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In the United States Court of Appeals

For the Eleventh Circuit

No. 24-10263

BIDI VAPOR LLC,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,

Respondent.

Petition for Review of a Decision of the
Food and Drug Administration
Agency No. STN-PM0003460.PD2

Before ROSENBAUM, NEWSOM, and MARCUS, Circuit Judges.

MARCUS, Circuit Judge:

In 2020, Petitioner Bidi Vapor LLC ("Bidi Vapor") filed a premarket tobacco product application ("PMTA") with the U.S. Food and Drug Administration ("FDA") for the Bidi Stick – Classic ("Bidi Classic"), a tobacco-flavored Electronic Nicotine Delivery Systems ("ENDS") product. The FDA sent Bidi Vapor a letter listing numerous deficiencies in its application, after which Bidi Vapor submitted supplemental information and data. Ultimately, Bidi Vapor did not address all of the issues that the FDA identified, and on January 22, 2024, the FDA issued a Marketing Denial Order, finding that Bidi Vapor had provided insufficient evidence to show that permitting the marketing of Bidi Classic would be appropriate for the protection of the public health. The FDA based its determination on three independent grounds: (1) Bidi Classic's high abuse liability; (2) the incompleteness of Bidi Vapor's study regarding leachable compounds; and (3) the lack of adequate comparison data regarding harmful and potentially harmful constituents. The Marketing Denial Order prevented Bidi Vapor from introducing Bidi Classic into interstate commerce.

Bidi Vapor now appeals the FDA's Marketing Denial Order, arguing that it should be set aside because the FDA violated the Tobacco Control Act and the Administrative Procedure Act or otherwise proceeded in an arbitrary, capricious, and unlawful manner. After careful review, and mindful that we must exercise appropriate deference to agency decisionmaking and not substitute our own judgment for that of the agency, we are satisfied the FDA

proceeded properly. The FDA's analysis regarding the abuse liability deficiency examined the relevant data and articulated a satisfactory explanation for its actions, connecting its factfinding to its decision to issue a Marketing Denial Order. This deficiency is legally sufficient to sustain the FDA's Marketing Denial Order, so we have no occasion to address, and do not address, the other two independent grounds articulated by the FDA. We deny Bidi Vapor's petition for review.

I.

The Tobacco Control Act of 2009 makes it unlawful for manufacturers to sell any "new tobacco product" without approval from the U.S. Food and Drug Administration. *See* 21 U.S.C. § 387j. A "new tobacco product" is any tobacco product that was not on the market as of February 15, 2007. *Id.* § 387j(a)(1). The Tobacco Control Act instructs the FDA to deny applications for new tobacco products if the Administration finds, based on the information before it, "a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* §§ 387j(c)(2), (c)(2)(A). Whether a new tobacco product is "appropriate for the protection of the public health" requires the FDA to consider "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," and the Tobacco Control Act specifically instructs that the FDA shall take into account "the increased or decreased likelihood that existing users of tobacco products will stop using such products," as well as "the increased or decreased likelihood that those who do

not use tobacco products will start using such products." *Id.* § 387j(c)(4). In 2016, the FDA determined that Electronic Nicotine Delivery Systems using nicotine derived from tobacco, including e-liquids and e-cigarettes, were "tobacco products" within the FDA's regulatory authority. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,028 (May 10, 2016).

Applications with the FDA for a new tobacco product must contain, among other information, "full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products," as well as "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product." 12 U.S.C. §§ 387j(b)(1)(A)–(B).

On September 8, 2020, Bidi Vapor applied to market Bidi Classic, Bidi Vapor's tobacco-flavored ENDS product.

On March 20, 2023, the FDA sent Bidi Vapor a deficiency letter. The deficiency letter identified 32 items for Bidi Vapor to address, which were necessary for the FDA to complete its scientific review. Among those items, the FDA identified three deficiencies relevant to this case: (1) the clinical studies Bidi Vapor submitted regarding nicotine exposure reported higher maximum nicotine exposure and total nicotine exposure after the use of Bidi Vapor's product compared to after the use of "usual brand" cigarettes;

(2) Bidi Vapor had failed "to conduct a study using non-targeted semi-quantitative chemical analysis to identify *all* possible leachables from the ENDS components" of Bidi Classic; and (3) Bidi Vapor incorrectly calculated or reported the limits of detection for many harmful and potentially harmful constituents (HPHCs) in comparison ENDS products, preventing the FDA from fully evaluating the aerosol HPHC data for Bidi Classic.

In response to the deficiency letter, Bidi Vapor submitted three amendments to the FDA. The FDA reviewed all of the evidence in multiple disciplines, including the regulatory, engineering, chemistry, microbiology, toxicology, behavioral and clinical pharmacology, medical, epidemiology, social science, environmental science, Bioresearch Monitoring, and manufacturing/lab disciplines. For all disciplines except for toxicology and Bioresearch Monitoring, the FDA also conducted a second round of review, or a "Cycle 2 review," after submission of Bidi Vapor's amendments. The FDA determined that "in light of the other non-toxicological deficiencies . . . that form the bases for denial of the PMTA, completing a cycle 2 toxicology review is not warranted."

On January 22, 2024, the FDA issued a Marketing Denial Order ("MDO") for Bidi Classic. The FDA identified "three independent deficiencies in the application that are each an independently sufficient reason to support a marketing denial order for the subject product."

One deficiency related to Bidi Classic's high abuse liability (the "abuse liability deficiency"). Abuse liability is "the ability of

the product to promote continued use and the development of addiction and dependence." Abuse liability evaluations "consider the addictiveness and abuse potential of the tobacco products and the exposure to nicotine during product use." The FDA noted that Bidi Vapor's sponsored clinical study showed that Bidi Classic has a "similar" or "higher abuse liability" than combustible cigarettes ("CCs") among current CC users with no experience using ENDS, and it has "higher abuse liability than CC among experienced ENDS users." Because a "new product with higher abuse liability compared to CC will promote compulsive and continued use of the new product despite harm or risk of harm," "tobacco users are likely to maintain or augment their nicotine dependence and addiction with use of the new product, and tobacco nonusers (including youth) who initiate use of the new product are likely to continue using it and develop nicotine addiction and dependence."

Another identified deficiency related to Bidi Vapor's submitted leachable study being incomplete (the "leachable contaminants deficiency"). "Leachables" are "chemical compounds that can migrate into an e-liquid . . . or into the aerosol, as a result of direct contact with or the interaction of materials or components" during the manufacturing process, under typical use conditions, or under storage conditions. Although Bidi Vapor used a technique in its study that was able to detect some leachable compounds with particular chemical properties (specifically, volatile organic compounds and some semi-volatile organic compounds ("SVOCs")), the technique is "not as effective at detecting and identifying other additional SVOCs and cannot detect non-volatile organic

compounds (NVOCs) or thermally labile leachable compounds." As a result, the FDA found that Bidi Vapor had again failed to provide a "comprehensive leachable study," given that "the health risks associated with the presence of other possible leachables . . . have not been fully evaluated and cannot be accounted for in the assessment of risks and benefits of the marketing of the new product."

Finally, the third deficiency the FDA identified related to the "lack of aerosol HPHC yields for comparison ENDS that are needed to evaluate comparative health risks of the new product subject to this review relative to other tobacco products from the same category" (the "comparison data deficiency"). Specifically, the HPHC data for comparison ENDS products "were not measured and collected in a manner that is sufficient or appropriate to compare to the new product's data." Because there was a "lack of information on methods used to collect the data," this "prevent[ed] FDA from assessing the reliability of the reported HPHC data." Thus, since this data relating to harmful or potentially harmful contaminants was not usable, the "FDA [could not] complete the assessment of risks and benefits and determine whether the marketing of the new product subject to this review would be [appropriate for the protection of the public health]."

This timely appeal followed, when Bidi Vapor filed its Petition for Review on January 26, 2024 pursuant to 21 U.S.C. § 387*l*(a). On February 2, 2024, Bidi Vapor moved for a stay pending appeal, which this Court denied on February 16.

On appeal, Bidi Vapor makes various arguments for why the FDA's Marketing Denial Order should be set aside. Bidi Vapor argues generally that the FDA (1) based its MDO on discrete deficiencies without ever engaging in a multifactored and multidisciplinary analysis weighing the potential benefits against its deficiencies; (2) effectively imposed "tobacco product standards" on Bidi Vapor, including product testing standards and nicotine restrictions, without going through notice and comment rulemaking; and (3) failed to conduct a "Cycle 2" toxicological review. Bidi Vapor also argues, specifically as to the abuse liability deficiency, that (1) the FDA reversed its prior policy regarding the need for a comparable level of abuse liability; (2) the MDO contradicted statements that nonusers and youth are unlikely to use Bidi Classic; and (3) the FDA failed to weigh evidence on switching in the context of other benefits to smokers and a low risk to nonusers and youth.

II.

This Court reviews the FDA's denial of an application to market a new tobacco product pursuant to the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *See* 21 U.S.C. § 387*l*(b). An agency's action, findings, and conclusions may be held unlawful and set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The 'arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.'" *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1202 (11th Cir. 2022) (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)). "It follows

that agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

As the Supreme Court recently explained: "Our well-worn arbitrary-and-capricious standard ensures that an administrative agency 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025) (alterations in original) (quoting *State Farm*, 463 U.S. at 43). "The scope of this review 'is narrow,' and reviewing courts must exercise appropriate deference to agency decisionmaking and not substitute their own judgment for that of the agency." *Id.* (quoting *State Farm*, 463 U.S. at 43). "When an agency relies on multiple grounds for its decision, some of which are invalid, we may nonetheless sustain the decision as long as one is valid and the agency would clearly have acted on that ground even if the other were unavailable." *Fontem US, LLC v. FDA*, 82 F.4th 1207, 1217 (D.C. Cir. 2023) (quoting *Casino Airlines, Inc. v. Nat'l Transp. Safety Bd.*, 439 F.3d 715, 717 (D.C. Cir. 2006)).

The FDA reasonably determined that denial of Bidi Vapor's PMTA was warranted based on the abuse liability deficiency. Bidi Vapor was required to submit information to the FDA showing that Bidi Classic was "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), and it failed to make that showing because Bidi Vapor's data showed that Bidi Classic was at odds with

the protection of the public health. As a result, Bidi Vapor's critiques that the FDA was required to balance the benefits and deficiencies of Bidi Classic, or that the FDA had to conduct a second cycle of toxicological review, are unpersuasive. Because the FDA did not act arbitrarily or capriciously in denying the Bidi Classic PMTA based on the independently sufficient abuse liability deficiency, we have no occasion to address, and do not address the two testing deficiencies offered by the FDA -- the leachable contaminants deficiency and the comparison data deficiency.

Moreover, the FDA did not impermissibly impose "tobacco product standards" on Bidi Vapor. "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.* (*Chenery II*), 332 U.S. 194, 203 (1947). Under the Tobacco Control Act:

> The Secretary *shall* deny an application . . . if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that . . . there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.

21 U.S.C. §§ 387j(c)(2), (c)(2)(A) (emphasis added). The FDA reasonably explained deficiencies in Bidi Vapor's submissions as part of its holistic adjudicatory review of Bidi Classic's risks and benefits. The FDA was required to consider: whether Bidi Classic

"presents less risk than other tobacco products," *id.* § 387j(b)(1)(A); "the risks and benefits to the population as a whole," *id.* § 387j(c)(4); "the increased or decreased likelihood that existing users of tobacco products will stop using such products," *id.* § 387j(c)(4)(A); and "the increased or decreased likelihood that those who do not use tobacco products will start using such products," *id.* § 387j(c)(4)(B). It reasonably considered all of those factors when issuing its MDO.

A.

For starters, the FDA reasonably determined that Bidi Vapor's evidence showed a high risk that Bidi Classic would increase the likelihood and severity of addiction, including among youth. In general, the FDA has explained, e-cigarettes can potentially benefit public health if they encourage combustible cigarette smokers to completely switch away from smoking combustible cigarettes, since doing so "may reduce exposure to some carcinogens and other toxicants known to be associated with tobacco-related diseases from using [combustible cigarettes]."

In making its evaluation, the FDA considers tradeoffs with respect to abuse liability -- "the ability of the product to promote continued use and the development of addiction and dependence." On the one hand, a product with low abuse liability is less likely to addict new users, but it also may be an inadequate substitute for products used by current users. On the other hand, a product with a high abuse liability "puts users who switch at risk of maintaining or augmenting their addiction and poses a high risk of addiction to

nonusers who initiate tobacco use or experiment with the new product." After reviewing Bidi Vapor's submission, the FDA determined that the nicotine concentration of Bidi Classic, at 60 mg/mL, was "on the higher end of most ENDS tested in the literature," which "range from 3–60 mg/mL." Notably, Bidi Classic "had higher nicotine exposure" even than most combustible cigarettes and other ENDS. Finally, the use of "nicotine salts" in Bidi Classic "reduces the harshness of the high nicotine concentration in the new product" and "mak[es] it more palatable."

Viewing together all of the evidence Bidi Vapor submitted, the FDA determined that Bidi Classic's abuse liability is "similar to or higher than the abuse liability of [combustible cigarettes] among inexperienced ENDS users" and in fact "will be higher than [combustible cigarettes]" in "experienced users of ENDS." Accordingly, the FDA found that Bidi Classic "increases the likelihood that tobacco users who try the new product will continue using it" and "increases the likelihood that tobacco nonusers, including youth, who try the new product will continue using it, particularly since the nicotine salts in the e-liquid will likely reduce the harshness of the high (6%) nicotine concentration," resulting in a "likely increase [in] nicotine dependence and addiction in all of these populations." As a result, the FDA reasonably determined that Bidi Classic's high abuse liability rendered it inappropriate for the protection of public health.

Bidi Vapor raises several arguments relating to the abuse liability deficiency: (1) the FDA reversed its prior policy regarding the

need for a comparable level of abuse liability; (2) the MDO contradicted statements that nonusers and youth are unlikely to use Bidi Classic; and (3) the FDA failed to weigh evidence on switching in the context of other benefits to smokers and a low risk to nonusers and youth. None of these arguments is persuasive, and none demonstrates that the FDA acted arbitrarily or capriciously.

For one thing, the FDA did not reverse its prior policy regarding the need for a comparable level of abuse liability in ENDS and in combustible cigarettes. The FDA explicitly acknowledged that a product with low abuse liability can be less effective at helping smokers of combustible cigarettes switch to ENDS or quit. On page 25 of the FDA's Technical Project Lead review of Bidi Vapor's PMTA, the FDA states that "if a new product has a low abuse liability, individuals who are currently dependent on nicotine may find it to be an inadequate substitute for the product they are currently using." The point that the FDA made was that there are tradeoffs between high and low abuse liability. A product with low abuse liability might be less addictive for new users, but it also might be an inadequate substitute for existing users. On the other hand, a product with a higher abuse liability might be better as a substitute product for existing users, but it also might addict more new users. Under the Tobacco Control Act, these considerations must be balanced. The FDA reasonably applied these principles, and its decision approving NJOY's Daily Extra Rich Tobacco 6% product (the "NJOY Product") is entirely consistent with its decision denying Bidi Classic's application despite the two products having the same concentration of nicotine.

Considering first the risks inherent in each product, the Technical Project Lead review of the PMTA for the NJOY product found "an abuse liability approaching that of combusted cigarettes" and the "inherent risk of addiction" of the NJOY product "to be no higher than other currently available tobacco products." Indeed, the FDA found that based on NJOY's clinical study, overall "nicotine exposure from [NJOY's] products did not exceed that of combusted cigarettes." In contrast, Bidi Classic has "similar to or higher abuse liability than CC among current CC users with no experience using ENDS, and higher abuse liability than CC among experienced ENDS users."

As for the benefits, the FDA's Technical Project Lead review of NJOY's PMTA notes that based on "the submitted clinical evidence" for the NJOY product, there was "support for a potential benefit of smokers trying to switch to the new products." On the other hand, as we've already observed, Bidi Vapor failed to make a similar showing of benefit, given the inconclusive results about whether combustible cigarette smokers would switch partially or completely to Bidi Classic. In sum, the FDA determined that Bidi Classic exposes users to more risks and has fewer benefits than the NJOY product, so its denial of Bidi Classic and approval of the NJOY product was not arbitrary and capricious. The FDA properly "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action[s]." *Wages & White Lion*, 145 S. Ct. at 917 (quoting *State Farm*, 463 U.S. at 43).

Next, the MDO was consistent with statements that nonusers and youth are unlikely to use Bidi Classic. To evaluate the overall public health consequences of a new tobacco product, the FDA must consider not only the likelihood that nonusers and youth use the product, but also the risk of addiction or nicotine dependence. After all, if people were certain to try a tobacco product but had no risk of developing addiction or dependence, then that product might pose less of a public health risk than would a different tobacco product that is only likely to be tried by a small percentage of people but that inevitably increases nicotine dependence and addiction risks.

That is the calculus that the FDA considered in this case. The FDA stated in its Technical Project Lead review of the PMTA that there was a "low likelihood of use of the new product," not that there was zero or near-zero likelihood. The FDA also stated that the "likelihood of increased nicotine dependence and addiction risks due to continued use of the new product among tobacco nonusers, including youth, who do initiate are concerning." Because those increased risks associated with Bidi Classic were so high, the FDA reasonably found that they outweighed the low likelihood of initial use.

Finally, the argument that the FDA failed to weigh evidence on switching in the context of other benefits to smokers and a low risk to nonusers and youth is unconvincing for many of the reasons previously discussed. The FDA explicitly recognized that "[f]or tobacco-flavored ENDS the risk to youth is lower compared to

flavored ENDS; accordingly, a lesser showing of benefit may suffice." The problem is that on balance, Bidi Vapor failed to make even that "lesser showing of benefit" for Bidi Classic. As we previously discussed, even though ENDS typically have the benefit of reducing toxicant exposure or adverse health outcomes, those benefits depend on current tobacco users "partially or completely switch[ing] to the new product." And the evidence submitted by Bidi Vapor and reviewed by the FDA "was inconclusive to demonstrate that current tobacco users (including CC users) would likely use the new product to partially or completely switch to the new product." Beyond the lack of evidence for Bidi Classic's benefits, there is also strong evidence that the risks of Bidi Classic, in the form of increased likelihood of addiction and nicotine dependence risks, are especially high. Again, the FDA reasonably found that Bidi Vapor failed to make its required "lesser showing of benefit."

In sum, because of Bidi Classic's high abuse liability and Bidi Vapor's failure to show Bidi Classic's benefits, the FDA reasonably determined that Bidi Classic was not appropriate for the protection of the public health.

B.

Bidi Vapor offers various arguments to challenge the validity of the FDA's MDO, but none of these arguments is persuasive. First, relying on *Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir. 2023), a decision from the U.S. Court of Appeals for the D.C. Circuit, Bidi Vapor claims that the leachable contaminants deficiency and the comparison data deficiency relied only on technical

deficiencies without evaluating on balance whether Bidi Classic presents less risk to public health than combustible cigarettes, and that the FDA's abuse liability deficiency failed to consider the potential for reduced harm, notwithstanding Bidi Classic's higher abuse liability.

The comparison to *Fontem* is not persuasive, however. In *Fontem*, the FDA issued a Marketing Denial Order against Fontem's vaping products. *Id.* at 1211, 1213. The MDO "rested entirely on the finding that Fontem had not sufficiently demonstrated that permitting its products to be marked would be 'appropriate for the protection of the public health.'" *Id.* at 1213 (quoting 21 U.S.C. § 387j(c)(2)(A)). In support of that conclusion, the FDA identified five "highly technical deficiencies," but did not "explain[] how the deficiencies relate to the overall public health consequences of Fontem's . . . products." *Id.* at 1219. Moreover, the FDA did not address "the possibility that existing users of combustible tobacco products such as cigarettes would reap health benefits by transitioning to Fontem's vaping products." *Id.* In other words, the FDA based its MDO only on "highly technical deficiencies" and never explained how those deficiencies connected to public health consequences, and it never considered the effects of Fontem's products on existing smokers' health.

In sharp contrast, the FDA reasonably explained the abuse liability deficiency. The FDA explicitly considered the effect of Bidi Classic on existing smokers' health. On page 5 of the MDO, the FDA states: "Due to the high abuse liability of the new product,

tobacco users are likely to maintain or augment their nicotine dependence and addiction with use of the new product." The FDA also explained that the evidence submitted by Bidi Vapor and reviewed by the FDA "was inconclusive to demonstrate that current tobacco users (including CC users) would likely use the new product to partially or completely switch to the new product."

Accordingly, unlike how the FDA in *Fontem* failed to directly consider the public health consequences of the tobacco product at issue, the FDA made no such error here. It considered the public health risks and benefits and tied the abuse liability deficiency to those risks and benefits. Because the FDA found that the abuse liability deficiency was "an independently sufficient reason to support a marketing denial order," we decline to address Bidi Vapor's arguments regarding the leachable contaminants deficiency and the comparison data deficiency. *See Fontem*, 82 F.4th at 1217.

Bidi Vapor also claims that the FDA ignored evidence it submitted in response to the deficiency letter, but a review of the administrative record indicates otherwise. The FDA, in fact, either explicitly or implicitly considered that data: in the MDO, the FDA explicitly states that it reviewed Bidi Vapor's responses to the deficiency letter. And the Technical Project Lead review of Bidi Vapor's Premarket Tobacco Product Application also reveals that the FDA considered those pieces of evidence. For example, the FDA explicitly listed the methodological problems in Bidi Vapor's submitted aerosol testing, indicating that the FDA considered that evidence. Next, the FDA credited Bidi Vapor's extractable study from

a chemistry perspective. Similarly, the FDA implicitly appears to have credited Bidi Vapor's *in vitro* studies, since the March 20, 2023 deficiency letter discussed problems with *in vitro studies* not containing sufficient information for a complete toxicological evaluation, but the subsequent MDO does not discuss that deficiency.

Finally, the FDA did not act arbitrarily or capriciously in choosing not to conduct a Cycle 2 toxicological review. As the FDA explained, after notifying the applicant of a deficiency, an additional cycle of review is aimed at assessing the applicant's efforts to cure deficiencies within a scientific discipline, but the FDA may decline to proceed with an additional cycle of review if review cannot cure the shortcomings already identified. This makes logical sense, given limited agency resources: if shortcomings in fields other than toxicology are dispositive and fatal to a company's application, then there is no reason that the FDA would need to also do a second round of review in toxicology, which would not address deficiencies in those other fields. In the best-case scenario for the applicant, a Cycle 2 toxicological review would remove as additional shortcomings toxicological deficiencies previously identified in a Cycle 1 toxicological review; it would do nothing to eliminate shortcomings in non-toxicology fields.

In this case, the FDA identified that the abuse liability deficiency was fatal to Bidi Vapor's PMTA. Specifically, the FDA observed that "ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents" than combustible cigarettes, but "whether this is true for any

particular new ENDS is considered on a case-by-case basis" -- and key to the FDA's analysis is whether "adults who use [combustible cigarettes] . . . switch completely to ENDS, or if they use both products but substantially reduce their cigarette smoking," which could result in "a reduction in health risks." Put differently, the FDA recognized that the health benefits associated with ENDS like Bidi Vapor depend on whether "current tobacco users . . . would likely use the new product to partially or completely switch to the new product (and therefore, reduce CC use, toxicant exposure, and adverse health outcomes)." Otherwise, if a cigarette smoker merely supplemented his cigarette smoking with Bidi Classic, he would be taking in the same amount of toxins from his combustible cigarette and adding nicotine from Bidi Classic, potentially causing "increased likelihood of addiction and nicotine dependence risks."

In this case, the FDA observed that:

> Although evidence from the applicant-provided studies showed some evidence of current tobacco users intending to try or progress to regular use of the new product, product use data showed a low likelihood of initiation and use of the new product overall among current tobacco users. *Additionally, evidence from the applicant-submitted data was inconclusive to demonstrate that current tobacco users (including CC users) would likely use the new product to partially or completely switch to the new product (and therefore, reduce CC use, toxicant exposure, and adverse health outcomes).* On the other hand, because the new product has a high nicotine concentration and is associated with high abuse liability, the

> continued use and increased likelihood of addiction and nicotine dependence risks, particularly among youth and adult tobacco nonusers, are concerning.

Thus, Bidi Vapor was unable to demonstrate that combustible cigarette smokers were likely to "partially or completely switch" to Bidi Classic. That omission negated any potential health benefits of Bidi Classic and any potential lower toxin levels associated with Bidi Classic, since those benefits are premised on the user switching away from combustible cigarettes.

Moreover, the FDA reasonably found that Bidi Classic carries additional risks in light of its high nicotine content, such as a greater likelihood of addiction or nicotine dependence. As a result, even if the FDA had conducted a Cycle 2 toxicological review, that review would do nothing to change the conclusions that (1) there is no indication that combustible cigarette users are likely to partially or completely switch from using combustible cigarettes to using Bidi Classic, and (2) as a result, there is no indication that users of Bidi Classic would realize health benefits.

In sum, the abuse liability deficiency does not rely on toxicological reasons, so a Cycle 2 toxicological review would not have negated those reasons. The FDA reasonably determined that it did not need to conduct a futile Cycle 2 toxicological review.

Ultimately, the burden was on Bidi Vapor to demonstrate that Bidi Classic is appropriate for the protection of public health. The FDA reasonably determined that because Bidi Vapor submitted studies and data about a product with a high abuse liability and

insufficient benefits, denial of the PMTA for Bidi Classic was well-justified. The FDA did not act in an arbitrary and capricious manner, and we deny Bidi Vapor's Petition for Review.

PETITION DENIED.