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**RESPONSE TO AUGUST 13, 2020 DEFICIENCY LETTER for PM0000634**

August 27, 2020

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## **FDA REQUEST 1**

You submitted “a representative sample of package labels” (see A4-1-4-box-white and A4-1-5-hat- white), but not all the package labels. In order to complete our evaluation, FDA needs to review all package labels for the *IQOS* 3 product as it is proposed to be used. Provide full color copies of all panels where applicable and reflect the actual size and include any variation in the labeling due to the different product colors. If resizing the labeling does not allow for the text to be read easily, the text may be provided separately and referenced.

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## **RESPONSE 1**

In response to the Agency’s request, please find in Appendices A4-1-4 through A4-1-15 specimens of package labeling for the *IQOS* 3 System kit, which contains the Holder and Charger, an AC adapter with USB charging cable for charging the Charger, and a cleaning tool.

Specimens of the user documentation were provided with the original Supplemental PMTA submission. That part of the labeling consisted of a Quick Start Guide (Appendix A4-1-1), Safety Warnings and Instructions (Appendix A4-1-2), and a Warranty Card (Appendix A4-1-3).

The *IQOS* 3 System package labeling depicts and describes the device and package contents and contains additional markings for identification and compliance with requirements for electronic devices.

There are few variations in labeling due to different product colors. Those variations are:

- The image of the device on “hat” is the actual color of the device inside of the kit (see difference 1 in Figure 1)
- The color of the “hat” corresponds to the color of the device (see difference 2 in Figure 1)
- The color bar on the top and bottom side of the box also indicates the color of the device inside of the kit (see difference 3 in Figure 1).
- The color is indicated on labels affixed to the kit box, at the bottom of the box, providing manufacturing information (Figure 2).

The proposed labeling for four colors of the *IQOS* 3 System kit, provided as the appendices, demonstrate differences in labeling due to different colors.

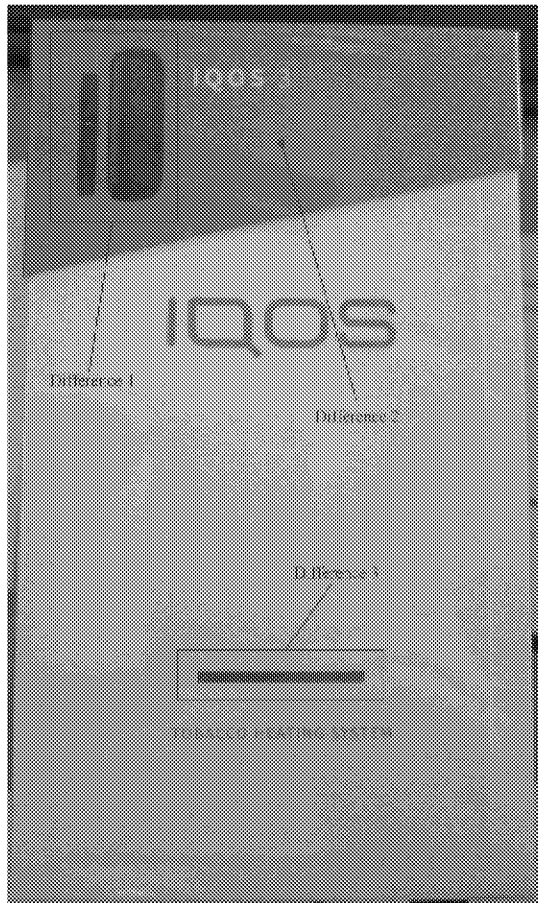
In addition, please note that labeling for the white color, that was previously provided with the original submission without dimensions, has been updated with a note indicating that the dimensions provided in the documents are expressed in millimeters.

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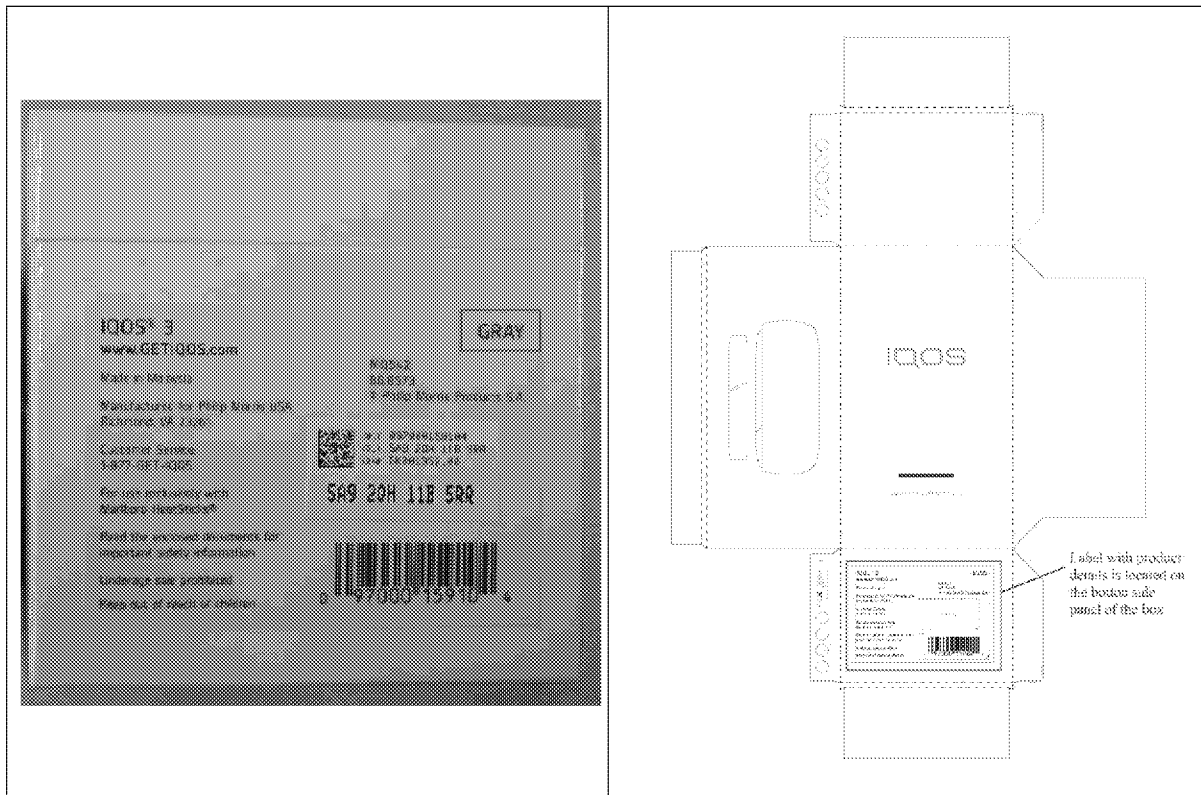


*Note:* The differences are highlighted with red color, which does not appear on the actual labeling

**Figure 1: Examples of the differences in the proposed labeling for *IQOS 3 System* indicating the color of the device**

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## **FDA REQUEST 2**

Your submitted Environmental Impact assessment Addendum lacks the current market volume of *IQOS* 2.4 and the first- and fifth-year market volume projections for the *IQOS* 3 and the *IQOS* 2.4. Provide this market volume information in number of units. Indicate whether you will continue to market *IQOS* 2.4 in the U.S. This information is used to assess the environmental impacts of manufacturing, use, and disposal of the new tobacco products.

## **RESPONSE 2**

The current market volume of *IQOS* 2.4 in the United States is provided in Table 1 below.

Units sold have been reported to FDA in periodic reports pursuant to the Marketing Order for PM0000424-PM0000426 and PM0000429.<sup>1</sup> Table 1 provides volume totals as reflected in those periodic reports, since the product was first launched in Atlanta in September of 2019 through the reporting period for the most recent periodic report. These volumes are based on early marketing in a limited number of markets to date. (b) (4)

(b) (4)

**Table 1: Current Market Volume of *IQOS* 2.4<sup>2</sup>**

| Periodic Reporting Period Ending: | Geography  | 2.4 Device Kits <sup>3</sup> | 2.4 Device Holders |
|-----------------------------------|------------|------------------------------|--------------------|
| 11/24/2019                        | Total U.S. | (b) (4)                      |                    |
| 2/29/2020                         | Total U.S. |                              |                    |
| 5/30/2020                         | Total U.S. |                              |                    |
| Total                             |            |                              |                    |

<sup>1</sup> Marketing Order, April 30, 2019, Appendix B, Section IV, p. 9.

<sup>2</sup> Volumes as reported in Periodic Reports for PM0000424 – PM0000426 and PM0000479, reported on 1/30/20, 4/30/20, and 7/30/20.

<sup>3</sup> Source: (b) (4)

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Estimates of the first- and fifth-year market volumes in the United States for the *IQOS* 3 and the *IQOS* 2.4 device (Holder + Charger) are provided in Table 2 below.

**Table 2: Estimates of the first- and fifth-year market volumes in the U.S. for the *IQOS* 3 and the *IQOS* 2.4 (Holder + Charger)**

| Product                | First Year <sup>4</sup>                    | Fifth Year                                 |
|------------------------|--|--|
|                        | Devices <sup>5</sup><br>(Holder + Charger) | Devices <sup>6</sup><br>(Holder + Charger) |
| <i>IQOS</i> 2.4 System | (b) (4)                                    | (b) (4)                                    |
| <i>IQOS</i> 3 System   |  |  |
| Total                  |  |  |

(b) (4)

<sup>4</sup> Based on smoking population from 2015 CDC Fact Sheet.

Actual experience would depend upon annual decline in smoking population.

Prevalence of *IQOS* derived from Population Health Impact Model in the PMTA/MRTPA for the Authorized Product (Section 6.5.2.4) which was based on PBA-07 and in-market experience from Japan.

<sup>5</sup> Reflects annual purchases of THD (Charger + Holder): [ ] Device split by variant based on same ratio as *HeatSticks* (footnote #3)

<sup>6</sup> Split between *IQOS* 2.4 and *IQOS* 3 [ ]

<sup>7</sup> Philip Morris USA Inc. (PM USA), as an affiliate of Altria Client Services LLC (ALCS), is licensed to distribute and sell the Authorized *IQOS* System in the U.S.

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### FDA REQUEST 3

Your submitted application indicates that (b) (4) will be manufacturing the printed circuit boards and that (b) (4) would perform final assembly, packaging and release to the market for the new tobacco product, IQOS 3. In your IQOS 2.4 application, you indicated that the device is manufactured by (b) (4). Indicate whether these are different facilities or the same facility. FDA needs to determine the significance of any potential environmental effects abroad and within the U.S. (see, 21 CFR 25.60). Past and current compliance with national, regional and local environmental requirements at the manufacturing facility serves as straightforward and efficient indicator of the environmental impact and future potential environmental effects from manufacturing the new product for the U.S. market.

### RESPONSE 3

The manufacture of both, the IQOS 2.4 and IQOS 3 devices for the U.S. market is performed by the (b) (4)

(b) (4)

In the facility located in (b) (4)

(b) (4)

In the facility located in (b) (4)

(b) (4)

(b) (4)

Both facilities (respectively referred to as (b) (4)) were inspected by FDA between October 9 – 13, 2017, the inspection was “closed” and the Establishment Inspection Report (EIR) was issued on May 23, 2019.

(b) (4)

<sup>8</sup> For PMTA and MRTP applications for the IQOS 2.4 System, additional information regarding the manufacturers of certain parts including manufacture of (b) (4) was provided as part of the response to Information Request dated August 4, 2017, for MR0000059-MR0000061 applications. In this response, it was stated that (b) (4) (responses to questions 1 and 7).

<sup>9</sup> For the IQOS 3 System sPMTA, detailed information about both manufacturing sites was provided in Module 3, Section 3.3.1 Manufacturers.

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Facilities (b) (4) comply with applicable (b) (4) environmental requirements, such as:

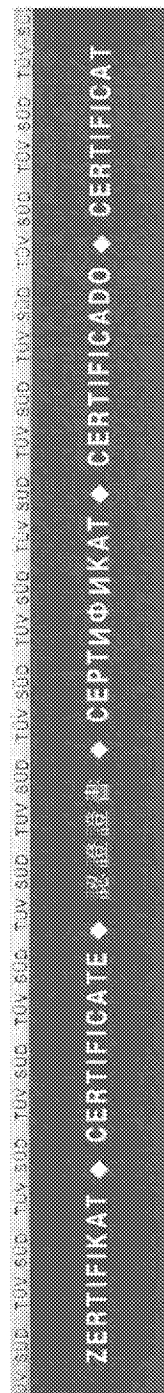
- Department of Environmental (DOE) under the Ministry of Housing and Local Government National Standard: Environmental Quality (Scheduled Wastes) Regulations 2005 and 2007
- Department of Environmental (DOE) under the Ministry of Housing and Local Government National Standard: Environmental Quality (Sewage and Industrial Effluents) Regulations 2009
- Department of Environmental (DOE) under the Ministry of Housing and Local Government National Standard: Environmental Quality (Clean Air) Regulations 2014
- Department of Occupational, Safety and Health (DOSH) under Ministry of Human Resource National Standard: Factories and Machinery (Noise Exposure) Regulations 1989
- Department of Environmental (DOE) under the Ministry of Housing and Local Government National Standard: Environmental Quality Act 1974 Section 23, Restriction of Noise Pollution
- Department of Occupational, Safety and Health (DOSH) under Ministry of Human Resource National Standard: Occupational, Safety and Health (Use and standards of exposures of chemicals hazardous to health) Regulations 2000

Detailed information about the local environmental requirements to which facilities (b) (4) (b) (4) comply with are provided in the appendix. The document also contains information about supporting documentation, which is available at the site for FDA's review.

(b) (4) also complies with the current ISO 14001 standard (see Figure 3).

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# CERTIFICATE

The Certification Body  
of TÜV SÜD Asia Pacific TÜV SÜD Group

certifies that

(b) (4)

has established and applies  
an Environmental Management System for

1. Manufacture of Printed Circuit Board Assemblies (PCBAs).
2. Assemblies of Electronics & Electromechanical Products and Modules.
3. Manufacture of Optoelectronics Components and Modules.

An audit was performed (b) (4)

Proof has been furnished that the requirements according to

ISO 14001:2015

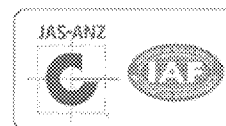
are fulfilled. The certificate is valid in conjunction with the main certificate  
from 2019-11-15 until 2022-11-18.

(b) (4)

2019-11-15

(b) (6)

Certification Body  
of TÜV SÜD Asia Pacific  
TÜV SÜD Group



Notified bodies by the EU Commission pursuant  
to Decision 768/2008/EC, Annex I, 10th  
column, entry 1000000000

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Figure 3: Current ISO 14001 certificate for (b) (4)

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## APPENDICES

- The files listed below are provided as appendices to this response:

| Filename                                   | Title / Description   |
|--|---|
| A4-1-4-box-white.pdf                       | <i>IQOS</i> 3 kit box – white color of the device   |
| A4-1-5-hat-white.pdf                       | <i>IQOS</i> 3 kit hat – white color of the device   |
| A4-1-6-sticker-white.pdf                   | <i>IQOS</i> 3 kit box sticker – white color of the device                                 |
| A4-1-7-box-gray.pdf                        | <i>IQOS</i> 3 kit box – gray color of the device  |
| A4-1-8-hat-gray.pdf                        | <i>IQOS</i> 3 kit hat – gray color of the device  |
| A4-1-9-sticker-gray.pdf                    | <i>IQOS</i> 3 kit box sticker – gray color of the device                                  |
| A4-1-10-box-blue.pdf                       | <i>IQOS</i> 3 kit box – blue color of the device  |
| A4-1-11-hat-blue.pdf                       | <i>IQOS</i> 3 kit hat – blue color of the device  |
| A4-1-12-sticker-blue.pdf                   | <i>IQOS</i> 3 kit box sticker – blue color of the device                                  |
| A4-1-13-box-gold.pdf                       | <i>IQOS</i> 3 kit box – gold color of the device  |
| A4-1-14-hat-gold.pdf                       | <i>IQOS</i> 3 kit hat – gold color of the device  |
| A4-1-15-sticker-gold.pdf                   | <i>IQOS</i> 3 kit box sticker – gold color of the device                                  |
| (b) (4) environmental-legal-compliance.pdf | List of complying environmental legal requirements for (b) (4) owned companies in (b) (4) |

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