

Module 6 : Research

6.2 Effect on Tobacco Use Behavior Among Current Tobacco Users

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1. INFORMATION ON TOBACCO USE BEHAVIOR AMONG TOBACCO USERS

1.1. Introduction

To measure the potential benefit of marketing a MRTP to the public, the FDA Modified Risk Tobacco Product Applications Guidance recommended investigating several areas, including (1) the effect on tobacco use behavior among current tobacco users, (2) the effect on tobacco use initiation among non-users, and (3) the effect of marketing on consumer understanding and perceptions¹. In this section, we provide data from both pre-market studies included in the original MRTPA², and postmarket studies conducted both within the United States and internationally, on the effect of *IQOS* on use behaviors among current tobacco users. In addition, we cross-reference Module 7 of the original MRTPA for the Authorized *IQOS* products with related appendices and data, and with subsequent amendments, and Module 7 of the supplemental PMTA for the Authorized *IQOS* 3 System (PM0000634), as well as Module 7 of the supplemental MRPTA for *IQOS* 3 System (MR0000192).

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¹ FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012.
<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

² MRTPA Modified Risk Granted Order - Exposure Modification of December 12, 2019, authorizing the marketing of the modified risk product *IQOS* 2.4 System Holder and Charger (STN: MR0000133).

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1.3. U.S. Sales Data and Postmarket Studies

1.3.1. Background

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1.3.2. Summary of U.S. Sales Data

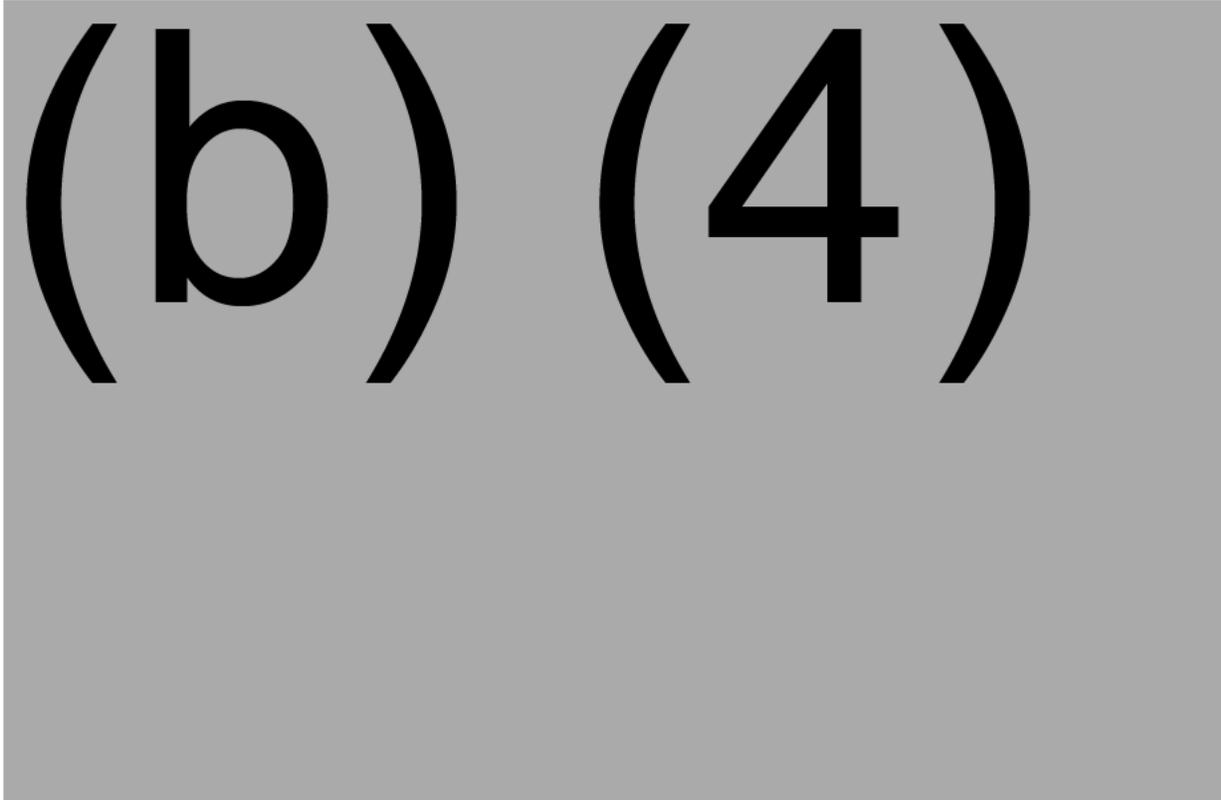
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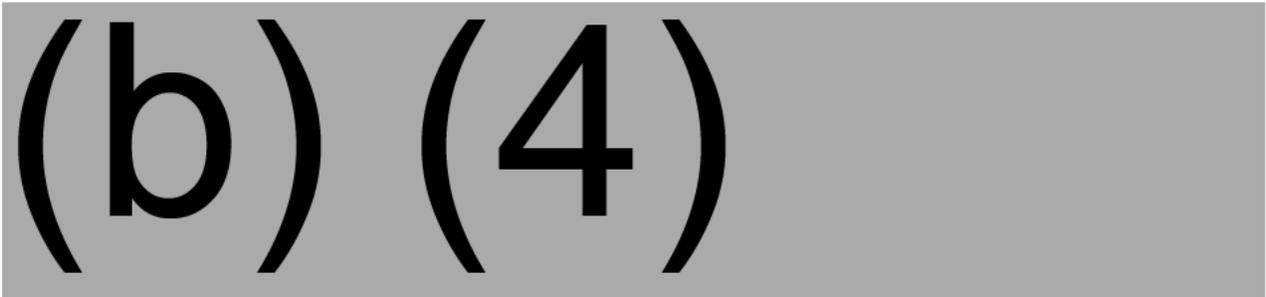
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1.3.3. U.S. Postmarket Studies



²³ 2022 Annual Report and PMSS report submitted on April 29, 2022 (Annex P01-5)

²⁴ IQOS 2.4 MR0000133 dated July 7, 2020 and IQOS 3.0 MR0000192 dated November 3, 2022.

²⁵ FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012.

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

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1.4. International Sales Data and Postmarket Studies

1.4.1. Background

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1.4.2. Summary of International Sales Data

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1.6. Conclusion

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Taken together, this evidence points towards continued commercialization of *IQOS* with the reduced exposure claim to be expected to benefit the health of the population as a whole, which is consistent with section 911(g)(2)(B) of the FD&C Act.

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2. REFERENCE STUDIES

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Chrea, C., Acquadro, C., Afolalu, E. F., Spies, E., Salzberger, T., Abetz-Webb, L., ... & Weitkunat, R. (2018). Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: The ABOUT™ Toolbox initiative. *F1000Research*, 7.

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