IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 21-60766
consolidated with
No. 21-60800

WAGES AND WHITE LION INVESTMENTS, L.L.C., doing business as TRITON DISTRIBUTION,

Petitioner,

v.

FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the United States Food and Drug Administration

PETITIONERS' UNOPPOSED MOTION FOR MODIFICATION, AMENDMENT, OR CLARIFICATION OF OPINION ENTERED ON JANUARY 3, 2024

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CERTIFICATE OF INTERESTED PERSONS

Nos. 21-60766 and 21-60800

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

1. Petitioners:

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   Vapetasia LLC

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5. *Amici Curiae* Organizations in Support of Petitioners

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American Vapor Manufacturers Association, Inc.
Consumer Advocates for Smoke-Free Alternatives Association, Inc.
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7. *Amici Curiae* Public Health Experts in Support of Petitioners

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8. *Amici Curiae* in Support of Respondent:

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Parents Against Vaping e-cigarettes
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/s/ Eric N. Heyer
Eric N. Heyer

Pursuant to Rule 27 of the Federal Rules of Appellate Procedure, Petitioners Wages and White Lion Investments, LLC d/b/a Triton Distribution ("Triton"), and Vapetasia, LLC, hereby move this Honorable Court to modify, amend, or clarify its majority opinion in *Wages and White Lion Inv., LLC v. FDA*, Nos. 21-60766, 21-60800, 90 F.4th 357, 2024 U.S. App. LEXIS 133 (Jan. 3, 2024), to reflect that Respondent Food and Drug Administration ("FDA") has not approved menthol-flavored electronic nicotine delivery systems ("ENDS") through the premarket tobacco application ("PMTA") process. Counsel for Respondent FDA indicates that FDA does not oppose the relief requested herein.

The Court, in explaining FDA's *post hoc* statements regarding flavored ENDS products, observed that FDA had excluded "menthol" from the definition of "flavored" ENDS products in its "pre-MDO guidance documents." *Wages*, 2024 U.S. App. LEXIS 133, at *28. The Court then went on to state:

> And presumably because of that exclusion, FDA has approved menthol-flavored e-cigarette products notwithstanding its ban on "flavored" products. . . . Yet in its en banc brief before the court, FDA makes a *post hoc* invocation of "recent data [that purportedly] demonstrate 'prominent menthol e-cigarette use' among middle- and high-school e-cigarette users." And FDA makes no attempt to explain why if that's true, it approved menthol products. Or more to the point, how it could rationally approve menthol products while denying petitioners' flavored products.

Id. at *28-29.

However, to date, FDA has not approved any PMTAs for menthol-flavored ENDS products.[1] Instead, FDA has denied several PMTAs for menthol-flavored ENDS products.[2] Indeed, FDA's decisions to deny applications for certain menthol-flavored ENDS products, based at least in part on FDA's *post hoc* justifications similar to those in this matter, form the basis of other petitions for review currently pending before this Court. *See R.J. Reynolds Vapor Company v. Food & Drug Administration*, No. 23-60037 (consolidated with Nos. 23-60128 and 23-60545). Thus, to resolve the inconsistency between the above-noted statement in the Court's opinion and FDA's actions, amendment, modification, or clarification of the Court's January 3, 2024 Opinion is appropriate. Such an amendment will also prevent any inconsistency or conflict with the Court's prior or future decisions in the menthol-related petitions for review currently pending before it.

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[1] *See* FDA Premarket Tobacco Product Marketing Granted Orders, available at https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders, last accessed Feb. 19, 2024.

[2] *See* FDA Premarket Tobacco Product Applications, available at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Premarket%20Tobacco%20Product%20Applications%20(PMTA), last accessed Feb. 19, 2024 (listing FDA press releases on marketing denial orders, including of menthol-flavored ENDS products).

Accordingly, Petitioners respectfully request that the Court amend, modify, or otherwise clarify its Opinion to reflect that the FDA has not approved PMTAs for menthol-flavored ENDS products.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2024, a true and correct copy of the foregoing was filed with the Clerk's Office for the United States Court of Appeals for the Fifth Circuit using the CM/ECF system and served via electronic mail via the Court's ECM/ECF system. Participants in this case are registered ECM/ECF users, and service will be effected via the ECM/ECF system.

/s/ Eric N. Heyer
Eric N. Heyer

CERTIFICATE OF COMPLIANCE

I hereby certify that Petitioners' Unopposed Motion for Modification, Amendment, or Clarification of Opinion Entered on January 3, 2024, complies with the type-volume requirement set forth in Federal Rule of Appellate Procedure 35(b)(2)(A). The word count feature found in Microsoft Word reports that the Motion contains 439 words, excluding the items exempted by Federal Rule of Appellate Procedure 32(f).

Petitioners' Unopposed Motion for Modification, Amendment, or Clarification of Opinion Entered on January 3, 2024, complies with the typeface and typestyle requirements of Federal Rule of Appellate Procedure 32 because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ Eric N. Heyer
Eric N. Heyer