April 22, 2022

Ms. Michele Mital
Acting Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993

RE: Enforcement of Marketing Denial Orders

Dear Director Mital:

The undersigned organizations write to express our concern that if FDA does not act decisively and quickly to enforce the MDO it issued against multiple products manufactured by Fontem US, LLC and affiliate of ITG Brands, it will be sending a message to manufacturers to believe that they can market their products with impunity after an MDO is issued.

After FDA recently issued MDOs to Fontem US, LLC (Fontem), an affiliate of ITG Brands, for several myblu e-cigarette products,[1] Fontem issued a response stating its intent to "use the administrative appeals process" to contest the MDOs and adding: "**Based on past practice, we expect the FDA will not seek to enforce the MDOs while this appeal remains ongoing, and we therefore expect the products to remain in the market during this period**. **All of our products remain available for sale and there is no legal prohibition against continuing to market the myblu vapor portfolio."**[2]

These statements appear flatly inconsistent with the MDO order issued by FDA and the enforcement policy expressed by FDA in its announcement of the myblu MDO. FDA stated:

> Tobacco products subject to a negative action regarding a premarket submission, including those subject to an MDO, may not be offered for sale, distributed or marketed in the US. Such products may not be introduced or delivered for introduction into interstate commerce, and *if the product is already on the market, the product must be removed from the market.* Currently, FDA's highest enforcement priorities are ENDS products for which no application is pending, *including, for example, those with an MDO* or those for which no application was submitted.[3]

This agency statement of enforcement priorities is not new, but rather is the latest expression of the enforcement policy initially expressed in the agency's statement of

[1] FDA, "FDA Issues Marketing Denial Orders to Fontem US for myblu Products" (April 8, 2022) (FDA Fontem statement), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-fontem-us-myblu-products
[2] https://www.blu.com/en/US/faqs/regulation/update-blus-response-to-fdas-marketing-denial-order
[3] FDA Fontem statement (emphasis supplied).

September 9, 2021: "[P]roducts for which no application is pending, *including, for example, those with a Marketing Denial Order* and those for which no application was submitted, are among our highest enforcement priorities."[4]

Contrary to the implication of the Fontem statement, these agency expressions of enforcement policy in no way suggest that a company's pursuit of an administrative appeal of an MDO somehow exempts it from agency enforcement action or in some other way alters its status as an illegally marketed tobacco product.[5] It seems apparent that Fontem, an affiliate of a major tobacco company, does not believe "based on past [FDA] practice," (in the company's words), that the agency will take enforcement action against companies that have received MDOs, despite the agency's contrary assurances.[6]

In light of Fontem's statement, to its downstream sellers, consumers, and the public, that its products have immunity from FDA enforcement and will not be removed from the market despite having received MDOs, it is critical for FDA to take immediate and public action to enforce its MDO decisions regarding Fontem's products.

Thus, we urge the agency to (1) state publicly and expressly that companies receiving MDOs are subject to immediate enforcement actions regardless of whether an administrative appeal is being pursued, and (2) bring enforcement actions against the myblu products receiving MDOs and other products which remain on the market despite receiving MDOs.

FDA must not countenance regulated entities like Fontem acting in open contempt of the law and of FDA enforcement authority.

Thank you for your consideration of our views.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

CC: The Honorable Dr. Robert M. Califf, FDA Commissioner

---

[4] Statement of Janet Woodcock and Mitch Zeller, "FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted" (September 9, 2021) (emphasis supplied), https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90#:~:text=FDA%20Statement-,FDA%20Makes%20Significant%20Progress%20in%20Science%2DBased%20Public%20Health%20Application,Deemed'%20New%20Tobacco%20Products%20Submitted&text=Statement%20From%3A,Janet%20Woodcock%2C%20M.D.

[5] In fact, 21 C.F.R. § 10.35(d) states in relevant part, "Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure … will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind."

[6] It also is worth noting that no judicial or administrative stay of the Fontem MDO has been issued.