EXHIBIT 6
(PUBLIC)

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Clark S. Cheney
Administrative Law Judge

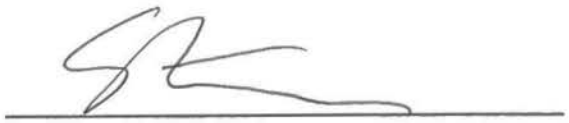
In the Matter of

CERTAIN TOBACCO HEATING
ARTICLES AND COMPONENTS THEREOF

Investigation No. 337-TA-1199

REBUTTAL EXPERT REPORT OF STACY EHRLICH

RELATING TO THE PUBLIC INTEREST



Stacy Ehrlich

October 23, 2020

entire industry how the Agency will evaluate those applications. Complainants themselves recognize this. [redacted]

121. Once concern in particular that could frustrate the authorization of certain ENDS PMTAs is the "epidemic" nature of youth abuse of ENDS products, discussed *supra*.

122. Even if FDA grants PMTA authorization to some ENDS products, there are likely to be many others FDA will not authorize, as the quality of both the ENDS products and their PMTAs vary widely.[147] Thus, it is likely that only a small percentage of those ENDS products covered by timely PMTAs will ultimately be authorized by FDA.

123. It also is unclear how long FDA will allow those products covered by pending PMTAs but not authorized by September 2021 to remain on the market during the Agency's continued review of those applications. FDA has said that it "would take into account relevant considerations in deciding whether to initiate enforcement action against a particular product as the one-year period for review comes to an end in September 2021," but has offered no guarantee of continued marketing.[148]

124. Mr. Clissold speculates that ENDS products for which PMTAs have been submitted by September 9, 2020, could remain on the market for longer than one year while FDA reviews those applications.[149] As one unsupported hypothetical, Mr. Clissold states that "it is entirely possible that as that [September 2021] deadline approaches, FDA may approach the courts for an

[146] Figlar Dep. at 47:5-7.

[147] See 1199_RESP00016335-46.

[148] 1199_RESP50000540-0541.

[149] Clissold Rep. ¶ 30.