Office of the Secretary

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C. 20436

December 15, 2023

Harold H. Davis, Esq.
Greenberg Traurig, LLP
101 Second Street, Suite 2200
San Francisco, CA 94105-3668

Re: Complaint Filed by R.J. Reynolds Tobacco Company and R.J. Reynolds Vapor Company Concerning Certain Disposable Vaporizer Devices and Components and Packaging Thereof (Docket No. 3700)

Dear Mr. Davis:

Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined to dismiss in part the complaint filed on behalf of R.J. Reynolds Tobacco Company and R.J. Reynolds Vapor Company (collectively "Reynolds") and not institute an investigation concerning certain disposable vaporizer devices and components and packing thereof as to: (i) proposed respondent Shenzhen Pingray Technology ("Pingray"); (ii) the cause of action set out in paragraphs 120 through 136 of the complaint (the "Authorization Claims"); and (iii) the cause of action set out in paragraphs 326 through 348 of the complaint.

Regarding Pingray, the information provided with the complaint, amendments, supplements, and exhibits does not allege unfair acts in the importation into the United States or a sale of the accused articles by proposed respondent Pingray as required by the statute and the Commission's rules.

Regarding the Authorization Claims cause of action set out in paragraphs 120 through 136 of the complaint, the Commission received a submission from the United States Food and Drug Administration ("FDA") recommending against instituting on the basis that the Authorization Claims would usurp its enforcement authority under the Food, Drug, and Cosmetic Act ("FDCA") and amount to a private right of action precluded by the FDCA. *See* FDA Letter from Mark Raza and Peter Dickos, EDIS Doc. ID 807175 at 1 (Oct. 27, 2023) ("FDA Letter").

As explained below, the Commission agrees with the FDA and finds that the Authorization Claims do not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A) ("Section 337").

Reynolds' Authorization Claims allege that each of the proposed respondents have violated the Lanham Act by making public statements falsely representing that their accused disposable vaping devices are FDA authorized or "allowed" for sale in the United States. Complaint, ¶¶ 120-136. Reynolds claims that proposed respondents' accused disposable vaping devices lack marketing authorization from FDA and they do not have a timely filed premarket tobacco product application pending with FDA, or a marketing denial order that has been stayed by FDA or a court. Complaint ¶ 121; Nov. 29, 2023 Reynolds letter, EDIS ID No. 809498. The only specific statement Reynolds identifies as purporting to show a false representation of FDA authorization is the package statement, "Sale Only Allowed in the United States." Complaint ¶ 126; Exhibit 3.

The FDA explains that the identified statement – "Sale Only Allowed in the United States" – must be included *verbatim* on the labels of all tobacco products (both authorized and unauthorized) sold in the United States pursuant to the FDCA, 21 U.S.C. § 387t(a). FDA Letter at 4 (explaining that a tobacco product in package form is "misbranded" if its label *does not* include such a statement). Further, the FDA states that "nearly every ENDS [electronic nicotine delivery systems] product now on the market (including at least one of Complainants' own) lacks FDA authorization, and thus is not lawful." *Id*. However, the FDA has decided as a policy matter against immediate enforcement against unauthorized ENDS products already on the market on the basis of striking a balance between the serious risk that e-cigarettes pose and their potential benefit in helping smokers transition from or significantly reduce smoking combustible cigarettes. *Id*. at 2. Given that the label at issue must be included on all tobacco products, FDA states that Reynolds' "theory would convert *every* FDCA-unauthorized product into a Lanham Act-violating product . . . boil[ing] down to an impermissible attempt to weaponize the Lanham Act to do indirectly what Complainants cannot do directly: enforce the FDCA's premarket authorization requirement." *Id*. at 4. Moreover, Respondents have pointed out that they are not aware of any domestic production of ENDS products. *See, e.g.,* Magellan et. al PI Sub. at 5 (Oct. 27, 2023) ("Respondents are unaware of any such articles made in the United States… As Complainants note, almost all vape products, including those sold by Complainants, are produced in China.").

Congress gave the FDA the authority to enforce the FDCA and prohibited private parties from bringing such actions. *See* 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States"); *see also POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 109 (2014)) ("the FDCA and its regulations provide the United States with nearly exclusive enforcement authority. . . . Private parties may not bring enforcement suits."); *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959, 966 (Fed. Cir. 2019) ("Private parties may not bring suits to enforce the FDCA."). If the Commission were to find the "Sale Only Allowed in the United States" statement to be misleading and therefore a violation of Section 337, it would effectively be a decision that nearly all disposable vaporizer devices could be subject to exclusion from importation. But the decision of whether to exclude unauthorized ENDS products from the market is a determination that is

squarely within the authority of the FDA, and it would usurp the FDA's authority to enforce the FDCA and impermissibly grant a private right of action to enforce the FDCA if the Commission were to institute an investigation based on the Reynolds complaint to resolve whether the accused products are not "allowed" and should be excluded from the market. Reynolds' Authorization Claims are therefore precluded by the FDCA. *See Amarin*, 923 F.3d at 968-69 (affirming the Commission's decision not to institute a Lanham Act claim that was "based solely on alleged violations of the FDCA's requirements"); *see also Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) ("permitting Mylan to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market ["with standard package inserts often used for FDA-approved drugs"] would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the [FDCA] and the regulations promulgated thereunder.").

Any suggestion that the Commission could institute and then consider the FDA's policy reasons for non-enforcement as part of its analysis of the public interest factors in connection with the Commission's remedy determination does not cure the preclusion issue related to the Authorization Claims. The public interest factors set forth in Section 337 are statutory criteria that the Commission considers in connection with its remedy determination upon finding a section 337 violation that may indicate that "articles should not be excluded from entry." *See* 19 U.S.C. § 1337(d)(1), (f)(1), (g)(1). The Commission is required to issue remedial relief upon the finding of a Section 337 violation unless "the effect of [the] exclusion [or cease and desist order] upon" the statutorily-enumerated public interest factors counsel otherwise. Thus, were the Commission to find a violation of section 337 based on Reynolds' Authorization Claims, it would be required to consider whether the accused ENDS products should not be excluded from entry based *inter alia* on whether it would be contrary to public health to do so. In that situation, the Commission would be asked to "step into the shoes of the FDA," FDA letter at 5, and decide whether unauthorized ENDS products should be excluded from the market. The FDCA precludes such action, however. Consistent with its statutory mandate, FDA is the authority that is to apply its expertise to determine the appropriate circumstances to enforce the FDCA.

Similarly, as to the cause of action set out in paragraphs 326 through 348 of the complaint, which alleges a violation of Section 337 based on unfair competition and unfair acts through violations of Customs laws and regulations, the Commission finds that this claim does not allege an unfair method of competition or an unfair act cognizable under Section 337 as required by the statute and the Commission's rules. As U.S. Customs and Border Protection explains in its submission: "In order to evaluate this claim on the merits, the Commission would necessarily have to determine the appropriate classification and duty rate for such merchandise. However, as identified above, Congress statutorily granted this authority to the Department of the Treasury and to CBP as the agency responsible for fixing the final classification and rate of duty applicable to imported merchandise." CBP Sub. at 3. CBP's submission further notes that enforcement of the Customs laws is within the province of CBP's authority and there is no private right of action to enforce the Customs laws. *Id.* at 4-5. The Commission agrees with the issues raised by CBP as to the Customs claims in the Reynolds complaint.

The Commission, however, has determined to institute an investigation with respect to the remaining respondents based on the complaint's false advertising claim under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), stated in paragraphs 137 through 142 of the complaint. The

Commission has also determined to institute an investigation with respect to the remaining respondents based on the complaint's false designation of origin claim under the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), stated in paragraphs 143 through 147 of the complaint. At this stage, it does not appear that those Lanham Act allegations are precluded by the FDCA. The Commission also determined to institute an investigation with respect to the remaining respondents based on the complaint's unfair competition claim based on violations of the Prevent All Cigarette Trafficking (PACT) Act.

Documents relating to this institution determination, including comments from the complainants, proposed respondents, and the public, can be found on the Commission's Electronic Document Information System (EDIS) under Docket Number 3700.

Sincerely,

Lisa R. Barton
Secretary to the Commission

cc: Proposed respondents

CERTAIN DISPOSABLE VAPORIZER DEVICES AND COMPONENTS AND PACKAGING THEREOF **Inv. No. 337-TA-1381**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INSTITUTION OF INVESTIGATION** has been served via EDIS upon the Commission Investigative Attorney, **Cortney Hoecherl,** and upon the following parties as indicated, on **December 15, 2023**.

Lisa R. Barton, Secretary
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