, 738 (D.C. Cir. 2011) ("The right to petition is cut from the same cloth as the other guarantees of [the First] Amendment, and is an assurance of a particular freedom of expression"). The right "extends to [petitioning] all departments of the Government, including administrative agencies and courts." *Id.* (quoting *Cal. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972)). That pathway is particularly important here, where Bellion's commercial speech might otherwise subject it to liability absent TTB's preapproval of health claim language.

Administrative agencies are obliged by the Administrative Procedures Act (APA) to respond to petitions of the kind here presented. *See* 5 U.S.C. § 555(e) (requiring a response to a petition along with a "statement of the grounds for denial").

Consistent with the constitutional requirement for prompt relief in matters trenching upon free speech, federal courts have routinely excused the exhaustion doctrine in the administrative context where, as here: (1) the unexhausted remedy would plainly be inadequate; (2) a constitutional claim remains at issue even after theoretical exhaustion occurred; (3) the relief requested cannot be granted by the agency (e.g., through a facial challenge to agency regulations); (4) exhaustion would be futile; and (5) the petitioner would otherwise suffer irreparable harm if unable to secure immediate judicial review. *See, e.g., Dawson Farms, LLC v. Farm Serv. Agency*, 504 F.3d 592, 606 (5th Cir. 2007); *Ace Prop. & Cas. Ins. Co. v. Fed. Crop Ins. Corp.*, 440 F.3d 992, 999–1000 (8th Cir. 2006); *McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 980 (9th Cir. 2002). In other words, to the extent the TTB refuses to promptly and timely respond to this petition, relief in the district courts will be appropriate to prevent Bellion's

imminent loss of First Amendment rights through TTB's prior restraint on truthful health claim language. It is the law that TTB prohibits health statements on the labels, in the labeling, and in the advertising of alcohol containing products, unless it acts to allow or approve of the statements. Hence, there is an immediate and all-encompassing prior restraint on precisely the claims Bellion seeks in this petition, which restraint can either be lifted promptly by TTB or judicial review is warranted under the common exceptions to the exhaustion doctrine.

The TTB's health claim regulations and review process described in Sections 7.54(e) and 5.42(b) have erected a total ban on health related claims in the marketplace, in part, because the TTB has yet to implement the administrative process or structure needed to consider a properly noticed health claim petition. The TTB conceded that point in prior rulemaking: "TTB agrees that the regulations make it difficult to present a substantive health claim (for example, one involving cardiovascular benefits associated with moderate alcohol consumption)…" *See* Final Rule, *Healht Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages*, 68 Fed. Reg. 10076 (Mar. 3, 2003). The lack of meaningful review procedures effects an unconstitutional prior restraint of health claims in the marketplace, and renders action on this instant petition necessary. TTB may not shirk its constitutional duty under the First Amendment to ensure that truthful health statements are not suppressed; consequently, in the face of the present petition, it must review it and it must do so promptly.

C. Bellion's Proposed Health Claims Are Truthful, Non-Misleading, and Satisfy the TTB's Health Claim Regulations

Bellion has proposed the use of eight (8) health claims that accurately reflect the scientific evidence concerning NTX® technology. Those statements are truthful, substantiated by scientific and medical evidence; are sufficiently detailed and qualified with respect to the

categories of individuals to whom the claim applies; adequately disclose the health risks associated with both moderate and heavier levels of alcohol consumption; and explain the categories of individuals for whom any alcohol consumption poses risks.

The claims sufficiently describe the categories of individuals to whom the claims apply. Bellion's functional spirit infused with NTX® is designed for use by all lawful consumers of alcoholic beverages. The ill-effects of alcohol use are common knowledge and sufficiently known by the TTB and consumers. According to the World Health Organization's most recent data, the harmful use of alcohol is among the top five risk factors for disease, disability, and death. *See* Vladimir Poznyak & Dag Rekve, *Global Status Report on Alcohol and Health 2014*, World Health Org., p. 2.[11] The long-term effects of alcohol consumption can damage most organs of the human body. *Caan, Woody; Belleroche, Jackie de, eds. (11 April 2002). Drink, Drugs and Dependence: From Science to Clinical Practice (1st ed.). Routledge. pp. 19–20.*

Liver diseases are the predominant health concern associated with alcohol consumption because over time heavy drinking causes the multifaceted disease known as Alcoholic Liver Disease ("ALD"). ALD is characterized by hepatic steatosis or increased fat deposits in the liver. It can cause alcoholic hepatitis, also known as inflammation of the liver, and cellular stress from oxidation of the liver. *See* Aditya Ambade & Pranoti Mandrekar, Oxidative Stress and Inflammation: Essential Partners in Alcoholic Liver Disease, International Journal of Hepatology, Volume 2012 (2012), Art. ID 853175.[12] After prolonged alcohol consumption, ALD culminates in irreversible destruction and scarring (fibrosis) of the liver tissue called

[11] *Available at* http://apps.who.int/iris/bitstream/10665/112736/1/9789240692763_eng.pdf?ua=1 (last accessed April 4, 2016).

[12] *Available at* http://www.hindawi.com/journals/ijh/2012/853175/ (last accessed April 4, 2016).

cirrhosis, which ultimately leads to liver failure. *See Mayo Clinic*, Alcohol Use Disorder: Complications, (July 25, 2015).[13] While it is axiomatic in the ALD context that the more heavily one consumes alcohol—and the greater frequency of drinking—the more likely one is to develop cirrhosis, it should be noted that alcohol tolerance varies from person to person, and for some people one drink a day is sufficient to leave permanent scars on the liver. *See* Jennifer, Robinson, M.D., *Understanding Cirrhosis of the Liver*, WebMD (February 1, 2015).[14] Thus, hepatoprotective effects that limit liver injury are cumulative and likely to benefit moderate drinkers over their adulthood.

The CDC reported 36,427 deaths in 2013 from chronic liver diseases, making it the 12th leading cause of death in the United States. *See* Jiaquan Xu, M.D., Sherry Murphy, B.S., Kenneth Kochanek, M.A., & Brigham Bastian, *Deaths: Final Data for 2013*, Nat'l Vital Statistics Reports Vol. 62 No. 2, 45 (February 16, 2016).[15] That category is broken down into two sections: (1) ALD, accounted for 18,146 deaths; and (2) other chronic liver diseases and cirrhosis, accounted for 18,281 deaths in the United States in 2013. *Id.* The annual inpatient cost for alcohol-related cirrhosis in 2014 was $850 million, and this figure does not account for the unknown millions more spent on outpatient treatments. *See* Lauren Beste, M.D., *Alcoholic Liver Disease*, Gastroenterology & Hepatology, Vol. 12, Issue 1, (January 2016).[16]

Aside from ALD, recent research is demonstrating that alcohol abuse causes the dual-

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[13] A*vailable at* http://www.mayoclinic.org/diseases-conditions/alcohol-usedisorder/basics/complications/con-20020866 (last accessed April 4, 2016).

[14] A*vailable at* http://www.webmd.com/digestive-disorders/understanding-cirrhosis-basic-information?page=2 (last accessed April 4, 2016).

[15] *Available at* http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf (last accessed April 4, 2016).

[16] A*vailable at* http://www.gastroenterologyandhepatology.net/index.php/archives/january-2016/alcoholic-liver-disease/ (last accessed April 4, 2016).

harms of accumulated DNA damage and alcohol-induced dysfunction to DNA repair, which coalesce into the well-known negative effects of alcohol on the brain, i.e. brain damage. *See* Inna Kruman, George Henderson, and Susan Bergeson, *DNA Damage and Nuerotoxicity of Chronic Alcohol Abuse*, 237 Exp Biol Med 7, 740-47 (July, 24, 2012).[17] Those twin effects of chronic alcohol consumption result in genomic instability and the death of neurons. *Id*. Those destructive effects to the very building blocks of the nervous system are likely the reason that brain damage, including central nervous system degeneration, are associated with chronic alcohol consumption. *Id*.

The ill-effects of alcohol abuse are well-documented. The problems associated with lower levels of alcohol consumption are also documented. *See, e.g.*, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, *State of the Science Report on the Effects of Moderate Drinking* (Dec. 19, 2003).[18] Studies suggest that even moderate drinking may contribute to genetic and organ damage. *See, e.g.*, Castelli, E., et al., *Indicators of genetic damage in alcoholics: reversibility after alcohol abstinence*, Hepatogastroenterology, 1999 May-Jun; Vol. 46(27):1664-8; Honor Whiteman, *Young adults "damage DNA" with weekend alcohol consumption*, MedicalNewsToday.com (Jan. 2, 2014);[19] Rendón-Ramirez, R., et al., *Oxidative damage in young alcohol drinkers: A preliminary study*, Alcohol Intn'l Biomed. Journal, 2013 November; Vol. 47(7):501-504. Given the frequency and volume of alcohol consumption in the United States, any product that affords liver and genetic protection during ethanol metabolism is

[17] A*vailable at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3685494/ (last accessed April 4, 2016).

[18] Available at http://pubs.niaaa.nih.gov/publications/ModerateDrinking-03.htm (last accessed April 11, 2016).

[19] *Available at* http://www.medicalnewstoday.com/articles/270735.php (last accessed April 11, 2016).

of considerable health value to consumers nationwide—even if that protective effect merely mitigates, as opposed to eliminates, the damage.

D. Bellion's Health Claims Concerning NTX® Hepatoprotective Effects and DNA Protection Are Truthful and Adequately Substantiated by Scientific and Medical Evidence

The hepatoprotective effect of NTX® is supported by the attached exhibits 1, 3, and 5, and through the more than 100 peer-reviewed scientific publications attached. Those reports, studies, and datasets are herein incorporated into this petition by reference, including the expert reports of Dr. Sidney Stohs and Dr. Harry Preuss. Bellion's experts explain that the requested health claims are supported by the scientific evidence, including product-specific testing, peer-reviewed literature, and animal and in vitro test data.

As discussed above, the harms of alcohol consumption are well documented, and the most common chronic alcohol issue is ALD, which is defined by lesions on the liver ranging from hepatic steatosis to cirrhosis and eventually liver failure. The cascading negative effects of alcohol on the liver are attributable to the mechanisms of alcohol toxicity, which can be summarized in five steps: (1) the metabolism of alcohol to highly toxic acetaldehyde and free radical species; (2) the production of reactive oxygen (ROS) and nitrogen species with resulting oxidative stress; (3) the inflammatory release of cytokines as tumor necrosis factor-alpha and interleukin-6; (4) abnormal lipid metabolism, oxidative DNA damage, formation of protein, and DNA adducts with metabolites of alcohol and acetaldehyde; and (5) ultimately induction of apoptosis or necrosis with subsequent multi-system organ failure. *See* Stohs Rep. at 2.

Biomarkers are biological indicators of the health of an organ. Just as blood sugar elevation is associated with diabetes, common biomarkers can be used to track the progression of

ALD. Elevations of these biomarkers indicate liver disease, while decreases occur as the liver heals. *See id*. at 2-3.

Liver health is generally measured or evaluated through several generally-accepted biomarkers. *See* Preuss Rep. at 3. Those markers indicate disruption of the hepatic function. Scientists evaluate measurements related to the blood serum levels of enzymes such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), and alkaline phosophatase (ALP). *See id*. Elevated circulating levels of those enzymes indicate liver injury from excess alcohol intake. *See id*. Moreover, a reduction of those serum levels occur as the liver begins to repair itself. *See id*.

Scientists may look to other biomarkers to evaluate liver function. The hepatic metabolism of alcohol causes excess production of tissue-damaging free radicals and reactive oxygen species (ROS). Markers of oxidative stress and oxidative tissue damage include the production of ROS, the lipid malondialdehyde (MDA), protein carbonyl formation, and DNA damage. Moreover, reductions in glutathione (GSH) levels could indicate intercellular antioxidant and chemoprotectant characteristics in human tissues, in part, because reductions in GSH levels are associated with changes to oxidative stressors. *See id*. at 3-4. Therefore, GSH content is considered an important marker for ROS and free radicals. *See id*. at 4.

The two primary approaches for successful prevention and reversal of liver damage are abstinence from alcohol and appropriate nutritional support. *See id*. Because the vast majority of alcohol users will not abstain, the need to develop safer means of alcohol consumption to reduce the associated morbidity and mortality, as well as the costs to society, are pressing. *See id*. To prevent and treat alcohol-induced liver toxicity the mechanism must disrupt and either inhibit or reverse the five steps of toxicity described above. *See id*. Studies in humans and

animals have demonstrated the hepatic protective effects of NTX® as well as its individual components during acute and chronic alcohol consumption. *See id*.

The two primary ingredients in NTX® are glycyrrhizin and mannitol, which work synergistically to protect the liver from the harmful health effects of alcohol. *See* Stohs Rep. at 4. A randomized, double-blind, placebo-controlled cross-over clinical trial involving 12 human subjects found that NTX® produced a significant decrease in the biomarkers for liver toxicity. *See id*. Another similar test with 31 human subjects showed a significant reduction in biomarkers of liver disease and oxidative liver effects, and the authors indicated that NTX® may be effective at reducing the negative effects of alcohol consumption. *Id*. Furthermore, the synergistic effects of mannitol and glycyrrhizin were demonstrated in a 28 day study in rats where the substances restored the biomarkers of liver function to as high as 80% of normal. *See id*. at 5. In all, over 70 studies show the key components of NTX® produce liver protecting, antioxidant, and anti-inflammatory effects. *See id*. at 7.

Antioxidants and Anti-Inflammation:

The health-related statements regarding the antioxidant, anti-inflammatory effects of NTX® that serve to protect the liver against oxidative damage have been thoroughly substantiated. Human and animal studies alike demonstrate the positive biomarker effects of glycyrrhizin by inhibiting the lipid accumulation in the liver and decreasing inflammatory cytokines, which reduction protects liver function. *See id*. at 8. Several studies have confirmed the tissue protective effects of mannitol, as it is already used as an antioxidant in conjunction with heart bypass surgeries and as an anti-inflammatory in tissue baths following kidney transplants. *See id*. at 9. Fifty human studies and a number of animal studies confirm NTX®'s primary ingredients protect against oxidative liver damage. *See id*. at 12.

A series of animal studies have therefore shown that licorice extract and mannitol favorably decrease reactive oxygen species (ROS) and similar metabolites, lipid peroxidation (MDA formation) as well as carbonyl protein formation secondary to alcohol-induced production. *See* Preuss Rep. at 4. Those studies also show a positive increase in the levels of endogenous antioxidant reduced glutathione (GSH). *See id*. Those key findings concerning glycyrrhizin and mannitol have been corroborated in clinical studies. *See id*. NTX® was shown to decrease alcohol-induced DNA damage in human peripheral lymphocytes. *See id*. at 5. NTX® was also shown to enhance the levels of the enzymes catalase, GPX, and SOD that are responsible for decomposing ROS. *See id*. Thus, NTX® had an ability to protect hepatocytes from the damaging influences of ROS and oxidative stressors. *See id*. Those findings were supported by over thirty published animal, in vitro, and human clinical studies confirming the antioxidant and anti-inflammatory properties of the components in NTX®.

Helps Maintain Normal Liver Function:

The published scientific evidence strongly supports NTX®'s ability to maintain normal or healthy liver function during and after alcohol consumption. Several published human, animal, and cell culture studies revealed that NTX® and its components foster normalization or near-normalization of many liver enzymes, including ALT, AST, GGT, ALP, SOD, GPX, and catalase. *See id*. at 6. NTX®'s proprietary formula (and its components) ameliorate alcohol-induced inflammation. Glycyrrhizin itself has been shown to reduce serum ALT and AST levels in patients with chronic hepatitis by at least thirty-five percent (35%). *See id*.

NTX®'s beneficial effects were documented in a randomized, doubled-blind, placebo-controlled clinical trial involving twelve human subjects through a cross-over model. NTX® provided significant decreases and normalization in the examined biomarkers correlating with

liver toxicity, to wit, ALT, AST, GGT, and ALP. *See id*. Another randomized, double-blind, placebo-controlled cross-over clinical trial involving thirty one (31) human subjects revealed that consumption of alcohol with NTX® significantly reduced the levels of ROS and facilitated development of normal liver enzyme circulating concentrations. *See id*.

The enzymes that are normalized were biomarkers of liver health. When those enzymatic levels decrease, as several randomized double-blind human studies have documented, the ability of NTX® to preclude alcohol toxicity and help maintain normal liver function is substantiated. *See* Stohs Rep. at 13. Several animal studies have shown the defensive and regenerative properties of NTX®, but one in particular on rats actually produced a marked reduction in alcohol-induced liver lesions. *See id*. at 17.

Supports the Liver's Regenerative Mechanism:

The health-related statements regarding reduction of risk for and amelioration of liver diseases including fibrosis and cirrhosis have also been scientifically substantiated. A published meta-analysis summarized the effects of a glycyrrhizin product in 838 patients through 12 randomized trials confirmed that the substance significantly decreased serum levels and improved liver function in alcoholic liver disease cases. *See id*. at 20. NTX® co-administered with alcohol has demonstrated a significant decrease in liver toxicity biomarkers, thereby facilitating increased liver function and regeneration, which reduces the risk of liver diseases like fibrosis and cirrhosis. *See id*. at 22.

Almost fifty published human clinical studies and a substantial number of animal studies have demonstrated that NTX and its specific components (e.g., glycyrrhizin and mannitol) support the liver's normal defense mechanisms against alcohol and other hepatoxins, thus promoting general liver health in those that might drink moderately. A meta-analysis of twelve

randomized human clinical studies evaluated data collected from 838 patients with alcoholic liver disease and concluded that glycyrrhizin significantly decreased serum ALT and AST levels. *See* Preuss Rep. at 8. Another study determined that glycyrrhizin reduced the incidence of liver fibrosis in rats co-administered glycyrrhizin. *See id.* Another double-blind, comparative, cross-over clinical trial examined the effects of alcohol on blood levels of ROS in the absence and presence of co-administered NTX®. *See id*. The results demonstrated that NTX® statistically and significantly reduced the alcohol-induced generation of ROS and ROS metabolites, and further decreased serum lipid peroxidation product MDA, while increasing serum levels of the endogenous antioxidant GSH. *See id*. at 8-9. NTX® also significantly decreased serum protein carbonyl levels. *See id*. at 9. That data demonstrated that NTX® co-administered with alcohol decreased the oxidative tissue damage that would otherwise have been observed during alcohol consumption and metabolism.

Reduces Alcohol-Induced DNA Damage:

NTX® aids in protection of DNA by reducing alcohol-induced damage. Health claims related to that effect are scientifically substantiated. A randomized, double-blind human study revealed that alcohol consumption is damaging to DNA because it damages peripheral lymphocytes, but NTX® significantly reduces the level of damage caused, revealing that it protects DNA. *See* Stohs Rep. at 30. One of the key ways NTX® protects DNA is via its anti-oxidant and suppression of oxidative damage effects. *See id*. Glycyrrhizin has been show to prevent DNA fragmentation and modulated programmed cell death. *See id*. One mechanism of DNA protection was shown in an in vitro model where glycyrrhizin directly bonded to the major and minor grooves and phosphate backbone of DNA, thereby protecting it from damage. *See id*. at 32.

Excess alcohol consumption generally contributes to the production of oxidative damage to DNA and the epigenome. *See* Preuss Rep. at 13. Reactive oxygen species activate or repress epigenetic elements like chromatin remodeling, micro-RNAs, DNA (de)methylation and histone modification. *See id*. at 13-14. Epigenetic changes, even slight alterations, may affect gene expression and could ultimately result in liver disorders. *See id*. at 14. After ingestion, alcohol can form adducts with DNA, inhibiting the formation of various proteins essential for healthy hepatic function. *See id*.. NTX® has been shown through scientific studies and laboratory work to inhibit those negative effects, in part, by restraining the formation of alcohol-induced DNA damage.

In one study involving thirty one (31) subjects in a randomized, double-blind, placebo-controlled cross-over clinical trial, patients challenged with alcohol presented apparent DNA damage in peripheral lymphocytes as measured by single cell electrophoresis comet assay, the cytokinesis-block micronucleus assay, and 8-hydroxy-2-deoxyguanosine formation. When similarly challenged with NTX-infused alcohol, patients presented with a significant reduction in DNA damage. *See id*. In addition, various other studies using human and animal tissues have shown that individually glycyrrhizin and mannitol prevent oxidative DNA damage. *See id*.

Based on the wealth of peer-reviewed literature, animal studies, human clinical test data, and product-specific testing, NTX® and its major components have been shown to reduce DNA damage from DNA single and double strand breaks induced by alcohol and other ROS generating systems in the liver.

Totality of the Scientific Evidence:

The well-documented scientific reports of Drs. Stohs and Preuss present balanced and objective evidence concerning the efficacy of NTX®. The more than 100 studies attached to this

Petition in Exhibit 5 substantiate the health claims requested in section III of this Petition. Significantly, in performing its review of the available scientific evidence under this Petition, TTB must in conformity with First Amendment standards consider all scientific evidence supportive of the requested claims. The TTB must acknowledge that human clinical testing in areas concerning alcohol exposure carries significant health and liability risks that render repeat (or expansive) testing impractical, costly, and perhaps unethical (e.g., long-term studies). The universe of scientific data is therefore limited by those practical considerations. Animal and in vitro models must be considered where supportive of the mechanism of action, or where such studies explain the biophysical or biochemical responses. Animal and in vitro models are often essential to develop or prove causal connections between the test components and a statistically significant effect later observed in human models.

E. NTX® Is Safe and Lawful when Added to Alcoholic Beverages

The TTB has already acknowledged that NTX® may safely and lawfully be added to alcoholic beverages because it has approved the use of NTX® in at least one alcoholic beverage, Bellion branded vodka. Plus, the TTB has authorized the use of mannitol, glycyrrhizin, and potassium sorbate, which are the three ingredients that comprise NTX®, in alcoholic beverages generally, subject to limitations. *See* TTB, *Limited Ingredients: Flavoring Substances and Adjuvants Subject to Limitation or Restriction* (explaining that mannitol, glycyrrhizin, and potassium sorbate may be added so long as they do not exceed 2.5%, 0.1%, and 0.1%, respectively).[20]

[20] *Available at* http://www.ttb.gov/ssd/limited_ingredients.shtml (last accessed April 5, 2016).

Similarly, the federal Food and Drug Administration ("FDA") allows mannitol, glycyrrhizin, and potassium sorbate to be added to foods, which also establishes that NTX® is safe. *See* 21 C.F.R. § 180.25 (approving the use of mannitol as a food additive, and noting that the ingredient is used as an anticaking agent and free flow agent); *id.* at §182.3640 (affirming that potassium sorbate, a chemical preservative, is generally recognized as safe ("GRAS") when it is used in accordance with good manufacturing practice); *id*. at §184.1408 (affirming that licorice and licorice derivatives, including glycyrrhizin, are GRAS when used as flavor enhancers in various foods, including alcoholic beverages).

To further attest to the safety of NTX®, Dr. Stohs' expert report identifies various studies that have evaluated the safety of NTX® and its constituents, and explains that during such studies, no serious adverse events were observed. *See* Stohs Rep. at 33-34.

F. The Proposed Claim Adequately Explains the Health Risks Associated with Both Moderate and Heavier Levels of Alcohol Consumption and Explains the Categories for Whom Any Alcohol Consumption Poses Risks

Consistent with section III *supra*, all Bellion advertising, labeling, and promotional material will feature the following disclaimer that corresponds with the proposed health claims:

> 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.

That disclaimer adequately and succinctly identifies the range of individuals who should not consumer alcohol, including, e.g., those with medical conditions or pregnant women. The claim

identifies the risks of moderate and heavy alcohol consumption that are not addressed through the NTX® technology.

Read in conjunction with the requested health claims, the speech conveyed to consumers precludes any suggestion or impression that alcohol is unequivocally safe to consume. Rather, the claim conveys the truthful and non-misleading impression that alcohol infused with NTX® is healthier than conventional alcoholic beverages, but not a "healthy" product in general terms.

G. The Proposed Claims Do Not Render NTX® a "Drug" Under Federal Law

The TTB has primary jurisdiction over the labeling and advertising of alcoholic beverages that are subject to the federal Alcohol Administration Act ("FAA Act"). *See* 27 U.S.C. § 205(e), (f); 27 C.F.R. Parts 4, 5, 7. The FAA Act applies to distilled spirits and certain wines and malt beverages. *See* 27 U.S.C. § 211(a)(5) (defining "distilled spirit" to mean "ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whiskey, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof, for non-industrial use"); *id*. at § (a)(6) (defining "wine" as, *inter alia*, containing 7 percent or more alcohol by volume); *id*. at § 211(a)(7) (defining "malt beverage" as "a beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption").

The FDA has also noted "that certain curative, therapeutic, or disease-prevention claims for an alcoholic beverage might place the product in the category of a drug under the Federal

Food, Drug, and Cosmetic Act (FFDC Act), 21 U.S.C. 321(g)(1)(B). *See* 68 Fed. Reg. 10076, 10078 (Mar. 3, 2003). The TTB agreed with the FDA, but also acknowledged that the TTB's system of "health claims" regulation is a separate regulatory model that mirrors the FDA's health claim model for foods and dietary supplements. In the preamble to its final rule for health claims and other health-related statements, the TTB explained:

> After giving careful consideration to these comments, and consulting with FDA, TTB does not agree that its health claim regulations should be identical to those of FDA. FDA regulations were promulgated pursuant to a very specific grant of authority by Congress under the NLEA. Because of the differences in statutory authority, as well as the differences in the products regulated under these two statutes, TTB's regulatory scheme for health claim labeling will differ from FDA's regulatory scheme.
>
> However, TTB agrees with the FDA comment in several respects. Most importantly, we agree that it is important to ensure that alcohol beverage producers do not violate the new drug provisions of the FFDC Act when seeking to use specific health claims on alcohol beverage labels. It would be where the use of that claim would render the product subject to FDA's jurisdiction over drugs. Furthermore, FDA's authority over new drugs has significant public health and safety consequences. TTB does not wish to create any confusion on the part of industry members regarding their obligations to comply with FDA's requirements over drug claims.
>
> In the past, ATF merely advised industry members that they should be aware of the fact that the use of a health claim on an alcohol beverage label may subject the product to FDA's jurisdiction. However, after reviewing the comments on this issue, we met with FDA to discuss a process whereby TTB and FDA could consult on the use of specific health claims on alcohol beverage labels. In this way, FDA would have an opportunity to object to the use of a specific health claim, based on its jurisdiction over drugs, prior to any TTB action.
>
> Accordingly, the final rule now provides that TTB will consult with FDA, as needed, on the use of specific health claims on labels. If FDA determines that a specific health claim is a drug claim that is not in compliance with the requirements of the FFDC Act, TTB will not approve the use of such statement on a label. There is no similar provision in the advertising regulations, since advertisers are not required to obtain prior approval from TTB. We will of course consult with FDA, as appropriate, if the question arises as to whether an advertisement is in violation of the FFDC Act.

Id. at 10098.

While the TTB has enacted regulations governing the use and dissemination of "specific health claims," and has accepted jurisdiction by "evaluat[ing] such statements on a case-by-case basis…,"[21] the TTB also lacks authority to impose FDA regulatory requirements on spirit products. Neither the FAA Act nor the interpretive case law confers authority on the TTB to look beyond the TTB's enabling regulations in, for instance, 27 C.F.R. § 7.29(e) to determine whether a product claim is permissible under regulations enforced by other sister agencies without jurisdiction.

The ATF (TTB's predecessor) has acknowledged that "there are differences between ATF's statutory mandate to prevent misleading statements on labels and in advertising of alcoholic beverages under the FAA Act, and the more specific authority given to FDA in regulating health claims on food labels pursuant to the NLEA." *See Health Claims in the Labeling and Advertising of Alcoholic Beverages*, ATF IC 9308, 1993 WL 719948 (ATF Aug. 2, 1993).

Those points notwithstanding, the TTB health claim regulations are clearly designed to exempt certain "health claims" from the federal "drug" model when used for spirit beverages and subject to TTB preapproval. The TTB regulations unambiguously provide for TTB approval of "health claims" and "specific health claims" that "characterize[] the relationship of the malt beverage, alcohol, or any substance found within the malt beverage, to a disease or health-related condition." *See* 27 CFR § 7.54(e)(ii). That language mirrors the FDA's "health claim" exemptions under the NLEA, wherein the FDA approves claims that also "characterize the relationship between the substance in a food to a disease or health-related condition…" *See, e.g.,*

[21] *See, e.g.,* 27 C.F.R. § 7.54(e).

21 C.F.R. § 101.70(f); 21 U.S.C. § 343(r)(1)(B) (defining a health claim to mean a claim that "characterizes the relationship of any nutrient . . . to a disease or a health-related condition . . .").. Through the passage of 27 C.F.R. §§ 7.29, 7.54, and similar regulations, the TTB unambiguously established a pathway for health claim approval that is specific to TTB's jurisdiction and independent of the FDA's statutory authority and regulatory models.

Nonetheless, the health claims requested by this petition are not treatment or drug claims but, rather, claims that describe the role of the NTX® dietary ingredients that is intended to affect the structure or function of humans through well-documented mechanisms showing that NTX® maintains, protects, or supports those structure (to wit, hepatic systems and DNA). The FDA expressly excludes such claims from the definition of "drug" under Section 403(r)(6) of the federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 343(r)(6). Certain of the claims pertain to the reduction in the risk of disease effected by NTX® but they are, in that respect, indistinguishable from claims FDA and the federal courts regard as health claims. The FDA expressly excludes such "health claims" from the definition of "drug." *See id*. at § 343(r)(1)(B), (3)-(5). Although the FDA's regulatory model regarding health claims is not applicable here in the TTB context, the FDA's system—from which the TTB's regulation is apparently modeled—expressly excludes health claims from the "drug" context. *See id*. at § 343(r)(1)(B) (defining health claim as one that characterizes a relationship between a substance and a disease or health-related condition).

H. The Proposed Health-Related Statements Constitute Protected Commercial Speech under *Central Hudson* and Its Progeny

The proposed health-related statements are protected commercial speech under *Central Hudson* and its progeny. *See generally Central Hudson Gas & Elec. Corp. v. Pub. Serv.*

Comm'n of N.Y., 447 U.S. 557 (1980); *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (applying *Central Hudson*'s test to strike regulations prohibiting beer producers from truthfully disclosing the alcohol content of beers). In *Central Hudson*, the U.S. Supreme Court acknowledged that the First Amendment protects commercial speech from unwarranted government intrusion, albeit less so than other constitutionally guaranteed expression. *See* 447 U.S. at 562. "The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation." *Id*. at 563. If a commercial "communication is neither misleading nor related to unlawful activity, the government's power is more circumscribed." In that instance, courts evaluate four elements in determining whether government censorship of commercial speech violates the First Amendment: (1) whether the speech concerns lawful activity and is not misleading; (2) whether the government's interest in prohibiting the speech is "substantial;" (3) whether the prohibition at issue "directly advances the governmental interest asserted;" and (4) whether the prohibition is "more extensive than is necessary to serve that interest." *Rubin*, 514 U.S. at 482 (citing *Central Hudson*, 447 U.S. 557 (1980)).

"The party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71, n. 20 (1983). "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (citations omitted). To ban the proposed health-related statements, the TTB must show either that the language is not protected speech or that TTB's interest in government censorship is substantial and the method of censorship advances those interests in a direct and

material way and that there are no obvious, less speech-restrictive alternatives (such as claim qualifications). *Id.* at 767.

i. The Health-Related Statements Concern Lawful Activity and are Not Misleading

As explained in section IV(C), *infra*, and through the supporting evidence attached hereto, the available scientific record substantiates the truthfulness of the proposed health-related statements. The sale of Bellion Vodka and/or other alcoholic beverages containing NTX through the use of truthful and non-misleading health claims constitutes constitutionally protected activity. Moreover, no evidence demonstrates that the proposed health-related statements create a misleading impression concerning the effects on health of alcohol. No evidence suggests that Bellion's health claims would promote an increase in alcohol consumption. Where TTB imposes an outright ban on a claim based on the alleged existence of implied claims, the TTB's decision must be supported by empirical evidence demonstrating that consumers actually understand the label to convey the implied claims and are misled by them.[22] The TTB's regulations acknowledge that claims should be remedied through disclaimers. Here, Bellion's claims are supported by reliable scientific evidence. Thus, at worst, the proposed health-related statements are only potentially misleading. That distinction is critical because potentially misleading speech

[22] Where TTB imposes an outright ban on a health-related statements, the TTB's decision must be supported by empirical evidence demonstrating that consumers actually understand the statement to convey the misleading claims, are misled by those claims, and that the proposed qualifying language would not otherwise remedy that misleadingness. *See Fleminger, Inc. v. U.S. Dep't of Health and Human Servs.*, 854 F. Supp. 2d 192, 216 (D. Conn. 2012) (explaining that, based on established precedent, agencies must have "empirical evidence in connection with the government's outright ban on the proposed health claim"); *see also Whitaker v. Thompson*, 248 F. Supp. 2d 1, 11 (D.D.C. 2002) (citing *Pearson v. Shalala*, 164 F.3d 650, 659–60 (D.C. Cir. 1999) (explaining that a complete ban of a claim would be approved only under narrow circumstances, i.e., when there was almost no qualitative evidence in support of the claim and where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer").

is entitled to constitutional protection under the First Amendment and may not be banned outright by this or any other federal agency. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) ("*Pearson I*").

To establish that the proposed health-related statements are potentially misleading (as opposed to truthful and non-misleading), the TTB must have factual evidence showing that they are misleading before it may censor them because the TTB—not Bellion—has the burden to justify restrictions on speech. *See Pearson I*, 164 F.3d at 659 (explaining, in part, that the required use of disclaimers is a burden on speech). The TTB cannot declare a statement misleading, and bar that statement outright, by uttering the word "misleading" or resorting to categorical labels. To prove any of the proposed health-related statements is deceptive, the TTB "must offer consumer data or other extrinsic evidence to show that the audience to which the advertisement is directed is in fact misled [or capable of being misled] by the advertisement." *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009) (citing *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007)); *see also Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002) (explaining that if a plaintiff challenges "a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers"); *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 117 F.3d 489, 497 (5th Cir. 2000) ("if the statements at issue are either ambiguous or true but misleading, the plaintiff must present evidence of actual deception") (citations omitted).

The TTB cannot show that any of Bellion's proposed health-related statements is misleading, because the TTB cannot show that (1) the health-related statement misleads consumers into thinking that alcoholic beverages containing NTX® are healthy; or (2) that

consumers will consume more alcoholic beverages than they otherwise would without the health-related statement.

Consumers remain aware that alcohol is unhealthy when consumed in excess or on a regular basis. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965) (exempting alcohol sellers from liability for failing to warn of alcohol dangers, which includes dangers from consumption "in excessive quantit[ies]" and consumption "over a long period of time," because those dangers are "generally known and recognized" by the public). Consumer impact surveys in the mid-1990s concerning health claims on wine products found that participants exposed to those health-related statements did not exhibit a diminished understanding of the risks of drinking. *See Lieberman*, *supra*, 58 Food & Drug L.J. at 515. Moreover, the proposed claim qualification, and indeed any comparable and reasonable qualification—which would be acceptable to Bellion—disabuses consumers of any notion that alcohol consumption is safe or that drinking to excess is advisable.

To the extent that the TTB would view the proposed health-related statements as specific health claims, the qualification or disclaimer proposed herein that will appear as part of them ensures that any potential misleadingness as to the effects on health of alcohol consumption will be dispelled. The proposed disclaimer: (1) is sufficiently detailed and qualified with respect to explaining the categories of individuals to whom the claim applies; (2) adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and (3) outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks.

In sum, there is no basis to conclude that the proposed health-related statements, with the accompanying claim qualification or disclaimer, are potentially misleading or misleading in any respect.

ii. Outright Censorship of the Truthful and Non-Misleading Health-Related Statements Does not Advance any Governmental Interest and Contradicts the TTB's Stated Objectives

Under *Central Hudson*, the government must assert a "substantial interest" in restricting speech. *Coors*, 514 U.S. at 483. Assertion of a substantial interest is not a trifling or insignificant burden on government action. Identifying the asserted interest is critical to an assessment under *Central Hudson*.

The TTB has previously explained that health-related statements must be regulated to prevent alcohol abuse by those consumers who might mistake alcohol for a healthy (or at least less harmful) product. In other words, the TTB has historically argued that it has an interest in prohibiting truthful statements which, by implication, "tend to create a misleading impression" that might encourage consumers to consume more alcohol to their detriment. If the TTB claims a state interest in protecting consumers from truthful information that could lead to abusive behaviors, it should be mindful of the fact that courts have already rejected that approach. *See 44 Liquormart*, 517 U.S. at 503 (explaining that courts express skepticism over government interests that "rest on the offensive assumption that the public will respond 'irrationally' to the truth").

Health-related statements for alcoholic beverages do not materially influence consumer drinking patterns, which undercuts the TTB's theory that protection of consumers from health claims is a significant state interest. *See* Lieberman, *The Power of Positive Drinking: Are Alcoholic Beverage Health Claims Constitutionally Protected?* 58 Food & Drug L.J. 511, 515

(2003). The ATF, the TTB's predecessor, considered this issue in 1998 when wine sellers asked for authority to promote the consumption of wine in moderation given evidence that consumption produced beneficial health effects. *Id.* The ATF commissioned a consumer impact study that found health claims on wine labels did not "induce wine drinkers to alter their drinking pattern, quantitatively or otherwise." *Id.* That study also found that "nothing in the proposed labels appeared to diminish focus group participant perceptions about the risk of drinking." *Id.* In other words, the health-related statements did not sway consumers into suddenly believing that the risks of alcohol consumption had dissipated.

Although the TTB might claim a substantial interest in protecting United States consumers from the ills of alcohol abuse, that interest is legally and factually distinct from a state interest in protecting consumers from truthful labeling content. Protecting consumers from truthful, verifiable, and non-misleading ingredient disclosures is a practice at odds with the TTB's mission and purpose, and lacks a "substantial" undergirding state interest. Perhaps for that reason, all nine Justices on the United States Supreme Court agreed that the ATF's prior label restrictions were unconstitutional in *Coors*, and at least one Justice would have applied "full First Amendment protection" to similar label disclosures involving alcohol content. *See Coors Brewing*, 514 U .S. at 491-92 (Stevens, J., concurring).

iii. Censoring the Health-Related Statements Will Not Advance an Interest in Protecting Consumers from the Ills of Alcohol Abuse

Even if the proposed health-related statements are banned, there is "no evidence to suggest that [the TTB's] speech prohibition will *significantly* reduce [or effect] marketwide consumption." *See 44 Liquormart*, 517 U.S. at 506. Under the third element of *Central Hudson*, a restriction on commercial speech is only valid if it directly advances the asserted governmental interest. *Coors*, 514 U.S. at 486. The government bears the burden "of showing that the

challenged regulation advances the Government's interest 'in a direct and material way.'" *Id.* at 486–87 (quoting *Edenfield v, Fane*, 507 U.S. 761, 767 (1993)). "That burden 'is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Id.* at 487 (quoting *Edenfield*, 507 U.S. at 770–71).

To meet its burden and show that regulation advances the governmental interest in a "direct and material way," the TTB must produce actual evidence that allowing the speech would harm the interest it seeks to further through the prevention of that speech. *See Pearson v. Edgar*, 153 F.3d 397, 404 (7th Cir. 1998) (overturning regulation prohibiting real estate brokers from soliciting where government "produced no evidence in this case that real estate solicitation harms or threatens to harm residential privacy"). The courts have made clear the TTB cannot meet that burden "by mere speculation or conjecture; rather a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 625–26 (1995). "Thus, the government must come forward with some quantum of evidence, beyond its own belief in the necessity for regulation, that the harms it seeks to remedy are concrete and that its regulatory regime advances the stated goals." *Pagan v. Fruchey*, 492 F.3d 766, 771 (6th Cir. 2007) (citing *Edenfield*, 507 U.S. at 770–72).

In *Pagan*, for instance, the Sixth Circuit concluded that an affidavit submitted by the government was insufficient to prove that the regulation at issue, the posting of "for sale" signs on cars, directly and materially advanced the state's interests in traffic safety and aesthetics. *Id.* at 772–73. While the government argued that "it would be difficult, expensive, and time-consuming to conduct studies and provide empirical evidence in support of [the regulation]," the

court held that government must nevertheless offer some "actual evidence" that the regulation "will directly advance the government's asserted interest." *Id.* at 773–74; *cf. Anderson v. Treadwell*, 284 F.3d 453, 462 (2d Cir. 2002).

The TTB must have "credible evidence" that allowing the speech at issue would harm the interest asserted. *Id.* at 489; s*ee also 44 Liquormart*, 517 U.S. at 503 (requiring the government to provide evidence that prohibiting price advertising would actually advance the governmental interest in temperance). For example, in *Coors* the government asserted that allowing breweries to disclose the amount of alcohol on their labels would promote "strength wars."[23] *Id.* However, the Court recognized that prohibition of alcohol content on beer labels failed to suppress strength wars to any degree. *Id*. at 490–91 (noting that "the Government did not offer any convincing evidence that the labeling ban has inhibited strength wars").

Here the TTB has no credible evidence that the proposed health-related statements would harm any state interest or that consumers would be misled by them, especially when those health claims are accompanied by the proposed disclaimer. Consumers decide how to drink alcoholic beverages (quantitatively and qualitatively) based on a variety of reasons that may include sociological and psychological factors. Convenience and circumstance likely factor more in the decision than health related-statements. For instance, the quantity of alcohol consumed may depend on the social environment, the availability of transportation, the age of the drinker, etc. Accordingly, the concept that prohibiting a health-related statement will influence the rate, amount, of frequency of alcohol consumption is sheer speculation.

iv. Prohibiting the Proposed Health-Related Statements Is Not Sufficiently Tailored to Any Governmental Goal

[23] A strength war, in that context, is a competition between breweries who "seek to compete for customers on the basis of alcohol content." *Coors*, 514 U.S. at 483.

To pass constitutional muster under *Central Hudson*, the final analysis requires the TTB to prove that a speech restriction is sufficiently tailored to its articulated goal. *Coors,* 514 U.S. at 490. Assuming *arguendo* that the TTB has a defined and substantial interest in regulating the proposed health-related statements, that interest is not directly advanced by the TTB's censorship of the claims here in isssue.

Even assuming that the TTB could demonstrate an important state interest, and that unqualified health-related statement have the potential to mislead, the TTB must then *prove* that there are no less speech-restrictive alternatives, such as the disclaimers required under its own regulations for specific health claims. *Pearson I,* 164 F.3d at 658-59 (requiring reliance on disclaimers as a less speech restrictive alternative to outright suppression); *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48, 71 (D.D.C. 2010) ("*ANH I*") (invalidating FDA disclaimer language and holding that FDA acted unconstitutionally by requiring a more onerous disclaimer without considering whether a short and succinct disclaimer would be a less restrictive means); *see also Pearson v. Shalala*, 130 F. Supp. 2d 105, 120 (D.D.C. 2001) ("*Pearson II*").

Here, as discussed above, the Petitioners propose a disclaimer to accompany the health-related statements that is sufficient to cure any potential for misleadingness regarding the effects of alcohol on health. The Petitioners proposed that disclaimer despite TTB having conceded in prior agency statements that burdensome disclaimers for specific health claims would be "extremely unlikely [to] fit on a normal alcoholic beverage label." *See* Health Claims in the Labeling and Advertising of Alcoholic Beverages, ATF IC 93-8, 1993 WL 719948 (ATF Aug. 2, 1993). Because "no label has [ever] met," the standard clearly reveals that the burdens of the TTB regulations have, to this point, effected a de facto market ban. *See, e.g.*, Erik Bierbauer,

Liquid Honesty: The First Amendment right to Market the Health Benefits of Moderate Alcohol Consumption, 74 N.Y.U. L. Rev. 1057, 1068 (1999) (explaining that "[t]he only health statement that ATF said it would accept was a four-page report with thirty-four footnotes, which the agency said presented a balanced view of drinking's good and ill effects.").

To the extent that the TTB will require a more onerous, lengthy, and burdensome disclaimer than the one proposed, the TTB would violate the First Amendment's requirement for reasonable claim qualification, which is to mandate "short, succinct, and accurate" qualifications. *Pearson II*, 130 F. Supp. 2d at 120. Moreover, there is no proof that onerous and lengthy disclaimers are the only ones capable of effectuating a legitimate government interest such that there are no "less restrictive means" through short, succinct and accurate disclaimers, such as the one proposed in this petition. *See Pearson I*, 164 F.3d at 658. Absent extrinsic evidence that such onerous disclaimers are required to cure any alleged misleadingness caused by the proposed health-related statements, requiring onerous disclaimers is unconstitutional. Indeed, the federal courts have explained repeatedly that the government acts unconstitutionally unless it can "demonstrate with empirical evidence that [much shorter] disclaimers … would bewilder consumers and fail to correct for deceptiveness." *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 5 (D.D.C. 2002); *Pearson I*, 164 F.3d at 659-60; *ANH I*, 714 F. Supp. 2d at 63 (invalidating FDA censorship because the "[a]gency has not provided any empirical evidence, such as 'studies' or 'anecdotal evidence,' that consumers would be misled").

V. Conclusion

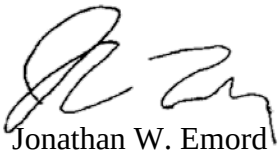
For the foregoing reasons, the Petitioners request that TTB authorize the proposed health-related statements concerning NTX®. Those claims include the following health claims in Bellion labels, labeling, advertising, and promotional statements:

- NTX® provides antioxidant and anti-inflammatory support;
- NTX® helps protect against alcohol-induced oxidative damage to the liver;
- NTX® helps maintain normal liver enzyme production and function;
- NTX® supports normal liver defenses and regenerative mechanisms;
- NTX® reduces the risk of alcohol-induced liver diseases, including fibrosis and cirrhosis;
- NTX® helps maintain normal liver functions;
- NTX® helps protect DNA from alcohol-induced damage; and
- NTX® reduces alcohol-induced DNA damage

Any questions concerning this Petition may be directed to Jonathan W. Emord, Esq. Emord & Associates, P.C., 11808 Wolf Run Lane, Clifton, VA 20124, (202) 466-6937. The undersigned certify on behalf of the Petitioners that to the best of their knowledge and belief, the Petition includes all information and views on which the Petitioners rely and is a representative and balanced submission that includes unfavorable information as well as favorable information known by the Petitioner to be pertinent to evaluation of the proposed health claims.

DATED: April 12, 2016.

Sincerely,



Jonathan W. Emord
Peter A. Arhangelsky
Bethany R. Kennedy
Counsel to Bellion Spirits, LLC
And Chigurupati Technologies
Private Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this April 11, 2016, copies of the foregoing Health Claim Petition and all supporting exhibits were mailed via UPS Next Day Air (in hardcopy and electronic format) to:

Teresa G. Knapp
Assistant Director, Advertising, Labeling and Formulation Division
Alcohol, Tobacco Tax and Trade Bureau
1310 G Street, NW, Box 12
Washington, DC 20005

Gail Davis
Deputy Assistant Administrator, Headquarters Operation
Alcohol, Tobacco Tax and Trade Bureau
1310 G Street, N.W., Box 12
Washington, DC 20005

Theresa McCarthy (Theresa.McCarthy@TTB.Gov)
Gail Davis (Gail.Davis@TTB.Gov)
Teresa Knapp (Teresa.Knapp@TTB.Gov)
Janet Scalese (Janet.Scalese@TTB.Gov)
Matthew Aboyme (Matthew.Aboyme@TTB.Gov)
John Manfreda (John.Manfreda@TTB.Gov)
Janet Slattery (Janet.Slattery@TTB.Gov)

Counsel for Bellion Spirits, LLC

/s/ Jonathan W. Emord
Jonathan W. Emord