Food and Drug Administration Center for Tobacco Products 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Note to file

On November 18, 2016, Philip Morris Products S.A. filed IQOS Modified Risk Tobacco Product Applications, which included preclinical, clinical and perception and behavior assessment sections. Unfortunately, files from these sections were inadvertently excluded in the initial posting of the Application. We are now posting these missing files from the preclinical, clinical and perception and behavior assessment sections of the Application in a supplemental release.

The zip file titled "Additional Preclinical Files" contains files that are located within the following Application folder:

- 72 PRECLIN/InVivo/90dMenth
- 72 PRECLIN/InVivo/AJ MOUSE

The zip file titled "Additional Clinical Files" contains files that are located within the following Application folder:

- 73 HUMAN\731 CLIN\01 PK01EU
- 73 HUMAN\731 CLIN\03 REXC03EU
- 73 HUMAN\731 CLIN\07 REXA07JP
- 73 HUMAN\731 CLIN\08 REXA08US

The zip file titled "Additional Perception and Behavior Assessment" contains files that are located within the following Application folder:

- 73 HUMAN\732 PBA
- 73 HUMAN\732 PBA\PBA02
- 73 HUMAN\732 PBA\PBA04
- 73 HUMAN\732 PBA\PBA06
- 73 HUMAN\732 PBA\PBA07