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ONE HUNDRED SIXTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

August 21, 2019

Mr. Ricardo Oberlander
President and Chief Executive Officer
Reynolds American Inc.
401 N. Main Street
Winston Salem, NC 27101

Dear Mr. Oberlander:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining the public health implications of electronic nicotine delivery systems (ENDS), including electronic cigarettes (e-cigarettes). We request information to better understand Reynolds American Inc.'s (Reynolds) research pertaining to the public health impact of e-cigarettes, Reynolds's marketing practices, and Reynolds's role in the promotion of e-cigarette use by adolescents under the age of 21.

On May 10, 2016, the Food and Drug Administration (FDA) published a final deeming rule to regulate all tobacco products, including ENDS such as e-cigarettes.[1] The final rule requires any tobacco product not on the market as of August 8, 2016 to undergo an FDA premarket review. Additionally, the deeming rule required manufacturers of tobacco products already on the market as of August 8, 2016 to submit a premarket tobacco application (PMTA) for each product to FDA for review by August 8, 2018. In August 2017, FDA issued guidance explaining that the agency would exercise enforcement discretion and extend the premarket compliance deadlines for several products, including a four-year extension for certain e-cigarettes, to August 8, 2022.[2] In March 2019, FDA issued revised draft guidance proposing to modify its enforcement discretion policy for most flavored ENDS products, noting that it will prioritize enforcement of most flavored ENDS products that may be offered for sale in a manner

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[1] Food and Drug Administration, *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products* (Aug. 8, 2016) 81 FR 28973.

[2] Food and Drug Administration, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability* (Aug. 10, 2017) 82 FR 37459.

that could allow for youth access.[3] The draft guidance also proposes changing the compliance deadline for most flavored ENDS products and moving the PMTA submission deadline to August 8, 2021.[4]

However, on July 12, 2019, a U.S. District Court judge ordered manufacturers of e-cigarettes and other ENDS products currently on the market under enforcement discretion to file PMTAs with FDA for review of their products within 10 months (May 2020).[5] Citing the "staggering toll inflicted on the public health by tobacco products," FDA has since stated that it "stands ready to accelerate the review of e-cigarettes and other new tobacco products."[6] Further, FDA indicated that manufacturers do not need to wait 10 months to submit premarket applications and encouraged the industry to use FDA guidance, already available, for their submissions.[7]

I am concerned that ENDS products, like Reynolds's Vuse Digital Vapor Cigarette, are continuing to be disseminated, marketed, and used while consumers lack adequate information to evaluate the health implications of using these products.[8] In fact, the Centers for Disease Control and Prevention (CDC) and state health officials are currently investigating 94 possible cases of "pulmonary illnesses linked to e-cigarette use" among young people reported in recent weeks across 14 states.[9] As of August 16, 2019, 31 cases had been confirmed, with many of these patients hospitalized—including some in intensive care and on ventilators—and medical authorities reportedly unclear as to "whether patients will fully recover."[10]

These concerns are heightened given the popularity of e-cigarettes, particularly flavored products, among young people. According to the 2018 National Youth Tobacco Survey, youth usage of e-cigarette products increased by nearly 80 percent among high school students and

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[3] Food and Drug Administration, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)* (Mar. 14, 2019).

[4] *Id.*

[5] *U.S. federal judge orders FDA to implement 10-month deadline for e-cig applications,* Reuters (July 12, 2019).

[6] Food and Drug Administration, *Statement on the agency's actions to tackle the epidemic of youth vaping and court ruling on application submission deadlines for certain tobacco products, including e-cigarettes* (July 15, 2019).

[7] *Id.*

[8] *See* Letter from Frank Pallone, Jr., Ranking Member, House Energy and Commerce Committee to Dr. Scott Gottlieb, Commissioner, Food and Drug Administration (Mar. 8, 2018).

[9] *Mystery lung illness linked to vaping. Health officials investigating nearly 100 possible cases*, Washington Post (Aug. 16, 2019).

[10] *Id.*

nearly 50 percent among middle school students in the prior year.[11] In fact, FDA and CDC found that 1.5 million more students used e-cigarettes in 2018 than 2017 and that youth e-cigarette usage has reached "epidemic proportions."[12] In light of these findings, in September 2018, FDA issued a warning letter to Reynolds and four other leading e-cigarette companies requesting "prompt action to address the rate of youth use" of its products.[13]

The U.S. Surgeon General has noted that young people may be trying e-cigarette products based on the belief that e-cigarettes are less harmful than other tobacco products.[14] Yet in a comprehensive study, the National Academies of Sciences, Engineering, and Medicine found that while the long-term health effects of e-cigarettes are not yet clear, there is "conclusive evidence that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances."[15] Further, the study also concluded that, "there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."[16]

Additionally, this spring, FDA announced that it is investigating reports that some people, especially youth and young adults, have experienced seizures following the use of e-cigarette products.[17] FDA explained that seizures can be a potential side effect of nicotine poisoning.[18]

In light of the concerns raised above, I request that you respond to the inquiries below and provide the following information by September 20, 2019:

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[11] Centers for Disease Control and Prevention, *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018* (Feb. 15, 2019).

[12] *Id.*

[13] Letter from Dr. Scott Gottlieb, Commissioner, Food and Drug Administration, to Mike Ogden, Reynolds American Inc. (Sept. 12, 2018).

[14] U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016).

[15] National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018).

[16] *Id.*

[17] Food and Drug Administration, *E-cigarette: Safety Communication – Related to Seizures Reported Following E-cigarette Use, Particularly in Youth and Young Adults* (Apr. 3, 2019).

[18] Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., and Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., on FDA's ongoing scientific investigation of potential safety issue related to seizures reported following e-cigarette use, particularly in youth and young adults (Apr. 3, 2019).

1. What research or studies has Reynolds conducted or financed related to its ENDS products? Please provide the studies and their results pertaining to the topics below, including whether it was conducted or considered prior to or after a product's introduction to the market. If any research is currently being conducted, please describe the research objectives, methods, and timeframe. If none of the above applies, please provide an explanation as to why Reynolds has not conducted or explored research related to the following:

    a. The public health impacts of adolescent use versus adult use of Reynolds's ENDS products.

    b. The potential appeal of Reynolds's ENDS products to adolescents and the appeal of each flavored product to adolescents and the reason for that appeal.

    c. The likelihood of adolescents and adults transitioning from Reynolds's ENDS products to combustible cigarettes or becoming dual-users of Reynolds's ENDS products and combustible cigarettes.

    d. Evaluation of the relative health implications of using Reynolds's ENDS products compared to abstaining from using any tobacco or nicotine products.

    e. Effectiveness of Reynolds's ENDS products in helping smokers quit smoking.

    f. Evidence that each of the non-tobacco-flavored Reynolds ENDS products are necessary for smoking cessation among adults.

    g. Evaluation of the health effects of exposure to each characterizing flavor used in Reynolds ENDS products.

    h. Comparisons of the health implications of dual-use of Reynolds's ENDS products and combustible cigarettes versus solely using a Reynolds ENDS product.

    i. The potential side effects of nicotine toxicity, including seizures or convulsions.

    j. The potential toxicity or other potential adverse health effects of exposure to each Reynolds's ENDS product, including each delivery system, each particular flavor, and each chemical component when heated and when idle, and whether evidence can be provided that every component of Reynolds's ENDS products have no adverse health effect when inhaled.

    k. Promotional and marketing research, including the use of social media, on the demographic characteristics (such as age) of adolescent and adult users of Reynolds's ENDS products.

2. What of the above information, if any, has been provided to FDA? Does Reynolds plan to submit this information as part of a PMTA in the future or otherwise make the information publicly available? If such information has not or will not be provided to FDA, please explain why.

3. Please provide all responses that have been provided to FDA, including the documents produced in association with those responses, as a result of letters from the agency to Reynolds since August 2017.

4. Is Reynolds aware of any adverse experiences by users of its products, including not only health effects like seizures but also product-related defects that could cause harm? If so, how many adverse experiences associated with Reynolds ENDS products have been reported to Reynolds or that Reynolds is otherwise aware of occurring. Have these adverse experiences been reported to FDA? If not, please explain why.

5. Is an intended use of Reynolds's ENDS products to help smokers quit smoking combustible cigarettes?

6. Given that Reynolds's products have not been approved by FDA as smoking cessation devices, does Reynolds indicate in its ads and packaging that its ENDS products have not been approved by FDA for use in smoking cessation, or that its products have not been reviewed and found to be safe or effective for that purpose? If so, when and where is this information conveyed to the potential purchaser or user?

7. Which of Reynolds's ENDS products currently available for purchase were on the market on or before August 8, 2016? Which of Reynolds's ENDS products currently available for purchase came on the market after August 8, 2016? For each product, indicate the number of retail outlets where the product was sold and the number of ENDS products sold to customers.

8. Please provide the sales information of all Reynolds ENDS products since January 2016, including a breakdown by store-front retail type and online sales of each product.

9. How much has Reynolds spent on marketing and promotions of ENDS products each year since the launch of Vuse delivery systems and products? Please provide a breakdown for each year by media, including television, newspapers, magazines, point-of-sale, direct mail, coupons, endorsement and testimonials, sponsorships, social media paid placement and influencers, website, other internet, promotion allowances for retailers and wholesalers, and retail-value-added services.

10. What is the placement and reach of Vuse television advertisements? Are these videos made available to view on other platforms such as YouTube? If so, what is Reynolds doing to ensure that adolescents are not seeing the advertisements?

11. In the past, has Reynolds paid social media influencers to market its ENDS products? Does Reynolds currently pay social media influencers to market its products? If so, please provide a list of all social media influencers who have been paid by Reynolds to market your products. Does Reynolds require all social influencers to disclose their connection with Reynolds in their posts? If so, what requirements if any does Reynolds impose for such disclosure? What steps does Reynolds take to ensure such disclosures are made?

12. Has Reynolds used or does Reynolds use social media bots to market its products? If yes, please provide a list of the handles or usernames or other identification of all bots used or paid for by Reynolds to market its products. Do all bots used or paid for by Reynolds disclose their connection with Reynolds in their posts? If so, how do they disclose that connection? What steps does Reynolds take to ensure such disclosures are made?

13. What age-verification strategies does Reynolds use to prevent the sale of ENDS products to underage minors online? What criteria does Reynolds use to determine the adequacy of age-verification strategies implemented by retail outlets for the sale of ENDS products? Does Reynolds use a delivery service for online sales that requires proof of age upon delivery, or use an independent third party to verify adequacy and compliance for retail sales?

14. Does Reynolds plan to submit PMTAs for its products prior to May 2020? If so, when does Reynolds intend to begin submitting applications?

An attachment to this letter provides additional information about responding to the Committee's request. Thank you for your prompt attention to this matter. If you have any questions, please contact Jesseca Boyer or Jacquelyn Bolen of the Committee staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman