May 9, 2019

Dr. Norman E. Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: JUUL Marketing Claims of Smoking Cessation

Dear Dr. Sharpless:

> FDA considers claims about smoking cessation to be more than simply "consumer-oriented marketing statements." As noted in the preamble to the proposed rule, claims related to smoking cessation have long been recognized as evidence of intended use, conferring drug or device jurisdiction, and smoking cessation claims also have long been associated with the intended uses of curing or treating nicotine addiction and its symptoms.[5]

Thus, FDA emphasized that "smoking cessation claims generally create a strong suggestion of intended therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose."[6] Indeed, FDA stated that the suggestion of therapeutic benefit in smoking cessation claims to be so strong that disclaimers of intended therapeutic use are ineffectual and simply create consumer confusion. Thus, the Tobacco Intended Use Rule preamble stated that "[i]n most cases, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion related to the intended therapeutic use of the product."[7] [8]

II. THE POTENTIAL FOR CONSUMER CONFUSION ABOUT THE THERAPEUTIC USE OF E-CIGARETTES

The preamble to the Tobacco Intended Use Rule makes clear that one of the purposes of the Rule is to alleviate consumer confusion about the intended use of e-cigarettes. FDA comments that "studies have shown that many consumers are using e-cigarettes to attempt to quit smoking . . . despite the fact that no e-cigarette has been approved for use as a smoking cessation aid. We believe that the rule will help to mitigate this confusion and help ensure that consumers do not mistakenly use tobacco products, which are inherently dangerous, for medical uses."[9]

This potential for consumer confusion is especially acute in adolescents. As FDA recognized, "unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products."[10] FDA cited an example of such confusion as to e-cigarettes:

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The current epidemic of e-cigarette usage by teens should heighten FDA's commitment to identify and take enforcement action against unsubstantiated claims that e-cigarettes will "help people get off from cigarettes"—particularly where such claims are likely to reach adolescents. If teens are led to believe that such claims imply that e-cigarettes are FDA-approved as "safe," teens who do not smoke could be more likely to initiate use of e-cigarettes and teen e-cigarette users may be more likely to continue their use.

As the following discussion shows, JUUL Labs has been engaged in a sustained marketing campaign that causes precisely the consumer confusion that the Tobacco Intended Use Rule was issued to prevent. JUUL's marketing blitz, which includes full-page print ads in major national newspapers, promotion through its website, and radio and television ads, communicates the message that an intended use of JUUL e-cigarette products is for therapeutic purposes. This marketing is directed at the general public and thus will reach millions of young people and millions of non-smokers of every age group. Particularly given JUUL's remarkable appeal to adolescents, and the epidemic of youth nicotine addiction that the product has caused, this massive marketing of the product for unapproved therapeutic uses should be of urgent concern to FDA.

II. JUUL'S ADVERTISING ESTABLISHES THAT THE INTENDED USE OF ITS PRODUCTS IS FOR THERAPEUTIC PURPOSES.

When JUUL was introduced to the market in 2015, and for some years thereafter, it was promoted with social media and other advertising using images that overtly targeted young people and, indeed, mimicked the imagery long used by cigarette companies to appeal to youth.[12] Its marketing during that period also focused on the social media platforms most used by teens, including Instagram, YouTube, and Twitter.[13] After JUUL came under intense public scrutiny and criticism for this youth-directed social media marketing, the company changed its marketing strategy to make it appear to be targeted only at adult smokers. A central theme of its recent and current message is that smokers should "Make the switch" from cigarettes to JUUL. As the following examples of JUUL advertising indicate, "Make the switch" is a message establishing that the intended use of JUUL now is for smoking cessation, a clear therapeutic purpose, making the advertised products drugs, devices, or combination products that must be approved prior to sale.

<u>Print Advertisements.</u> Exhibit 1 to this letter is a print ad from JUUL that communicates the message that the average cigarette smoker goes through a pattern of quitting and then relapsing to smoking. This idea is conveyed by the repetition of the phrase "Quit. Start smoking again." The repetition of this phrase is followed by the word "Switch" and then the statement: "The average smoker tries to quit 30 times. Make the switch."

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[12] Jackler, Robert K. et al., "JUUL Advertising Over its First Three Years on the Market" (Jan. 24, 2019).
[13] See J. Huang, et al., "Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market," *Tobacco Control* 2018: 1-6; Chu, D-H, et al., "JUUL: Spreading Online and Offline," *Journal of Adolescent Health*, 2018, 63(5), 582-586.

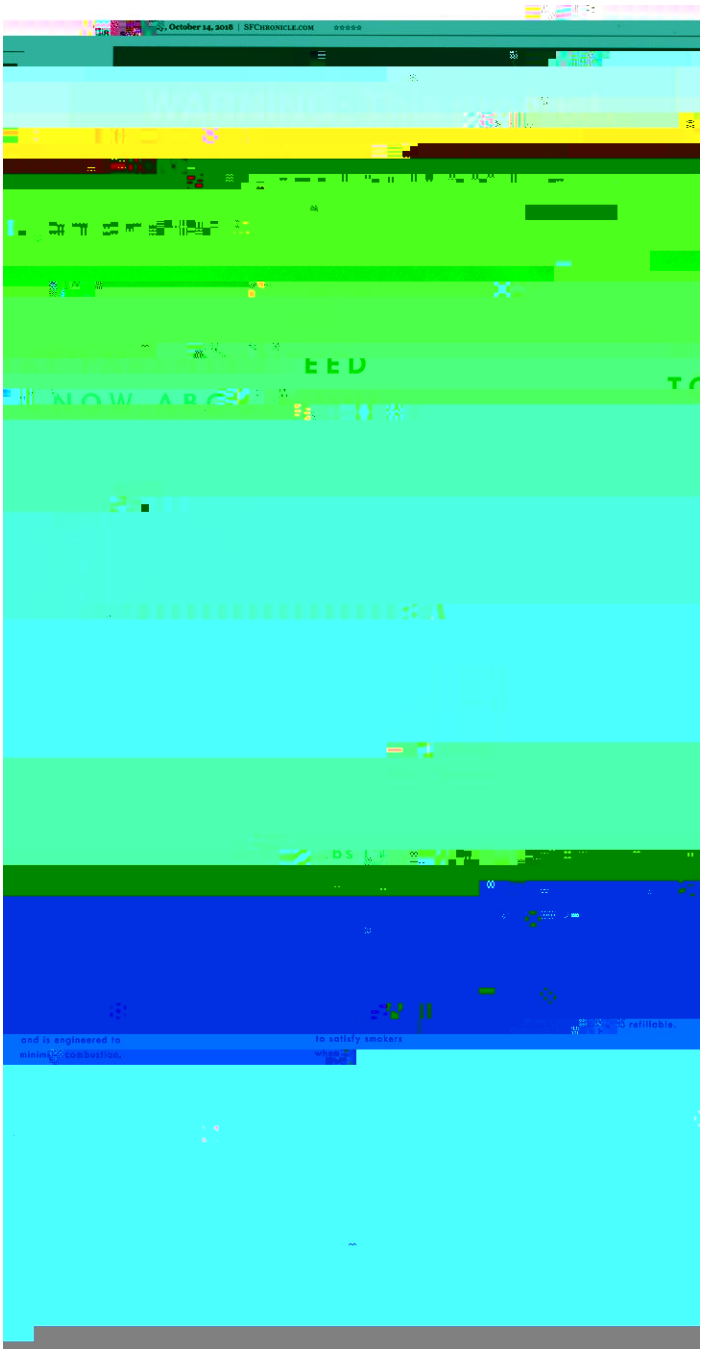
focused on the use of JUUL to switch from smoking cigarettes. It is incumbent on FDA to investigate all of JUUL's recent marketing and to determine whether the entire JUUL campaign, viewed cumulatively, is evidence that the intended use of this product is therapeutic.

Although JUUL features multiple disclaimers on its website,

Exhibit 3

Exhibit 5

Exhibit 6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and is engineered to
minimize combustion.
to satisfy smokers
refillable.

Exhibit 7