

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 22-1076**September Term, 2021****FDA-04/08/2022 Order****Filed On: July 12, 2022**

Fontem US, LLC,

Petitioner

v.

United States Food and Drug Administration,

Respondent

BEFORE: Rogers, Millett, and Wilkins, Circuit Judges

ORDER

Upon consideration of the emergency motion for stay pending court review, the response thereto, the reply, and the Rule 28(j) letter and the response thereto; and the motion for leave to file the reply under seal, it is

ORDERED that the motion for leave to file the reply under seal be granted. It is

FURTHER ORDERED that the emergency motion for stay be denied. Petitioner Fontem US, LLC has not satisfied the stringent requirements for a stay pending court review. See Nken v. Holder, 556 U.S. 418, 434 (2009); D.C. Circuit Handbook of Practice and Internal Procedures 33 (2021). We consider (1) whether Fontem “has made a strong showing that [it] is likely to succeed on the merits; (2) whether [it] will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding;” and (4) whether the public interest favors a stay. Nken, 556 U.S. at 434.

Fontem has not made a strong showing that it is likely to succeed on the merits. As to multiple bases for the marketing denial order identified by the Food and Drug Administration (“FDA”), the agency likely afforded Fontem fair notice. See Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 156 (2012). The FDA also pointed to record evidence indicating that it likely found each of the grounds for the marketing denial order independently sufficient to support its decision. See ADD-220-223; see also ADD-179, ADD-182-186. “[W]hen an agency relies on multiple grounds for its decision,” we may “sustain the decision as long as one is valid and the agency would clearly have acted on that ground even if the other[s] were unavailable.” Casino

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Airlines, Inc. v. Nat'l Transp. Safety Bd., 439 F.3d 715, 718 (D.C. Cir. 2006) (internal quotation marks and citation omitted).

Nor do the other factors favor a stay. Fontem has demonstrated that the marketing denial order is causing it harm, but by waiting more than two months after the marketing denial order's issuance to seek emergency relief, Fontem weakened its claim of irreparable harm. That delay also suggests it may have been practicable to seek a stay from the agency. See Fed. R. App. P. 18(a). The public interest favors the likely proper enforcement of laws that protect the public health. See MediNatura, Inc. v. FDA, 988 F.3d 931, 945 (D.C. Cir. 2021) ("The public has a strong interest in [FDA] enforcement . . . to protect public health."). It is

FURTHER ORDERED, on the court's own motion, that this case be expedited and the following briefing schedule apply:

Petitioner's Brief	August 10, 2022
Respondent's Brief	September 9, 2022
Petitioner's Reply Brief	September 30, 2022
Deferred Appendix	October 7, 2022
Final Briefs	October 14, 2022

The Clerk is directed to calendar this case for oral argument on the first appropriate date following completion of briefing. The parties will be informed later of the date of oral argument and the composition of the merits panel.

The court reminds the parties that

In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing. . . . When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing.

See D.C. Cir. Rule 28(a)(7).

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Petitioner should raise all issues and arguments in the opening brief. The court ordinarily will not consider issues and arguments raised for the first time in the reply brief.

To enhance the clarity of their briefs, the parties are urged to limit the use of abbreviations, including acronyms. While acronyms may be used for entities and statutes with widely recognized initials, briefs should not contain acronyms that are not widely known. See D.C. Circuit Handbook of Practice and Internal Procedures 43 (2021); Notice Regarding Use of Acronyms (D.C. Cir. Jan. 26, 2010).

Parties are strongly encouraged to hand deliver the paper copies of their briefs to the Clerk's office on the date due. Filing by mail may delay the processing of the brief. Additionally, counsel are reminded that if filing by mail, they must use a class of mail that is at least as expeditious as first-class mail. See Fed. R. App. P. 25(a). All briefs and appendices must contain the date that the case is scheduled for oral argument at the top of the cover. See D.C. Cir. Rule 28(a)(8).

Per Curiam

FOR THE COURT:

Mark J. Langer, Clerk

BY: /s/

Tatiana Magruder

Deputy Clerk