

No. 21-3902

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Oct 27, 2021
DEBORAH S. HUNT, Clerk

BREEZE SMOKE, LLC,)
)
 Petitioner,)
)
 v.)
)
 UNITED STATES FOOD AND DRUG)
 ADMINISTRATION,)
)
 Respondent.)

ORDER

Before: MOORE, GILMAN, and KETHLEDGE, Circuit Judges.

Breeze Smoke, LLC petitions for review of a Food and Drug Administration (“FDA”) order denying its Premarket Tobacco Product Applications for certain of its electronic nicotine delivery systems (“ENDS”). Breeze Smoke now moves for an emergency administrative stay. The FDA responds in opposition.

We have no rule expressly permitting or prohibiting a temporary administrative stay. Although we have granted such relief, *see, e.g., United States v. McGowan*, No. 20-1617, 2020 WL 3867418, at *1 (6th Cir. June 28, 2020); *In re State of Ohio Bd. of Pharm.*, No. 20-3875 (6th Cir. Sept. 15, 2020), as have other circuits, *Brady v. Nat’l Football League*, 638 F.3d 1004, 1005 (8th Cir. 2011) (order), there is no prevailing standard setting forth when it is appropriate to issue such a stay. Unquestionably, however, the need for immediate relief to prevent irreparable harm and the parties’ due diligence in pursuing relief are relevant.

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Regardless of any harm that might result here, Breeze Smoke has not diligently pursued a stay. First, Breeze Smoke did not seek a stay below, pursuant to Federal Rule of Appellate Procedure 18(a)(1), claiming that to do so would have been impracticable, as the marketing denial order takes effect immediately and FDA review of a request for a stay could take months. Second, it waited eighteen days after the denial of its applications to petition us for review. Third, upon seeking review in this court, Breeze Smoke did not request expedited review on the merits, an emergency stay of the FDA's order, or an administrative stay. Rather, it sought such relief only after another ENDS manufacturer, Turning Point Brands, Inc., voluntarily dismissed its petition for review from an FDA marketing denial order. *Turning Point Brands, Inc., et al. v. U.S. Food & Drug Admin.*, No. 21-3855. Finally, when Breeze Smoke did seek expedited review, it did so only on the merits of its petition, choosing not to pursue expedited review of its motion to stay.

Accordingly, the motion for an administrative stay is **DENIED**. Upon receipt of Breeze Smoke's reply, we will expedite our consideration of the motion to stay and issue a decision as soon as practicable.

ENTERED BY ORDER OF THE COURT



Deborah S. Hunt, Clerk