Jamie D. Underwood Direct: +1.202.637.3365 jamie.underwood@lw.com

LATHAM & WATKINS LLP

April 23, 2020

BY EDIS

The Honorable Lisa R. Barton Secretary to the Commission U.S. International Trade Commission 500 E Street, S.W., Room 112 Washington, DC 20436 555 Eleventh Street, N.W., Suite 1000 Washington, D.C. 20004-1304

Tel: +1.202.637.2200 Fax: +1.202.637.2201

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Re: Certain Tobacco Heating Articles and Components Thereof, ITC Docket No. 337-TA-3447

Dear Secretary Barton:

Enclosed please find as a courtesy filing the Public Interest Comments of the Smoke-Free Alternatives Trade Association.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood of LATHAM & WATKINS LLP

Enclosure

cc: Service List



1155 F Street NW Suite 1050 Washington, DC 20004



Docket No. 3447

April 20, 2020

VIA EDIS

The Honorable Lisa R. Barton Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436

Re: Certain Tobacco Heating Articles and Components Thereof

Dear Secretary Barton:

The Smoke-Free Alternatives Trade Association ("SFATA") submits the following comments to the U.S. International Trade Commission ("ITC") in response to the Public Interest Statement filed on April 15, 2020, in the Federal Registry, Volume 85 No. 73. Complainants ask the ITC to issue a limited exclusion order, cease and desist orders and other requirements, during the 60-day Presidential Review period pursuant to 19 U.S.C. 1337(j). The request would affect the U.S. market on all IQOS heat not burn ("HNB") systems.

SFATA believes that while electronic cigarettes and vapor products provide significant harm reduction products in the battle against death and disease from smoking, HNB systems also offer significant alternatives to traditional combustible tobacco products, including cigarettes. Additionally, this measure would harm competitive conditions in the United States for smoke free alternative products, frustrate choices for



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consumers who want to switch from using cigarettes and stifle innovation in a space that has the potential to save many lives.

SFATA, a 501(c)(6) organization, is a national trade association of businesses that work in, or in service of, the electronic vapor products industry, including manufacturers, distributors and retailers. SFATA's core mission is to advocate for a reasonably regulated U.S. marketplace which allows its member companies to provide smoke-free reduced harm alternative products to smoking adult consumers, while promoting a positive and truthful public image for vapor products and educating businesses and policy makers regarding our industry.

Factors influencing Remedial Order That are in Accordance with Public Interest

SFATA cannot comment on the underlying merits of the allegations in the above referenced litigation. Nevertheless, SFATA recognizes there is a strong public interest in protecting intellectual property rights and strongly recommends that members utilize this tool in their own businesses. The protection of intellectual property rights provides businesses with a climate of predictability, encourages innovation, investment and the exchange of technology and property rights. While these allegations made by the complainants are significant, SFATA cannot support the removal of the subject HNB products by the ITC.



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Exclusion of HNB Products Would Frustrate Market Conditions for Consumers

The electronic vapor industry considers the subject IQOS products to be competition to its inhalable vapor products. At its core, the electronic vapor industry has always recognized the issue that combustible tobacco products pose significant health issues to the consumer in the long term. With this in mind, not all consumers find electronic vapor products to be an acceptable alternative to conventional smoking. However, heated tobacco products, including HNB products, hold promise for Americans who are trying to quit/reduce traditional cigarette smoking. SFATA therefore believes there is a strong need for a ready availability of several alternative products to help smokers in accomplishing their goal, including IQOS. The ITC removing IQOS products from the U.S. market will severely limit smokers who have already found such products to be an aid to reducing/quitting cigarettes. While one HNB tobacco product has undergone the FDA's Substantial Equivalence ("SE") process, only IQOS has been authorized by the FDA through the Pre-Market Tobacco Application ("PMTA") pathway, which requires a finding that the product is appropriate for the protection of public health.

PMTA clearance is required for any new HNB tobacco product, and that process could take years to complete, exclusion would result in one product only be available *for an indeterminate period*. Further, having no choice in HNB tobacco products could increase prices, causing many tobacco users to return to traditional cigarettes or turning to the black market.



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SFATA believes that consumer choice is at the heart of the solution in helping smoking adults' transition to alternative products that potentially provide for harm reduction. Every consumer is different, and thus no one particular flavor or product is the sole solution to helping consumers transition away from combustible tobacco. In addition, reducing the U.S. market to a single supplier would foster the very monopolistic practices Congress and the ITC have sought to prevent.¹

Exclusion of IQOS Would Stifle Innovation in the Reduced Risk Product Space

Encouraging the development of non-combustible products would stimulate innovation in a space that has the potential to save many lives. As more Americans than ever seek to quit traditional cigarette smoking, companies and individuals interested in creating innovative alternative tobacco products are weighing the costs/benefits of participating in the U.S. market. In SFATA's view, if the U.S. market continues to be too expensive and uncertain, it will reduce the probability that companies will attempt to keep their current products on the market as well as bring new products to market. IQOS has undergone the FDA's robust review process. Excluding a product already authorized, with the potential to help millions of smokers, even if temporarily, sends the wrong public health message and stifles the introduction of new solutions. Policies encouraging

¹ See Certain Automatic Crankpin Grinders, Inv. No. 337-TA-60, Alberger, Bedell, and Stern Comm'n Op. at 18 (Dec. 1979).



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