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FDA's Marketing Denial Order Issued to Bidi Vapor's Non-Tobacco Flavored ENDS Products are Set Aside and Remanded by the 11th Circuit Court of Appeals for being Arbitrary and Capricious

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Last year, Bidi Vapor LLC (Bidi or the Company), represented by Keller and Heckman LLP Partners Eric Gotting and Azim Chowdhury, petitioned the 11th Circuit Court of Appeals to review the Food and Drug Administration's (FDA) order denying the Premarket Tobacco Product Applications (PMTA) for its non-tobacco flavored BIDI® Sticks, a disposable electronic nicotine delivery system (ENDS) device. Following a stay of the Marketing Denial Order (MDO) issued in February by the court, on August 23, 2022, the 11th Circuit granted Bidi's petition for review and, in a ground-breaking 2-1 majority opinion, set aside and remanded the MDO, which the Court held was arbitrary and capricious because FDA failed to consider relevant evidence before it, specifically Bidi's aggressive and comprehensive marketing and sales-access-restrictions plans.

With respect to Bidi's applications, the Agency did not review the data and evidence that it has long made clear are critical to the 'appropriate for the protection of the public health' (APPH) analysis for PMTAs including, among other things, "product information, scientific safety testing, literature reviews, consumer insight surveys, and details about the company's youth access prevention measures, distribution channels, and adult-focused marketing practices," which "target only existing adult vapor product users, including current adult smokers," as well as Bidi's retailer monitoring program and state-of-the-art anti-counterfeit authentication system. Because "agency action is lawful only if it rests on a consideration of the relevant factors," and the Agency failed to consider the marketing and sales access restrictions plans, the MDO was deemed arbitrary and capricious.

Accordingly, the court set aside Bidi's MDO and remanded it back to FDA for further review. Since its MDO was issued, Bidi has continued to supplement its comprehensive applications with additional science, including clinical and behavioral studies supporting that its products are APPH.

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