IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-878 (ABJ)
RIGHT TO BE SMOKE–FREE COALITION, et al., Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-1210 (ABJ)

DEFENDANTS' SUPPLEMENTAL BRIEF ON RIPENESS

Defendants respectfully submit this response to the Court's October 26, 2016, order directing supplemental briefing on ripeness.

1. "[W]hat is it exactly that a manufacturer of a nicotine-free liquid is required to do to comply with the Rule . . . at this time?"

Perhaps nothing. Not all nicotine-free e-liquids ("NFLs") are subject to the deeming rule. Assuming an NFL is not made or derived from tobacco, it is subject to the rule only if it meets the definition of a "component or part"—that is, if it is "intended or reasonably expected" either "(1) To alter or affect [a] tobacco product's performance, composition, constituents, or characteristics; or (2) To be used with or for the human consumption of a tobacco product," and is not an accessory. 21 C.F.R. § 1100.3. An NFL that is intended or reasonably expected to be mixed with liquid nicotine would qualify as a "component or part." 81 Fed. Reg. at 29,017.

If an NFL does not meet this definition, then the manufacturer need not comply with the rule at all. If an NFL does meet this definition, then the manufacturer is subject to all applicable provisions of the TCA. *See* Defs.' Br. at 6–7, 18–19. The manufacturer must, for example, include the NFL in its product list (due December 2016), 81 Fed. Reg. at 29,006, submit a list of the NFL's ingredients (compliance period for "small-scale" manufacturers ends August 2017; for others, February 2017), *id*. at 29,006, 29,009; and refrain from distributing free samples, 81 Fed. Reg. at 29,054. The compliance period to submit premarket tobacco applications for NFLs that were on the market when the deeming rule took effect ends in August 2018. *Id*. at 29,010–12.

Like nearly any consumer protection regulation, the onus is on the manufacturer to ensure that any covered products are in compliance. As noted in the preamble, NFLs "will be evaluated on a case-by-case basis," *id*. at 29,032, that takes into account "the totality of the circumstances," *id*. at 29,015—including "direct and circumstantial objective evidence, which encompasses a variety of factors such as circumstances surrounding the distribution of the product or the context

in which it is sold, and sales data," *id*. (citations omitted). Manufacturers may wish to consider:

- Whether labeling or advertising—including on the internet and social media—features or promotes use with liquid nicotine;
- Whether the same or other marketing, distribution, or promotional efforts—including product placement, joint packaging, or combined-purchase discounts—reflect intended use with liquid nicotine;
- Whether consumers are expected to mix the product with liquid nicotine—as might be reflected in consumer surveys, media reports, or literature.

Defining a "component or part" of a tobacco product by its "intended or reasonably expected" use is not meaningfully different from how other categories of products are defined and regulated under the FDCA. For example, whether a product qualifies as a "drug" depends on its "intended use"—an objective standard that turns in part on whether the product's labeling and advertising indicate that it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g); *see also United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001). That inquiry is not always clear cut, and it sometimes results in fact-intensive litigation. But where a manufacturer prematurely seeks a declaratory judgment that its product does not meet the definition of a "drug"—before the FDA has taken any final enforcement action—courts routinely dismiss for lack of ripeness. *E.g.*, *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4 (D.D.C. 1989) (suit seeking declaration that skin cream is not a "drug" unripe).[1]

This case is no different. Indeed, the FDA has not so much as issued a warning letter to any manufacturer suggesting that an NFL is a tobacco product, *see* Defs.' Br. 36 (describing warning letters)—a preliminary step that would not be a final agency action subject to APA review in any event. *Holistic Candlers & Consumers Assoc. v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012) (FDA warning letters do not constitute final agency action). The Court should reject

[1] *See also Regenerative Sciences, Inc. v. FDA*, No. 09-411, 2010 WL 1258010 (D. Colo. Mar. 26, 2010) (suit seeking declaration that stems cells are not "drugs" or "biological products" unripe); *Health Sci. Funding LLC v. FDA*, No. 15-5635, 2016 WL 3078748, at *4 (D.N.J. May 31, 2016) (suit seeking declaration that dehydroepiandrosterone qualifies as a "medical food" unripe).

Plaintiffs' efforts to circumvent these bedrock ripeness requirements.

2. "How would the FDA undertake its case-by-case analysis . . . without the information to be supplied in the pre-market review application . . . ?"

If an NFL is not a "tobacco product"—that is, if it is not made or derived from tobacco and does not meet the definition of a "component or part"—then it is not subject to the deeming rule, and a premarket application is not required. Thus, the FDA does not expect to receive a premarket application for all NFLs.

If the FDA became aware of a potential violation—for example, if it had reason to believe that a particular NFL was intended to be mixed with liquid nicotine but was not in compliance with the TCA—then the agency would review all relevant and available information to assess whether the NFL met the definition of a "tobacco product," just as the FDA reviews available information to determine whether a product is a drug under the FDCA, even without a new drug application. As indicated above, that review could include information about how the product is labeled, distributed, marketed, promoted, packaged, sold, and actually used by consumers.

3. "Given the two-year pre-market review compliance period, how would a challenge to the regulation of a nicotine-free e-liquid be adjudicated, if it is not ripe now?"

There are several scenarios in which a challenge, once ripe, could properly be decided. For example, if a particular NFL qualified as a "tobacco product," then the manufacturer would run afoul of the TCA by:

- Failing to include the NFL on its product list (due December 2016);
- Failing to submit a list of the NFL's ingredients (compliance period for small-scale manufacturers ends August 2017);
- Continuing to market products that were already on the market when the deeming rule took effect (on August 8, 2016) after the compliance period ends (in August 2018) without submitting a premarket application.

Critically, none of these scenarios would become ripe unless the FDA first took a concrete enforcement action against the manufacturer. *See* Defs.' Br. 36–37 (explaining steps). The

agency could not do so without making a "fact-based determination about the 'intended use' of" the particular NFL at issue. *Estee Lauder*, 727 F. Supp. at 4. And while any enforcement action, such as for an injunction, 21 U.S.C. § 332, a civil money penalty, *id*. § 333(f)(9), or a seizure of goods, *id*. § 334, would be reviewable in federal court, preenforcement challenges during the "preliminary phase[s] of the administrative procedure do[] not fit the statutory scheme nor serve the policy of the [Food, Drug, and Cosmetic] Act." *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600 (1950). The "FDA . . . ha[s] pre-enforcement review procedures that it will—and must be allowed to—follow in order to develop an administrative record for [the] court to review." *Health Sci. Funding*, 2016 WL 3078748, at *4. Where, as here, "the FDA has not taken any specific action with respect to [Plaintiffs] or any of [their] products," "the issues presented are not ripe for judicial review." *BBK Tobacco v. FDA*, 672 F. Supp. 2d 969, 976–77 (D. Ariz. 2009).

4. "If a manufacturer waits to challenge the regulation until the time of enforcement, will it not be too late at that juncture . . . to secure pre-market review?"

No. A manufacturer may seek premarket review at any time. If an NFL qualifies as a "tobacco product," enforcement could theoretically begin well before the premarket compliance period ends in August 2018—for example, if the manufacturer neglects to include the NFL on its product list. Even if a violation arises after that, the FDA would typically give manufacturers a reasonable time to come into compliance before initiating an enforcement action. *See* Defs.' Br. 36. Regardless, August 2018 simply marks the end of a grace period: At that point, NFL manufacturers will be in essentially the same position that manufacturers of any other product subject to premarket review under the FDCA, including drugs—for which there are no analogous compliance periods—are *already* in. The mere possibility that a product could qualify as a "drug"—and potentially be required to change its marketing for noncompliance with the FDCA—does not render a premature challenge ripe. *See supra* at 2. So too here.

5. "[T]he impact of the rules concerning modified-risk tobacco products . . . , including whether liquids marketed as 'nicotine free' are modified risk products."

The modified risk provisions do not change the analysis. If an NFL is not a tobacco product, then by definition it is not a modified risk tobacco product. And if an NFL is a tobacco product, the mere possibility that it could qualify as a modified risk product would not render a premature challenge ripe, for reasons similar to those already discussed: A product marketed in violation of the modified risk provisions would be considered adulterated, 21 U.S.C. § 387b(8), and would be subject to the same enforcement process as other FDCA violations. *See supra* at 3–4. In any event, the FDA does not intend to enforce the modified risk provisions against NFLs not made or derived from tobacco that merely claim to be "nicotine-free." Given that NFLs not made or derived from tobacco would qualify as tobacco products if intended or reasonably expected to be mixed with nicotine, in these unique circumstances, the FDA expects that consumers are unlikely to understand "nicotine-free" statements of NFLs as assertions of harm reduction in comparison to nicotine-containing e-liquids. Regardless, any false or misleading "nicotine-free" claims can be addressed through the TCA's separate misbranding provisions. *Id*. § 387c(a).

* * * * *

Imagine three NFLs. One is packaged with liquid nicotine. The second, packaged alone, is candy flavored and advertised to "make your nicotine buzz even sweeter." The third, spearmint flavored, is billed to "satisfy your oral fixation better than chewing gum." The first of these surely qualifies as a component or part; at oral argument, Nicopure conceded that e-cigarettes packaged with nicotine were regulable. That alone is enough to reject Plaintiffs' facial challenge with respect to NFLs—but the Court need not reach that issue. Plaintiffs say nothing about the NFLs they manufacture, leaving to guesswork which of these examples their NFLs most resemble. The FDA is not required to make that fact-bound determination in a vacuum, and neither is the Court.

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Respectfully submitted,

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