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Via CTP Portal and UPS Overnight Delivery

Robert M. Califf M.D., MACC
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Dr. Califf:

We write to share important information related to so-called nicotine analogues that have begun to appear in the U.S. marketplace and which may be evading FDA regulation. As you know, in March 2022, Congress clarified the definition of covered tobacco products to include those using synthetic nicotine, with the intent to establish FDA's clear authority over nicotine-containing products.

The sale of products with an active ingredient designed to imitate nicotine poses a new threat to creation of a fully regulated market. These include "Metatine" (Charlie's Holdings Inc.'s *Spree Bar* product) and "Nixamide" (Outlaw Dip Co's "*Nic-Safe*" product), suggesting these chemicals are "alternative solutions to nicotine" that are not subject to FDA regulation, including tobacco regulatory requirements and that they do not require a Pre-Market Tobacco Product Application (PMTA). Additionally, "Imotine" (from Novel Compounds LLC) is being marketed as a new vapor and pouch product additive that does not require a PMTA.

We believe these companies are intentionally exploiting FDA's regulatory authority because the tobacco and nicotine products regulatory framework is not working as it was envisioned. The Center for Tobacco Products is not making enough science- and evidence-based decisions through the PMTA pathway to authorize less harmful smoke-free products and make them available to adult smokers who can't or won't quit all tobacco use. Rather than go through the established legal regulatory processes for products containing nicotine and wait years for authorization decisions, these companies appear to have determined that it is easier to create new chemical compounds and develop products for sale to U.S. consumers that avoid regulatory oversight and decision-making.

Furthermore, the lack of evidence basis supporting these chemicals is cause for concern. Unlike nicotine which has been studied extensively and is subject to decades-worth of scientific literature, a paucity of evidence supports these newly emerging nicotine analogues. We did identify the attached study published in *Tobacco Control* in March 2024 which focuses on the product *Spree Bar* utilizing "Metatine." As you will see, the authors raise their concerns that the purpose of this and similar chemicals is to evade regulation.

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We encourage FDA to carefully and quickly evaluate these new compounds to determine what regulatory authority it has over these products, and whether manufacturers' public characterizations of the regulatory status of these products are misleading. In particular, we encourage FDA to evaluate the explicit and implicit claims being made about these substances and the products that contain them to assess whether these products fall under the purview of the Center for Tobacco Products as a tobacco product, the Center for Drug Evaluation and Research as an unapproved new drug, or the Center for Food Safety and Applied Nutrition as legally marketed foods or dietary supplements. To that end, we have attached information, including website links and current public statements, to support FDA's fact gathering and analysis.

Additionally, after such a review, we urge FDA to quickly determine and broadly announce its policy on these nicotine analogue substances and take immediate enforcement actions if the Agency determines that the sale and marketing of products containing these substances violate the Federal Food, Drug, and Cosmetic Act and FDA regulations.


It is critically important that FDA move with urgency to assess this situation and exert its regulatory authority where appropriate. FDA's inability to react to an emerging synthetic nicotine market and massive importation of flavored disposable nicotine products has allowed an unregulated market to fester and evade FDA's authorities. If not regulated and subject to timely enforcement action, these so-called nicotine analogue products will only serve to exacerbate the already-existing illicit market, compounding FDA's enforcement challenges and the public's frustrations.

At Altria, we have long-supported a federal regulatory framework designed to ensure that all tobacco and nicotine-containing products are made, distributed, and sold within an FDA-regulated system that minimizes underage use, provides adult smokers who can't or won't quit tobacco use with proven lower-risk choices, and ensures all adult consumers benefit from FDA oversight over all the products they buy.

The introduction and growth of chemicals intended to imitate the effects of nicotine, if left unchecked, could present unknown risks to U.S. consumers and undermine FDA's authority.

Thank you for your interest, and please contact me if you have questions or need more information.

Sincerely,

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Paige Magness
 Signer Name: Paige Magness
Signing Reason: I approve this document
Signing Time: 5/9/2024 | 3:28:51 PM EDT
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Spree Bar, a vaping system delivering a synthetic nicotine analogue, marketed in the USA as 'PMTA exempt'

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BACKGROUND

In February 2021, the popular vaping company, PuffBar, started selling disposable e-cigarettes in the USA containing synthetic nicotine, claiming to be exempt from federal and state laws regulating products containing tobacco-derived nicotine.¹ US lawmakers responded to the emerging synthetic nicotine market by clarifying that synthetic nicotine products are subject to the US Food and Drug Administration's (FDA) regulatory regimen for tobacco products.^{1–3} As of 14 April 2022, the FDA has been authorised to regulate tobacco products containing nicotine from any source, including laboratory synthesis, requiring manufacturers to submit a premarket tobacco product application (PMTA).³ In October 2022, the FDA sent a warning letter to the company, alerting the owners that its products are 'marketed unlawfully and are subject to enforcement action at FDA's discretion'.^{4,5} Currently, the company appears to be selling Puffbar-branded e-cigarette products without nicotine only.⁶

While many countries have updated their tobacco product laws to cover synthetic nicotine, or are in the process of doing so, a recent WHO report warned that non-nicotine tobacco alkaloids or synthetic nicotine analogues could be used by manufacturers to bypass regulatory schemes focusing on nicotine alone.² Non-nicotine tobacco alkaloids such as anabasine, nornicotine, anatabine and myosmine have well-known addictive and reinforcing effects.^{7–10} Starting in the 1970s, tobacco companies also developed various synthetic nicotine analogues and studied whether they could be used to dissociate nicotine's central and peripheral effects, to create more desirable products, to circumvent regulation or to develop pharmaceuticals.¹¹ The tobacco companies, however, never used these synthetic nicotine analogues in commercial products until now.

Spree Bar, a 'PMTA exempt' electronic cigarette system

The concern that companies might use synthetic nicotine analogues in order to avoid regulation is no longer hypothetical. As of October 2023, vape stores in the USA had started selling a new electronic cigarette pod system named Spree Bar, advertised as 'PMTA exempt' (figure 1).¹² Spree Bar products are promoted through convenience store advertising and web channels, using youth-appealing and young adult-appealing artificial intelligence-generated characters (figure 1). The

products are marketed as containing 'Metatine', a trademarked name for a synthetic nicotine analogue (figure 2).^{13–15} The trademark name owner and wholesaler of Spree Bar, Charlie's Holdings (Costa Mesa, California, USA), states:

'SPREE BAR is prefilled with flavoured e-liquid containing proprietary Metatine. Metatine is a synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids. Although Metatine (sic) produces the same sensation as nicotine and may also be addictive, Metatine is not made or derived from tobacco or nicotine, and Metatine does not consist of or contain nicotine from any source.'

SPREE BAR products containing Metatine (and no tobacco-derived materials or nicotine) do not meet the definition of a 'tobacco product' in the Federal Food, Drug and Cosmetic Act (FDCA) and do not require a PMTA to be sold in the USA.¹²

The wholesaler also claims that selling Spree Bar products would allow vendors to keep more profits since they cannot be taxed as tobacco products: 'Metatine products are exempt from nicotine excise taxes in many states, which can result in massive savings for retailers and consumers. Metatine can be combined with many flavours and is legal to sell in nearly all 50 states'.¹⁶

Charlie's Holdings explicitly stated that it was using a synthetic nicotine analogue in Spree Bar, rather than nicotine itself, in order to avoid FDA regulation. The company further explained that it had abandoned its pending PMTA submissions for its nicotine-containing e-cigarette products and was instead focusing on Spree Bar because it was 'frustrated' by the pace of the FDA's PMTA reviews and by the fact that 'no company in the world, to date, has received an FDA marketing order for a flavoured disposable vape product'.¹⁴

'METATINE' (6-METHYL NICOTINE) AS A NICOTINE REPLACEMENT: TOXICOLOGY AND ADDICTIVENESS

'Charlie's Holdings, the supplier of Spree Bar, established a website with the address 'metatine.com' stating that:

The substance Metatine has the International Union of Pure and Applied Chemistry (IUPAC) designation 2-methyl-5-[(2S)-1-methylpyrrolidin-2-yl]pyridine...¹⁷

2-methyl-5-[(2S)-1-methylpyrrolidin-2-yl]pyridine is synonymous with (S)-6-methyl nicotine



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SPREE BAR PRODUCTS SUSTAINABILITY ABOUT METATINE™ CONTACT US **WHOLESALE**

THE HUMANITY OF ARTIFICIAL INTELLIGENCE

6000 PUFFS PMTA EXEMPT POD DEVICE

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ORDER NEW INNOVATIVE POD SYSTEM

Combining award-winning flavors with cutting-edge technology to produce an **AMAZING** vaping experience! Created by smokers for smokers, SPREE BAR comes in 9 wildly popular flavors... that LAST... all day! State-of-the-art rechargeable AND reusable battery! Flavor pod system is good for the environment... and your wallet!

SEE THE FLAVORS

SOCIALIZE WITH US ON INSTAGRAM **FOLLOW US**

Figure 1 Screen shot of the Spree Bar website taken on 10 August 2023, with a statement claiming that the products are 'PMTA exempt'.¹² PMTA, premarket tobacco product application.

(Chemical Abstracts Number: CAS 13270-56-9) (figure 3).¹⁸ 6-methyl nicotine is a structural analogue of nicotine (figure 3), with a methyl group substitution at position 6 of nicotine's pyridine ring. Recently awarded patents describe new synthesis protocols to generate 6-methyl nicotine from petrochemical precursors.^{19–21} One such patent was assigned to Shenzhen Zinwi

Biotech, a leading e-liquid company that also sponsored a toxicological study at Guangdong Pharmaceutical University. This study reported that 6-methyl nicotine has increased cytotoxicity compared with nicotine in a permanent human bronchial epithelial cell line (BEAS-2B), but milder effects on the upregulation of lung cancer-related proteins.^{19,22} The authors conclude 'that new

Metatine™

A synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids.

Metatine™ is not made or derived from tobacco or nicotine and does not consist of or contain nicotine from any source. Nevertheless, Metatine™ may be addictive.

Products containing Metatine™ (and no tobacco-derived materials or nicotine) do not meet the definition of “tobacco product” in the Federal Food, Drug, and Cosmetic Act and **do not require a PMTA to be sold in the US.**



Figure 2 Section of a screen shot of the Metatine website taken on 23 September 2023, stating that products containing the active ingredient, 6-methyl nicotine, do not meet the definition of ‘tobacco product’ in the Federal Food, Drug and Cosmetic Act and do not require a PMTA to be sold in the USA.¹⁷ PMTA, premarket tobacco product application.

electronic cigarettes with 6-MN might offer some advantages over conventional electronic cigarettes containing nicotine’, providing evidence that the sponsoring company is seeking to encourage use of the compound, 6-methyl nicotine (abbreviated as 6-MN), in e-cigarettes.²² However, no toxicological data in humans are available for 6-methyl nicotine, and in vivo study in rats revealed that the 50% lethal dose for 6-methyl nicotine is at least 1.5–3 fold lower than for nicotine, suggesting that 6-methyl nicotine is more toxic than nicotine.^{23–24}

Another patent, assigned to Shanghai Lingnuo Biotech, includes human studies in which e-cigarette users were asked to rate the ‘throat hit’ and other psychophysical qualities of e-cigarette aerosol containing 6-methyl nicotine.²⁰ In one of these studies, 1 mg/mL 6-methyl nicotine was found to be as satisfying as 3 mg/mL nicotine and to produce a similar ‘throat hit’, with the authors concluding that ‘6-methyl nicotine can be used for replacing nicotine in electronic aerosolisation’.²⁰ Only 10 test subjects participated in this study, with unknown background,

with puffing protocols not mentioned, and with no statistical analysis provided.

While a manufacturer-sponsored study claimed that 6-methyl nicotine may be less addictive than nicotine,²² previous pharmacological studies demonstrated that 6-methyl nicotine is threefold more potent at replacing [³H]nicotine from rat brain membranes and five times more potent at producing prostration behaviour.²⁵ 6-methyl nicotine was found to be twice as potent as nicotine as an analgesic in the tail flick test, and 3.3 times as potent in increasing spontaneous motor activity.²⁶ Since these behaviours are triggered by nicotinic receptor activation, it can be supposed that 6-methyl nicotine is, in fact, more addictive than nicotine.

6-METHYL NICOTINE PRODUCTS IN THE US MARKETPLACE

To our knowledge, Spree Bar is the first and, as of now, only product using 6-methylnicotine marketed in the USA and available for purchase by consumers. Spree Bar products and Metatine are discussed in Reddit posts, including initial user reports, suggesting increasing awareness by e-cigarette users in the USA.^{27–28} The authors of the present study purchased Spree Bar products on 7 October 2023, receiving delivery on 17 October 2023, confirming availability in the USA.²⁹ We identified another company, Novel Compounds (Cheyenne, Wyoming, USA), advertising 6-methylnicotine under the trademark ‘Imotine’ as a wholesale product to manufacturers.^{30–32} However, we did not identify any US-marketed products yet using this brand name version. An abstract presented by a US-based chemical analytical services company at a recent tobacco industry conference describes a method for the quantification of 6-methyl nicotine and detected its presence in e-liquids, confirming efforts by the industry to market such products.³³ Given the growing activity from several industry groups, we expect that additional 6-methyl nicotine-containing products will be marketed in the USA soon.

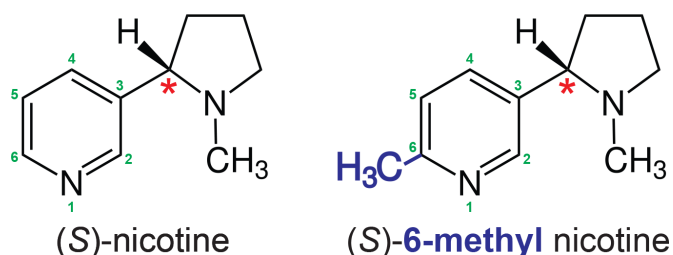


Figure 3 Chemical structures of (S)-nicotine (left), the major form of nicotine in tobacco and (S)-6-methyl nicotine (right), trademarked as ‘Metatine’, with a methyl group substitution (blue) at position 6 of the pyridine ring (positions numbered in green). The red asterisk indicates the chiral centre of nicotine.

6-METHYL NICOTINE: REGULATORY CHALLENGES AND SOLUTIONS

Are products containing 6-methyl nicotine, differing from nicotine by a methyl group, subject to the PMTA requirement and the other provisions of the US Tobacco Control Act (TCA), or are they indeed 'PMTA exempt'? The TCA, as amended in 2022, now covers products 'made or derived from tobacco, or containing nicotine from any source'.³⁴ The TCA defines 'nicotine' as '12. Nicotine. The term 'nicotine' means the chemical substance named 3-(1-methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine'.³⁵ 6-methyl nicotine has a different chemical formula C[11]H[16]N[2] and name. If the FDA concludes that 6-methyl nicotine is a 'complex' of nicotine and takes enforcement action against Spree Bar or other similar products, the manufacturers would likely challenge that determination in court.³⁶ Other jurisdictions define the term 'nicotine' differently. For example, Article 2 (Definitions) of the European Union's (EU) Tobacco Products Directive (TPD) states: '(19) 'nicotine' means nicotinic alkaloids'.³⁷ The term 'alkaloid' denotes both natural and synthetic nicotinic ligands, thus 6-methyl nicotine would fall within the scope of the EU's TPD.³⁸

Should the FDA (or a future court decision) conclude that 6-methyl nicotine is not 'nicotine' within the meaning of the TCA, then it does not mean that products containing 6-methyl nicotine are necessarily exempt from all FDA regulation. A federal appeals court ruled in 2010 that 'customarily marketed' nicotine-containing products cannot be regulated as drugs or drug-delivery devices if they are sold 'without claims of therapeutic effect'.³⁹ However, that decision was based on the premise that these products would be subject to FDA regulation as tobacco products, and the case's reasoning would not apply to products that do not fall within the TCA's definition of a 'tobacco product'.³⁹ The proclamations on Spree Bar's website that Metatine 'produces the same sensation as nicotine' and 'may also be addictive,' combined with the similarity in chemical form to nicotine and evidence of similar physiological effects, strongly suggest that the FDA could alternatively seek to regulate the 6-methyl nicotine in Spree Bar as a drug under the FDCA.⁴⁰ If the FDA determines that 6-methyl nicotine is being marketed as a drug intended to produce particular physiological effects (the FDCA defines drugs in part as 'articles (other than food) intended to affect the structure or any function of the body'),⁴¹ then it would not be possible for it to be sold legally without the manufacturer first obtaining FDA approval.

When companies market products like Spree Bar as exempt from FDA regulation, it reduces confidence in the FDA's regulatory scheme and undermines the FDA's efforts to protect public health. The FDA should quickly announce its policy with respect to such products and take appropriate enforcement action. Congress might also consider clarifying that products containing non-nicotine tobacco alkaloids or synthetic nicotine analogues are tobacco products under US law, by amending the TCA to expressly say as much. For example, it could follow the EU's approach and define 'nicotine' to more broadly include all nicotinic alkaloids, thus enabling the FDA to regulate e-cigarette products containing 6-methyl nicotine the same way it regulates all other e-cigarette products.^{37 38}

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Contributors SEJ and MLB conceptualised and designed the study and wrote the first draft of the paper; SVJ provided advice on product choice and figures design. SVJ and PJZ contributed to revision of the manuscript. All authors critically reviewed, edited and approved the final draft before submission. SEJ attests that all listed

authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Metatine

Metatine™

Using patented technology and several trade secret processes, Metatine is a synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids. Notably, even though Metatine is a non-nicotine compound, vape devices that contain Metatine provide adult users with a strong sense of satisfaction, pleasure and enjoyment that is largely indistinguishable from traditional vape products.



Synthesis and Analysis

Metatine is synthesized using a trade secret process. The starting material is not nicotine and the finished product does not contain nicotine.

Metatine has been tested for tobacco-specific nitrosamines (TSNA's) degradants, chemical impurities, and other volatile organic compounds. The results indicate that Metatine poses no additional risk compared to additives found in conventional vape products currently on the market.

Toxicity

Metatine is structurally similar to nicotine, it is expected that Metatine will have a toxicity profile similar to nicotine. Nicotine is considered acutely toxic. It is not mutagenic nor a carcinogen. Metatine is not listed as a carcinogen by IARC, FDA, NIOSH, or NTP. Nicotine is considered to potentially have adverse reproductive effects. Vapes that contain nicotine or Metatine are not intended for pregnant or lactating women. Pure Metatine is not corrosive to metal or glass but does mildly corrode plastic. It is not a skin or eye irritant in rabbits. It is negative in the mouse bone marrow micronucleus genotoxicity test. See Additional Warnings.



Regulatory Status

Since Metatine does not contain nicotine, is not derived from tobacco, and is not a component or part of a tobacco product, it does not fall under the regulatory purview of the FDA's Center for Tobacco Products.

Metatine does not meet the definition of nicotine as stated in the Family Smoking Prevention and Tobacco Control Act, is not a salt or complex of nicotine, and is not itself derived from nicotine or tobacco; accordingly, Metatine is not subject to FDA tobacco requirements. Metatine products are not required to obtain FDA premarket authorization (often known as a PMTA) required for new tobacco products, like e-cigarettes.

Metatine is not recognized as a drug in the official United States Pharmacopoeia and is not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. It is intended only as a satisfying alternative for adult tobacco users and vapers.





<https://outlawdip.com/blogs/blog/what-is-nixamide>

HOME SHOP BUILD A CUSTOM 6 PACK FLAVOR OF THE MONTH CLUB

WHAT IS NIXAMIDE™? A NICOTINE ALTERNATIVE.

NOV 22, 2023 | JARED BOYCE

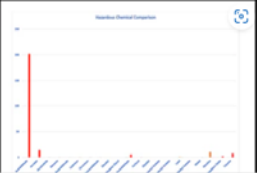
MADE FROM A PROPRIETARY ALTERNATIVE SOLUTION TO NICOTINE (PATENT PENDING), NIXAMIDE™ IS STRUCTURALLY DIFFERENT FROM NICOTINE – INDEPENDENT OF ITS STEREOCHEMISTRY – AND NOT FALLING UNDER THE TCA ([TOBACCO CONTROL ACT.](#))

NIXAMIDE™ HAS BEEN SPECIALLY FORMULATED TO DELIVER THE SAME SATISFACTION, PLEASURE AND ENJOYMENT AS TRADITIONAL TOBACCO PRODUCTS AND NICOTINE VAPING FOR ADULT CONSUMERS USING A PROPRIETARY BLEND WITH THE MAIN INGREDIENT BEING *NICOTINAMIDE.

[NICOTINAMIDE](#) IS A FORM OF VITAMIN B3 FOUND IN FOOD AND USED AS A DIETARY SUPPLEMENT AND MEDICATIONS. SIDE EFFECTS ARE MINIMAL. AT HIGH DOSES, LIVER PROBLEMS MAY OCCUR. NORMAL AMOUNTS ARE SAFE DURING PREGNANCY. NICOTINAMIDE IS IN THE VITAMIN B FAMILY OF MEDICATIONS, SPECIFICALLY [VITAMIN B3 COMPLEX](#). IT IS AN AMIDE OF NICOTINIC ACID. FOODS THAT CONTAIN NICOTINAMIDE INCLUDE YEAST, MEAT, MILK, AND GREEN VEGETABLES.

[TOXICOLOGY TESTING](#) SHOWED THAT NIXAMIDE™ IS LESS TOXIC THAN STANDARD NICOTINE, EITHER IN COMBUSTIBLE TOBACCO OR IN VAPES.

DOCUMENTS:




Nixamide



<https://outlawdip.com>


HOME SHOP BUILD A CUSTOM 6 PACK FLAVOR OF THE MONTH CLUB



\$5.99
OUTLAW WINTERGREEN FAT CUT

SELECT STRENGTH:
SELECT STRENGTH:


CHOOSE A VARIANT FIRST



\$5.99
OUTLAW KILLER VANILLER POUCHES

SELECT STRENGTH:
SELECT STRENGTH:


CHOOSE A VARIANT FIRST



\$5.99
OUTLAW RAMBLIN' ROOTBEER FAT CUT

SELECT STRENGTH:
SELECT STRENGTH:

CHOOSE A VARIANT FIRST



\$5.99
OUTLAW WILD WATERMELON POUCHES

SELECT STRENGTH:
SELECT STRENGTH:

CHOOSE A VARIANT FIRST

<https://outlawdip.com/collections/top-sellers/products/outlaw-killer-vanille-pouches>

[What is Nixamide™? A Nicotine Alternative. – Outlaw Dip Company Inc.](https://outlawdip.com/blogs/blog/what-is-nixamide)

www.outlawdip.com/blogs/blog/what-is-nixamide



THE FDA RESPONDS TO NICOTINE ALTERNATIVE NIC-SAFE™ (NIXAMIDE™)

IN A RECENT CONFIDENTIAL LETTER SENT TO OUTLAW DIP CO. - THE FDA RESPONDS AND UPDATES THEIR STATUS ON THE USE(S) OF THE ZERO NICOTINE ALTERNATIVE CALLED NIC-SAFE™. WE WOULDN'T LIVE UP TO OUR NAME OF OUTLAW'S IF WE DIDN'T SHARE THESE CONFIDENTIAL RESULTS WITH YOU! (OR AT LEAST WHAT WE CAN!)

NOW, BEFORE WE DIVE IN TO THE MEAT AND POTATOES; WHAT IS NIC-SAFE™ FOR THOSE WHO DON'T ALREADY KNOW?

IN SHORT:

NIC-SAFE™ (NIXAMIDE) IS MADE FROM A PROPRIETARY ALTERNATIVE SOLUTION TO NICOTINE (PATENT PENDING.) MADE FROM NATURAL B3 VITAMINS, NIXAMIDE HAS BEEN SPECIFICALLY FORMULATED TO DELIVER THE SAME SATISFACTION, PLEASURE, AND ENJOYMENT AS TRADITIONAL TOBACCO AND NICOTINE PRODUCTS. GIVING YOU THE BUZZ THAT ALTERNATIVE NICOTINE USERS CRAVE AND TURN TO WHEN THEY NEED TO LAY OFF THE NICOTINE.

READ MORE ABOUT NIC-SAFE AND ITS PROPERTIES, AND HOW IT WORKS [HERE](#).

NOW ON TO THE MAIN POINT: THE RECENT LETTER SENT TO OUTLAW DIP CO. THE FDA OFFICIALLY RESPONDS TO THE USE OF ZERO NICOTINE NIXAMIDE. STATING -

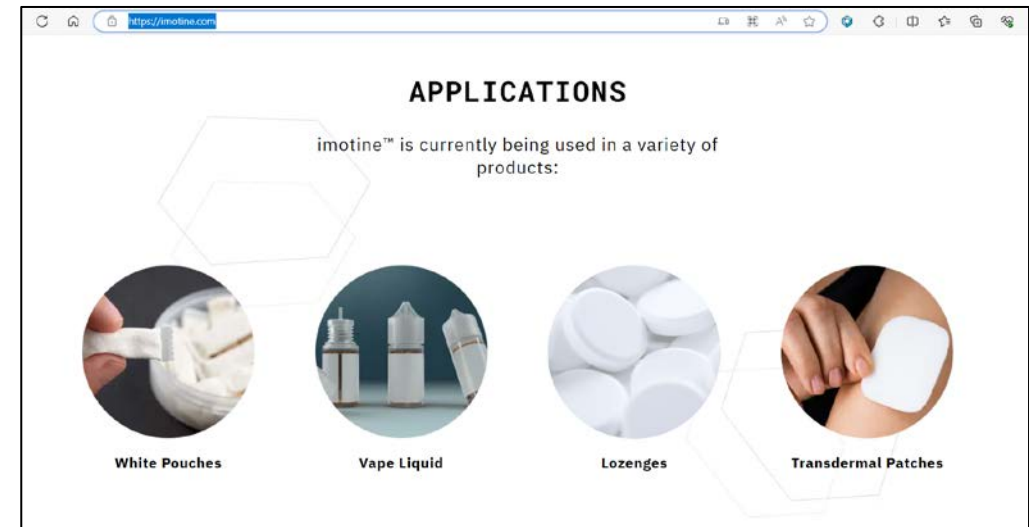
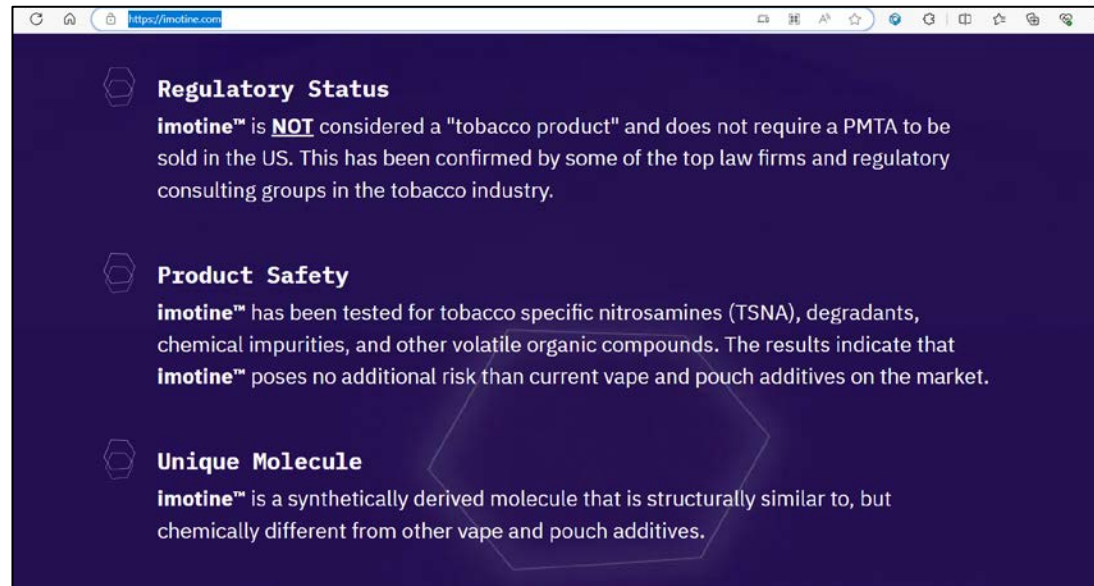
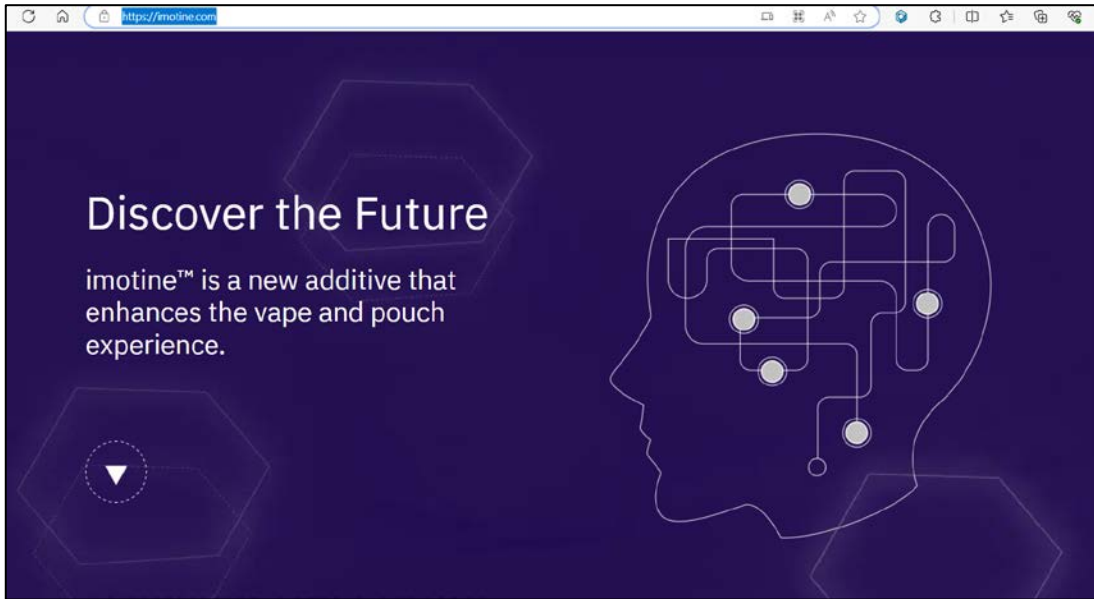
"...WE HAVE NO HESITATION IN PROVIDING OUR OPINION THAT NIXAMIDE™ IS NOT A "TOBACCO PRODUCT" AS DEFINED IN THE FOOD, DRUG AND COSMETIC ACT ("FDCA" OR THE "ACT"), AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 ("TCA") AND THE CONSOLIDATED APPROPRIATIONS ACT OF 2022 ("CAA").1."

LET'S TAKE A DEEPER LOOK INTO THE FDCA SECTION 201 FILE SO WE CAN BETTER UNDERSTAND WHAT THIS MEANS...

"In a recent confidential letter to Outlaw Dip Co. - the FDA responds..."

"...we have no hesitation in providing our opinion that Nixamide is not a 'tobacco product'..."

Imotine



[Experience Enhanced Vaping & Pouches with imotine™: The Future of Additives](https://www.imotine.com)

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