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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

DC Circ. Says FDA Botched Part Of E-Cig Review

By **Jonathan Capriel**

Law360 (August 29, 2023, 7:27 PM EDT) -- A D.C. Circuit panel chastised the U.S. Food and Drug Administration Tuesday for moving the "regulatory goalpost" when the agency denied premarket authorization to Fontem US LLC's unflavored e-cigarettes products, but took no issue with its denial of the company's flavored vapes.

The FDA neglected to properly weigh the health risks and potential benefits of Fontem's unflavored vapes, the three-judge panel said in its opinion, which vacated the agency's premarket denial of the company's products. Instead of considering the possible "health benefits" smokers of traditional cigarettes could "reap" by switching to Fontem's vapes, the agency rejection order focused on "highly technical deficiencies" unrelated to public health.

"But nothing in the denial order explains how the deficiencies relate to the overall public health consequences of Fontem's unflavored products," the panel said. "And despite the express statutory requirement that the agency consider the 'risks and benefits to the population as a whole,' including the 'increased or decreased likelihood that existing users of tobacco products will stop using such products,' nowhere in the denial order did the FDA address the potential benefits of Fontem's products for the public at large."

At the same time, the panel said that the FDA acted "lawfully" when it rejected Fontem's flavored products, because the agency concluded that they pose a risk to public health, specifically children. The regulators reasoned that permitting flavored products into the market would likely attract young people into using nicotine vapes and have minimal impact on getting adult smokers to quit cigarettes.

Fontem, the makers of myblu e-cigarettes, applied to the agency for premarketing approval for its flavored and unflavored products in April 2020. The FDA ultimately denied the request in April 2022.

The company submitted two petitions to the court to review the agency's denial order. The FDA argued that the court did not have jurisdiction on the first bid because Fontem had filed an administrative appeal before submitting to the court. The agency argued that the second appeal was the operative one before the court.

The panel disagreed, saying that a company can contest a marketing denial to the court provided that the appeal is submitted within 30 days after the FDA makes its finding. Fontem's later bid was filed almost eight months after the denial was issued and is therefore untimely, the panel ruled.

On Fontem's unflavored products, the FDA took issue with the manufacturing process or about the stability of its products. It said the company failed to provide detailed information about what quality control it conducted on its "e-liquid," the maximum temperature of the certain parts in the vapes and "toxicant yields."

In theory, the panel said, the FDA could have tossed Fontem's products on these grounds if the agency had "promulgated valid manufacturing regulations or tobacco product standards." However, the agency "opted not to issue" such rules or standards, which left the FDA with really only one avenue to reject the products, according to Tuesday's opinion.

"The agency chose to proceed through ad hoc adjudication under the public health provision," the panel said. "Having opted not to issue manufacturing regulations or tobacco product standards, the FDA had to evaluate Fontem's application under the all-things-considered, holistic analysis required to deny a product on public health grounds."

The panel's order also appeared to be critical of the FDA's process.

The agency demanded more data from the company, suggesting that "such information would be sufficient for the agency to approve Fontem's products." But after Fontem fulfilled that request, the FDA would then chastise Fontem for not providing information on topics the agency "never explicitly sought."

"Shifting the regulatory goalposts without explanation is arbitrary and capricious," the panel said. "The lack of consistency and notice to regulated entities is another unlawful consequence of the agency's departure from the holistic public health inquiry."

The agency was well within the law when it refused to authorize Fontem's flavored products, the panel ruled. The FDA demanded "robust and reliable evidence" that adult smokers would benefit from a flavored product before it would grant it, reasoning that this proof would need to outweigh the real risk that these vapes pose to young people.

"In the agency's judgment, the primary study Fontem conducted did not show flavored products had any added benefit for adult smokers relative to unflavored products," the panel said. "The FDA concluded that Fontem failed to show the benefits of its flavored products to adult smokers outweighed the substantial risks of flavored products to youth."

U.S. Circuit Judges Neomi Rao, Justin R. Walker and Douglas H. Ginsburg sat on the panel for the District of Columbia Circuit.

Fontem is represented by **Philip J. Perry**, **Andrew D. Prins** and **Jacob Rush** of **Latham & Watkins LLP**.

The FDA is represented by Garrett Coyle and Brian M. Boynton of the U.S. Department of Justice and Samuel R. Bagenstos of the U.S. Department of Health and Human Services.

The case is Fontem US LLC v. FDA, case number 22-1076, in the U.S. Court of Appeals for the District of Columbia Circuit.

--Editing by Dave Trumbore.