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4. LABELS, LABELING AND ADVERTISING

The Tobacco Control Act specifies that an MRTP application shall include a description of any proposed advertising and labeling, TCA § 911(d)(1) (21 U.S.C. § 387k(d)(1)). The Act also requires submission of sample product labels and labeling, TCA § 911(d)(4) (21 U.S.C. § 387k(d)(4))[1] This section addresses both of these requirements.

These materials and the related promotional communications are designed to responsibly enhance brand awareness and drive conversion among adult smokers.

THS is composed of a Tobacco Heating Device (THD) and Tobacco Sticks. For commercialization, the THD (THD version 2.4) will bear the brand name "*iQOS*". The Tobacco Sticks will be referred to as "*HeatSticks*" and will be sold under the *Marlboro* brand name.

4.1. Description of the Proposed Advertising and Labeling

FDA recommends in its "Draft Guidance for Industry, Modified Risk Tobacco Product Applications" ("MRTPA Draft Guidance") that the description of proposed advertising and labeling include "copies of any draft promotional materials (e.g. advertising and labeling) developed by the time of filing that the applicant expects will be used in marketing the MRTP" and "[a] description of how you intend to communicate the proposed modified risk claim(s) to consumers." (FDA MRTPA Draft Guidance, 2012, pp. 11-12).

4.1.1. Copies of Draft Promotional Materials

PMP S.A. is submitting with this application two types of draft promotional materials that have been developed. The submitted promotional materials were evaluated as part of three PBA studies: THS-PBA-05-RRC-US, THS-PBA-05-RRC2-US and THS-PBA-05-REC-US. The main results from these studies are summarized in Section 6.4 of this application and full study summaries are available in Module 7 of this application (A7.3.2.PBA05RRCSum_FINAL, A7.3.2.PBA05RRC2Sum_FINAL and A7.3.2PBA05RECSum_FINAL).

[1] The Federal Food, Drug, and Cosmetic Act defines "label" as "a display of written, printed or graphic matter upon the immediate container of any article" and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. §§ 321(k), 321(m). PMP S.A. is applying these definitions for purposes of this application.

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iQOS Brochure – The brochure is a multipage informational pamphlet that will be geared toward adult smokers through channels including, but not limited to, retail as well as events in adult-only facilities. An electronic version of the brochure will also be available through digital channels including, but not limited to, age-restricted digital platforms. The brochure's purpose is to educate adult smokers on THS, including what it is and how it works, to provide risk information, and to communicate to adult smokers how THS is differentiated from conventional cigarettes and e-cigarettes. An extract of the *iQOS* Brochure is presented in Section 4.1.1.1. The complete *iQOS* Brochure samples are available as appendices to this chapter (A4.1.1 Brochure RRC, A4.1.2 Brochure RRC, A4.1.3 Brochure RHC, A4.1.4 Brochure RHC, A4.1.5 Brochure REC and A4.1.6 Brochure REC).

iQOS Direct Mail –THS may be promoted to adult smokers by use of direct mail. The purpose of the direct mail is to generate awareness and facilitate the opportunity to try THS among adult smokers. To support this objective, direct mail communications may also contain (b) (4) An extract of some pages of an *iQOS* Direct Mail is presented in Section 4.1.1.2. The complete *iQOS* Direct Mail samples are available as appendices to this chapter (A4.1.7 DirectMail RRC, A4.1.8 DirectMail RRC, A4.1.9 DirectMail RHC, A4.1.10 DirectMail RHC, A4.1.11 DirectMail REC and A4.1.12 DirectMail REC).

Additional derivative promotional materials will be developed closer to the time of commercial distribution of THS. These derivative materials will differ from the submitted materials by channel, format, and layout but they will have several common elements. The following are the key communication elements of the draft brochure and direct mail materials, some or all of which may be included in future derivative promotional materials:

Modified Risk Claim – The draft promotional materials include the modified risk claim under the heading "AVAILABLE EVIDENCE TO DATE".

Heat-Not-Burn – This concept communicates to adult smokers that THS contains actual tobacco but that the tobacco is not combusted during the usage experience. Emphasizing the presence of tobacco differentiates THS from some alternative products, such as e-cigarettes, that use nicotine-containing liquid. Stating that THS heats tobacco rather than burning also supports differentiating statements about absence of ash and less lingering smoke odor and supports reduced exposure claims that are linked to the modified risk claim. The following are some examples of this communication element in the submitted draft promotional materials:

- "Real Tobacco. No Fire." (*iQOS* Direct Mail)
- "The *iQOS* Tobacco Heating System heats real tobacco — instead of burning it. So you get smooth, real tobacco flavor with no fire, no ash, less odor, and less mess." (*iQOS* Direct Mail)
- "*iQOS* is an innovative new option for adult smokers to enjoy real tobacco. It's an electronic tobacco heating system, designed for *Marlboro* HeatSticks. *iQOS* gives you a real tobacco experience." (*iQOS* Brochure)
- "It's electronic – but not an electronic cigarette." (*iQOS* Brochure)
- "Real tobacco – without the fire or ash." (*iQOS* Brochure)

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- "Unlike conventional cigarettes, with *iQOS*, tobacco isn't burned, so you get real tobacco enjoyment with less worry about disturbing those around you." (*iQOS* Brochure)

Warnings – The draft promotional materials contain warnings, either in conjunction with the modified risk claim or standing separately. PMP S.A.'s preferred option uses a statement titled "IMPORTANT WARNING" that communicates limitations of the modified risk claim and reminds adult consumers about the risks of the product. An alternative option is to use the statutorily-mandated warnings for cigarettes. Where the "Important Warning" developed by PMP S.A. is used in the draft promotional materials, the language has been formatted to fit the area that is normally reserved for the statutorily-mandated warnings for cigarettes. Where the statutorily-mandated warnings are used, it is formatted according to the requirements set forth in the Federal Cigarette Labeling and Advertising Act ("FCLAA"). 15 U.S.C. § 1333.

(b) (4) – Where applicable, the draft promotional materials may include an (b) (4) (b) (4) For example, the direct mail submitted with this application includes a (b) (4) (see for example A4.1.7 DirectMail RRC). The purpose of (b) (4) is to (b) (4) (b) (4) .

Audience Description – The draft brochure contains a specific statement about who THS is intended for and who it is not for. The purpose of the statement is to make clear who should use THS and inform non-intended audiences that THS is not for them and therefore they should not use it.

Imagery – The draft promotional materials contain photography that shows the product in situation, in a variety of set-ups, and that constitutes the type of imagery to be used for the brand campaign.

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4.1.1.1. An extract of an iQOS Brochure - Reduced Risk of Harm (Important Warning)

An extract of an *iQOS* Brochure is presented in this Section. A sample of complete *iQOS* Brochure is available as an appendix to this chapter (A4.1.3 Brochure RHC)



Figure 1 Extract of *iQOS* Brochure

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4.1.1.2. An extract of an iQOS Direct Mail - Reduced Risk of Harm (Important Warning)

An extract of an *iQOS* Direct Mail is presented in this Section. A sample of complete *iQOS* Direct Mail is available as an appendix to this chapter (A4.1.9 DirectMail RHC)



Figure 2 Extract of the *iQOS* Direct Mail

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4.1.2. Communication of the Proposed Modified Risk Claim

The intention is to communicate the proposed modified risk claim(s) to adult smokers through product labels, labeling, and advertising. The labels on packages of Tobacco Sticks, copies of which are provided, will contain the modified risk claim. At this time, there is no intention to include the modified risk claim on the label or labeling of the THD.

The modified risk claim will be included in advertisements, although not necessarily in all advertisements. For example, inclusion of the modified risk claim is likely to appear in direct mail, but at this time may not be feasible in certain promotional materials with limited space for text. Communication of the modified risk claim in advertising is demonstrated by the draft promotional materials submitted with this application.

THS is a unique product concept in the U.S.. To facilitate trial and adoption of THS by adult smokers, a variety of promotional channels will likely be used to provide adult smokers with information to help them make an informed trial or purchase decision. These channels include, but are not limited to, the following:

- Print and digital advertisements
- Age-restricted digital channels
- Direct mail
- Social media platforms with age restricted access
- Brochures and point-of-sale materials at retail locations
- Inserts and onserts on packages of conventional cigarettes

4.2. Sample Product Labels and Labeling

PMP S.A. is submitting package labels for the Tobacco Sticks, which will be sold as *HeatSticks* under the *Marlboro* brand name. The submitted labels include Tobacco Stick packages and cartons. One version of printed film cellophane overwrap for the Tobacco Sticks packages is also provided. This type of cellophane overwrap can be used over existing package labels to convey equity and promotional messaging. When the overwrap includes printed messaging, it is designed so that it allows mandatory copy from the underlying package label (e.g. health warnings) to show or so that mandatory copy identical to that on the underlying package label is duplicated on the cellophane overwrap. The cellophane overwrap may be removed by the consumer when opened by means of a tear strip (A4.2.8 iQOS PrintedFilm R, A4.2.16 iQOS PrintedFilm MS, A4.2.24 iQOS PrintedFilm MF). THe package label for the THD is also provided, which will be sold under the brand *iQOS* (A4.2.25 iQOS DevicePackage, A4.2.26 iQOS DevicePackage).

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Marlboro HeatSticks will be sold in Regular (one variant) and Menthol (two variants, respectively identified as "Smooth Menthol" and "Fresh Menthol") variants[2]. The submitted package and carton labels are identical except for the aspects that differentiate them as Regular and Menthol by name and by color. All packaging variations contain the modified risk claim. The *HeatSticks* package labels comply with package marking requirements for cigarettes. Depending upon FDA's determination regarding health warnings, however, the package labels may bear a warning that is tailored to the modified risk claim and titled "IMPORTANT WARNING" instead of bearing the warning for cigarettes mandated by the FCLAA. *Marlboro HeatSticks* Regular package and carton are available as appendices to this chapter. (A4.2.1 HeatSticksPack R RRC, A4.2.2 HeatSticksPack R RRC, A4.2.3 HeatSticksPack R RHC, A4.2.4 HeatSticksPack R RHC, A4.2.5 HeatSticksPack R REC, A4.2.6 HeatSticksPack R REC, A4.2.7 HeatSticksCarton R). *Marlboro HeatSticks* Menthol (both "Smooth" and "Fresh" variants) package and carton are available as appendices to this chapter (A4.2.9 HeatSticksPack MS RRC, A4.2.10 HeatSticksPack MS RRC, A4.2.11 HeatSticksPack MS RHC, A4.2.12 HeatSticksPack MS RHC, A4.2.13 HeatSticksPack MS REC A4.2.14 HeatSticksPack MS REC, A4.2.15 HeatSticksCarton MS, A4.2.17 HeatSticksPack MF RRC, A4.2.18 HeatSticksPack MF RRC, A4.2.19 HeatSticksPack MF RHC, A4.2.20 HeatSticksPack MF RHC, A4.2.21 HeatSticksPack MF REC A4.2.22 HeatSticksPack MF REC, A4.2.23 HeatSticksCarton MF).

The *iQOS* device package (A4.2.25 iQOS DevicePackage, A4.2.26 iQOS DevicePackage) will contain the THD, consisting of the *iQOS* Pocket Charger and *iQOS* Holder, a USB cable for charging the *iQOS* Pocket Charger, and an *iQOS* Cleaner. In addition, the *iQOS* device package will include a *User Guide* (A3.4.1 Userguide) and a *Quick Start Guide* (A3.4.2 Quickstartguide), both of which are submitted with this application as labeling. The package label for the *iQOS* device depicts and describes the device and package contents, and contains additional markings for identification and compliance with requirements for electronic devices. The User Guide contains detailed instructions about the device and its operation. The Quick Start Guide provides brief, primarily visual, instructions for using the *iQOS* device. Both types of user guide are discussed in more details within Section 3.4. Description of the Conditions for Using the Tobacco Product. The THD package label and accompanying labeling do not include the modified risk claim.

[2] In the PBA studies in which the *HeatSticks* packs were part of the tested materials (i.e., THS-PBA-05-RRC-US, THS-PBA-05-RRC2-US and THS-PBA-05-REC-US), the assessed Menthol *Heatsticks* pack was slightly different from the two Menthol *Heatsticks* packs included with this submission. Those differences were (1) the absence of the differentiators "Smooth" or "Fresh" on the tested *Heatsticks* pack; and (2) a different tone of green, the same used on the "Fresh Menthol" *Heatsticks* pack. The Menthol *Heatsticks* pack tested included the same "modified risk" claim and alternatively the "Important Warning" or the Surgeon General's warning as the *Heatsticks* pack samples included with this submission.

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4.3. List of References

Food and Drug Administration. Modified Risk Tobacco Product Applications: Draft Guidance for Industry [Internet] 2012 [cited 2015 Oct 01]. Available from: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf.

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