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1	UNITED STATES INTERNATIONAL TRADE COMMISSION
2	Washington, D.C.
3	Before the Honorable Clark S. Cheney
4	Administrative Law Judge
5	
6	x
7	In the Matter of Investigation No.
8	
9	CERTAIN TOBACCO HEATING ARTICLES 337-TA-1199
10	AND COMPONENTS THEREOF
11	x
12	
13	
14	
15	
16	Monday, January 25, 2021
17	
18	EVIDENTIARY HEARING - VOLUME I - REMOTE
19	
20	
21	The parties met, via remote videoconferencing, pursuant to
22	notice of the Administrative Law Judge, at 9:00 a.m.
23	Eastern.
24	
25	Reported by: Karen Brynteson, RMR, CRR, FAPR

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1 correct?

2 A. They are. They're called e-cigarettes, vape 3 products, or ENDS.

Q. Okay. And you talked a little bit about PMTAs
during your direct examination. And Reynolds has put in a
PMTA for its Solo product and its Vibe product, correct?
A. We have, yes.

All right. It has also put in PMTAs for its 8 Ο. other e-cigarette devices, the Ciro and the Alto, correct? 9 10 Α. Among other products, yes, that's correct. 11 Okay. And you agree, Dr. Figlar, that if the Ο. 12 FDA denies Reynolds' PMTA applications for its Vuse 13 products, then Reynolds has to pull those products from the market, correct? 14

A. If -- if that were the case, that would be true,16 yes.

17 Q. All right.

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18 A. We don't feel that that's likely, but that would19 be the case.

Q. I understand. But, Dr. Figlar, you don't know if the FDA is going to authorize Reynolds' PMTAs for its Vuse products, correct?

A. No, I don't know it but we're very, very
confident, obviously, in our applications. But, you know,
we don't -- we don't know until the FDA makes a judgment.

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1 Right. So, Dr. Figlar, it's possible that the Ο. Vibe and the Solo domestic industry products will have to 2 be removed from the market this year, right? 3 4 Α. This year, I'm not sure. It depends on when the FDA is going to make a decision before one would have to, 5 6 you know, remove products from the market. But, you know, 7 we will see. Ο. Well, if the FDA denies the applications, 8 Reynolds is going to pull the products, correct? 9 10 Α. Well, obviously I think Reynolds would -- would run the course of -- of administrative review, but -- but, 11 12 yes, if ultimately the FDA makes that decision, then we would have to remove those products from the market. 13 14 Okay. Now, there's another FDA term that's been 0. 15 discussed in this case called an MRTPA, correct? 16 I suppose, yes, I know what an MRTPA is, yes. Α. 17 0. Right. An MRTPA stands for Modified Risk 18 Tobacco Product Application, correct? That is correct. 19 Α. Right. And if an MRT application is granted, a 20 Ο. 21 company can advertise a tobacco product as, for instance, a 22 reduced risk or a reduced exposure product, correct? 23 It depends on what the FDA decides with regard Α. to those advertising claims, but, yes, there's a G-1 and 24 25 G-2 path, exposure or risk.

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