

23-1038 FOOD AND DRUG ADMINISTRATION V. WAGES AND WHITE LION INVESTMENTS, L.L.C.

DECISION BELOW: 90 F.4th 357

LOWER COURT CASE NUMBER: 21-60766, 21-60800

QUESTION PRESENTED:

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a person to obtain authorization from the Food and Drug Administration (FDA) before introducing a new tobacco product into interstate commerce. The agency may grant such authorization only if the applicant shows, among other things, that the marketing of the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In this case, the agency denied respondents' applications for authorization to market new e-cigarette products because they had failed to show that marketing the products would be appropriate for the protection of the public health. The Fifth Circuit set aside FDA's denial orders as arbitrary and capricious, relying on legal theories that have been rejected by other courts of appeals that have reviewed materially similar FDA denial orders. The question presented is:

Whether the court of appeals erred in setting aside FDA's denial orders as arbitrary and capricious.

CERT. GRANTED 7/2/2024