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khlaw.com
202.434.4100

Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Writer's Direct Access
Azim Chowdhury
(202) 434-4230
chowdhury@khlaw.com

December 1, 2023

Via Electronic Mail

Charlotte Owen
Rick Avila
Geoff Habicht
Ready Mix Naturals, LLC
1435 N Highway 123 Byp
Seguin, TX 78155

**CONTAINS CONFIDENTIAL
BUSINESS INFORMATION**

**Re: FDA Tobacco Product Status of Zero-Nicotine Nixamide™ and
Nixamide™-Containing E-Liquids and Vape Products**

To Whom It May Concern:

The purpose of this letter is to respond to your request for our opinion regarding the status, under the laws and regulations administered by the U.S. Food and Drug Administration (“FDA”) Center for Tobacco Products (“CTP”), of Ready Mix Naturals, LLC’s zero-nicotine Nixamide™ product, which is intended to be used as a component of e-liquids that do not contain nicotine or tobacco-derived ingredients. Based on our review of confidential and proprietary information on the product, we have no hesitation in providing our opinion that Nixamide™ is not a “tobacco product” as defined in the Food, Drug and Cosmetic Act (“FDCA” or the “Act”), as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (“TCA”) and the Consolidated Appropriations Act of 2022 (“CAA”).¹ Furthermore, vape products and e-liquids that contain Nixamide™ in lieu of nicotine would also not fall within meaning of a tobacco product provided they do not (1) otherwise contain tobacco-derived substances or nicotine or (2) fall within meaning of a tobacco product “component and part”. This opinion is based on several factors, including:

¹ Under FDCA Section 201(rr)(1), 21 U.S.C. § 321(rr), a tobacco product “means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” The statute further provides that a tobacco product does not mean (1) a drug under Section 201(g)(1) of the Act, a device under Section 201(h), or combination product as described in Section 503(g); or (2) an article that is a food under Section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

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- Nixamide™ is a proprietary blend of nicotinamide (CAS Reg. No. 98-92-0) and either vegetable glycerin (“VG”), propylene glycol (“PG”), or combinations thereof.
- In the TCA, “nicotine” is defined by its International Union of Pure and Applied Chemistry (IUPAC) name and chemical formula as the “chemical substance named 3-(1-methyl-2-pyrrolidiny)pyridine, which has a molecular formula of C₁₀H₁₄N₂, including any salt or complex of nicotine.” *See* 21 U.S.C § 387(12).
- None of the Nixamide™ ingredients are made or derived from tobacco or nicotine, or use tobacco or nicotine as a starting substance. Specifically, no form of nicotine, including S(-)-nicotine (CAS Reg. No. 54-11-5), R-(+)-nicotine (CAS Reg. No. 25162-00-9), or racemic-(±)-nicotine (CAS Reg. No. 22083-74-5) is used as an ingredient of Nixamide™ or used in the synthesis of Nixamide™ or any of its ingredients.
- Analytical test results have confirmed that nicotine is not present in Nixamide™ at an appropriately sensitive limit of detection.
- Vape products and e-liquids that contain Nixamide™ in lieu of nicotine would also not fall within meaning of a tobacco product provided they do not (1) otherwise contain tobacco-derived substances or nicotine (at more than insignificant residual impurity levels), or (2) fall within meaning of a tobacco product “component and part”.²

* * * *

² This means that Nixamide™-containing e-liquids and vape products should not be used in a manner that could imply that they are intended or reasonably expected, based on a totality of the circumstances to (1) alter or affect a tobacco product’s performance, composition, constituents, or characteristics; or (2) be used with or for the human consumption of a tobacco product. This means that, for example, the finished Nixamide™ e-liquids should never be mixed or used with e-liquids that contain nicotine or tobacco-derived substances, or consumed via an open-tank vape device that is normally used with nicotine e-liquids. Similarly, closed-system vape devices (e.g., disposables and pod systems) that are pre-filled with Nixamide™ e-liquid should not be capable of being refilled, or manipulated or altered in any way that could allow the device to be used with or for the consumption of nicotine, tobacco, or tobacco-derived substances. In other words, once all of the pre-filled Nixamide™ e-liquid has been vaped, the device (or pods) are intended to be discarded and not reused. We recommend that the packaging and labeling of all Nixamide™-containing e-liquids and vape devices should contain disclaimers that the products are not intended to be altered in any way and, specifically, should not be used with or for the consumption of nicotine or tobacco. E-liquid manufacturers that are replacing nicotine with Nixamide™ should be sure to inform their consumers on how to properly handle and use Nixamide™ e-liquids.

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Accordingly, based on the information that you provided, we have no hesitation in concluding that Nixamide™ is not a tobacco product as defined in the FDCA. Furthermore, vape products and e-liquids that contain Nixamide™ in lieu of nicotine would also not fall within meaning of a tobacco product provided they do not (1) otherwise contain tobacco-derived substances or nicotine or (2) fall within meaning of a tobacco product “component and part”. Accordingly, neither Nixamide™ nor e-liquids and vape products made with Nixamide™ are subject to the Tobacco Control Act and FDA’s premarket authorization requirement for new tobacco products.³

We trust that this letter is responsive to your request for our opinion. Should you have any questions or concerns, please do not hesitate to let us know.

Cordially yours,



Azim Chowdhury

4856-8590-8372, v. 1

³ This letter does not assess the safety of Nixamide™-when used as intended, or whether Nixamide™-containing products could be subject to any other potentially applicable legal requirements.