BIDI™ Vapor Submits Premarket Tobacco Application to FDA

Maker of Bidi™ Stick asks for authorization to continue marketing e-cigarettes in the U.S.

MELBOURNE, Fla. (September 8, 2020) — Bidi™ Vapor, LLC, the manufacturer of the disposable vape pen called Bidi™ Stick, announced that it has submitted its Premarket Tobacco Product application (PMTA) to the U.S. Food and Drug Administration (FDA), Center for Tobacco Products, for review. The submission included a family of disposable e-cigarette products under the Bidi™ Stick brand name.

The application detailed 11 flavored varieties with nicotine concentrations of 6% weight/volume as part of the company’s proprietary e-liquid formulation. Starting from a science-based foundation, Bidi™ Vapor has engineered its electronic nicotine-delivery system (ENDS) products using its own patented technology, ensuring quality control and assurance from the raw chemicals and components purchased through to the manufacturing process in a cGMP (current Good Manufacturing Practice) facility. The product then goes through various in-vitro and in-vivo toxicity testing (including genotoxicity tests) at a GLP (Good Laboratory Practice) approved lab, as well as HPHC (Harmful and Potentially Harmful Constituents) analysis of both the aerosol and e-liquid in ISO 17025 certified labs.

Included in its PMTA submission, Bidi™ Vapor also conducted one “combined” consumer and three independent surveys of people aged 21 and over.
Possibly the largest submission compiled across all ENDS manufacturers, Bidi™ Vapor’s application runs over 285,000 pages, providing science-based evidence demonstrating that the Bidi™ Sticks are Appropriate for the Protection of Public Health (APPH). The application further supports the public need to provide options to adult smokers of combustible tobacco products, officials with the Melbourne, Fla.-based company said.

“Bidi™ Vapor fully supports proper regulation of the category so that all ENDS products meet the highest manufacturing, safety and marketing standards for adult smokers, with the ultimate goal of improving the public health,” said Niraj Patel, owner of Bidi™ Vapor. “We look forward to working with the FDA as it constructs its regulatory policy based on science and facts.”

In developing Bidi™ Stick as a viable option for adults smokers 21 and older, Bidi™ Vapor has produced a “premium” disposable ENDS device that has medical-grade components, batteries equivalent to those in cellphones and a mouthpiece design combined with other structural components to provide a consistent vaping experience, officials said.

The company’s mission is to offer the adult smoker options to traditional, combustible tobacco that will meet their nicotine-delivery needs, said Patel, a Florida entrepreneur with pharmaceutical and chemical degrees. "But we are also concerned about vaping among those who are under the age of 21," Patel said. “We believe that with the proper age-verification restrictions in place, we can meet the needs of the adult smoker while deterring underage use.”

Regarding the concern about minors possibly having access to vaping products, Bidi™ Vapor uses several stages of legal-age and identity verification with its products:

- AgeChecker.net, a third-party provider that uses multiple databases to confirm the identity of an online customer.
- A call within 24 hours to the online customer to verify the purchase, as well as the person’s age and identity.
- Requiring a government identification and the signature of an adult 21 years or older upon delivery of product.
- At the retail level, Bidi Vapor requires retailers sign a Retail Pledge, designed to affirm compliance to age-verification policies that the company itself abides by.

Regarding its stance on sustainability, the company created the Bidi™ Cares campaign, using the slogan, “Save your Bidi. Save our Planet.” Multiple components of the product, including the battery, are recyclable, and the campaign encourages customers to return 10 of their used devices for a free one upon their next purchase.
From device design to responsible marketing to its sustainability efforts, Patel hopes to continue his family’s tradition in the nicotine and tobacco business, developing options for users 21 and older of combustible tobacco products. Patel’s family has a history in India of managing a tobacco business, where they processed and supplied tobacco leaves.

The PMTA process will allow the FDA to review ENDS from individual manufacturers to potentially authorize continued marketing in the United States, officials said. The deadline for PMTA submissions is Sept. 9, 2020.

“We are confident that upon review, the FDA will authorize the Bidi™ Stick for continued marketing in the United States,” Patel said. “It is a high-quality product that adult smokers have discovered can be a viable option to combustible tobacco.”

At Bidi™ Vapor, innovation is key to our mission, with the Bidi™ Stick promoting environmental sustainability while providing a unique vaping experience to adult smokers. Contributing to a smoke-free world for our future generations is in Bidi™ Vapor’s DNA.

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**Forward-Looking Statements**

This press release includes statements that constitute “forward-looking statements” within the meaning of federal securities laws, which are statements other than historical facts that frequently use words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “position,” “should,” “strategy,” “target,” “will,” and similar words. All forward-looking statements speak only as of the date of this press release. Although we believe that the plans, intentions, and expectations reflected in or suggested by the forward-looking statements are reasonable, there is no assurance that these plans, intentions, or expectations will be achieved. Therefore, actual outcomes and results could materially differ from what is expressed, implied, or forecasted in such statements.

This release contains certain forward-looking statements that are based on current plans and expectations and are subject to various risks and uncertainties. Our business may be influenced by many factors that are difficult to predict, involve uncertainties that may materially affect results, and are often beyond our control. Factors that could cause or contribute to such differences include, but are not limited to, factors detailed by us in our public filings with the Securities and Exchange Commission.

All forward-looking statements included in this press release are expressly qualified in their entirety by such cautionary statements. Except as required under the federal securities laws and the rules and regulations of the Securities and Exchange Commission, we do not have any
intention or obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

WARNING: This product can expose you to chemicals including formaldehyde, which is known to the state of California to cause cancer, and nicotine, which is known to the state of California to cause birth defects or other reproductive harm. For more information, go to www.p65warnings.ca.gov.

Nicotine is a highly addictive chemical. Depending on how you use Bidi Vapor products, you may be exposed to higher levels of nicotine than with other tobacco products. No tobacco product is safe or without risk. The risks and effects of using Bidi Vapor products have not been established. Bidi Vapor products can expose you to chemicals that are known to cause health risks, including cancer, reproductive harm, cardiovascular injury, and immunosuppressive conditions, as well as disrupt normal brain development in young people. Consult with a physician for further information.

Additional Warnings:

1. Bidi Vapor products should be kept out of reach of children.
2. Bidi Vapor products should not be used around a fire or any flammable materials.
3. Do not use Bidi Vapor products if there is any deformity, leakage, or discoloration.
4. Do not insert anything into Bidi Vapor products.
5. Do not disassemble or tamper Bidi Vapor products.
6. Do not attempt to refill Bidi Vapor products.

Bidi Vapor products are not suitable for use by:

1. Any persons under the legal age (21)
2. Adult non-smokers or non-tobacco users
3. Any persons with allergies or sensitivities to any of the listed ingredients, including nicotine
4. Women who are pregnant or breastfeeding
5. Any persons who cannot use tobacco products because of underlying medical conditions, such as asthma or other lung conditions, depression, heart disease, high blood pressure, diabetes, or stomach ulcers.

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