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U.S. Food and Drug Administration
Docket Management Staff (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket #: FDA-2021-N-0408-0001 - Modified Risk Tobacco Product Application: Application for the IQOS 3 System Holder and Charger Submitted by Philip Morris Products S.A.

Introduction

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. CAGW was founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson to implement the recommendations of President Ronald Reagan's Private Sector Survey on Cost Control, also known as the Grace Commission.

Comment

The Family Smoking Prevention and Tobacco Control and Federal Retirement Act (TCA) was enacted on June 22, 2009. Its purpose is to protect the public health by providing the Food and Drug Administration (FDA) with certain authority to regulate tobacco products. FDA's regulatory authority includes "how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health:

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use."

The Philip Morris IQOS line includes such products. The system uses a heat-not-burn technology that is composed of a charger and an inhaling device that heats a processed tobacco plug called a Heatstick. Unlike a cigarette that burns tobacco at temperatures of 1,100°F (590°C) or greater, which creates toxic and harmful chemicals such as tar, benzene, and carbon monoxide that cause cancer or other tobacco-use related diseases, the IQOS warms the Heatstick to approximately 570°F (300°C). The device imitates smoking a cigarette, but users inhale an aerosol instead of smoke, thus reducing harmful chemicals by as much as 90 to 95 percent.

Philip Morris admits their product is not a smoking-cessation device but is instead a harm-reduction device that delivers the nicotine smokers crave. The goal is to get smokers, that cannot, or do not want to, quit smoking and move to a less harmful product.

On April 30, 2019, the FDA permitted the sale of IQOS 2.4 system, the first electronic device to do so via the premarket tobacco production application (PMTA) pathway. At that time, the FDA said, "Following a rigorous science-based review through the premarket tobacco product application (PMTA) pathway, the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes. The products authorized for sale include the IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks. While today's action permits the tobacco products to be sold in the U.S., it does not mean these products are safe or 'FDA approved.' All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to."

The agency's proposed rule, "Premarket Tobacco Product Applications [PMTA] and Recordkeeping Requirement" was published in September 2019 and stated that the FDA review period would be 180 days. However, the PMTA for the first IQOS, which was submitted in March 2017, was not completed until April 2019, more than 1.5 years beyond the designated period to complete the review and permit the sale of the product.

On July 7, 2020, the FDA authorized the marketing of the IQOS as a modified risk tobacco product (MRTP). While it was the second product to be authorized as such, with Swedish Match USA snus being the initial one, it was the first tobacco product to receive exposure modification orders. This allows "the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population." The Center for Tobacco Products Director Mitch Zeller said at the time that, "Data submitted by the company shows that marketing these particular products with the authorized information could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch."

Although the agency's 2012 "Modified Risk Tobacco Product [MRTP] Applications - Draft Guidance" document stated it was the FDA's intent to act upon a MRTP application within 360 days after its receipt, the first IQOS application was submitted in December 2016 but did not receive the marketing order until July 2020, more than 3.5 years later.

PMI submitted the IQOS 3 PMTA in March 2020 and received authorization to sell it on December 8, 2020. While still greater than the guidance document's stated 180 days review period, CAGW is pleased the time frame has been greatly reduced. It can be surmised that the prior long delays were due to agency officials' inexperience in dealing with new procedures and new products concerning tobacco harm reduction.

The IQOS 3 supplemental MRTP application was submitted on March 18, 2021 and is now under FDA's review. According to PMI's application, the IQOS 3 is a modified version of the "IQOS 2.4 System Holder and Charger," which was granted its PMTA marketing order in April 2019 and MRTP marketing order in July 2020. The system is intended to be used with any variant of authorized HeatSticks.

Learning from current adult consumers across the globe on the use of the IQOS 2.4 system and because of advances in electronic technology, PMI developed the new IQOS 3 to respond to customer's suggestions and concerns and submitted the new design to the FDA. This action makes the U.S. product more in line with IQOS devices already being sold in other countries.

The minor changes include:

- Improved battery life with faster charging;
- Mechanical cleaning between use;
- Simplified holder insertion into the charger;
- An option to reduce perceived heat;
- Upgraded USB connector to the USB-C standard; and
- Minor user interface modifications like a touch feedback feature, LED light.

While the TCA requires new versions of devices such as the IQOS to be authorized by the FDA, the IQOS 3 still operates in the same way as its predecessor by heating the tobacco instead of burning it and substantially reduces the harmful chemicals that are found in combustible cigarettes. On December 7, 2020, the FDA issued a marketing order for the IQOS 3, stating "Based on our review of your PMTA, we determined that the new tobacco product, as described in your application and specified in Appendix A, is appropriate for the protection of the public health. The issuance of this marketing granted order confirms that you have met the requirements of section 910(c) of the FD&C Act and authorizes marketing of your new tobacco product."

In addition, the Technical Project Lead stated the "scientific review of the PMTA found that the comparison between IQOS 2.4 and the proposed IQOS 3 device is appropriate. The applicant has provided adequate information on the manufacturing process and product quality controls that will help ensure that the IQOS 3 device is manufactured consistently and will meet the applicant's specifications. The aerosol from the IQOS 3 device has been evaluated and found to be comparable to that from use of the IQOS 2.4 device. No new exposures or risks for the new device were identified." Importantly, the review also found there "were no new safety concerns or unexpected adverse experiences identified. The user information from international survey data found no evidence of increased uptake of IQOS by youth or young adults, and IQOS 3 seemed to be more accepted by consumers with a slightly decreased likelihood of dual use with cigarettes as compared to IQOS 2.4."

This is good news for smokers that want to move away from dangerous and deadly combustible cigarettes and use a less harmful product that is "appropriate for the protection of the public health."

Considering these facts and to prevent any confusion by consumers that the IQOS 3 is somehow an inferior product compared to the IQOS 2.4 because it can be marketed at a modified risk tobacco product while the IQOS 3 cannot, CAGW urges the FDA to review and quickly process the MRTP application that is now before the agency. Since both the IQOS 2.4 and IQOS 3 provide the same beneficial results of substantially lowering and delivering fewer levels of toxins that are found in combustible cigarettes, there is no reason for this process to be delayed. Smokers need clarity regarding the entire IQOS line of products so they can make informed decisions on moving away from cigarettes.

Certainly, health officials would prefer that individuals do not become addicted to any products, including those that contain nicotine, and continued education by parents and health officials on the negative consequences of doing so should continue. Because a certain segment of the population will always engage in risky behavior by smoking cigarettes, the FDA, as stated in the TCA, most not only regulate these innovative tobacco products, but also promote their use.

Fortunately, there are many innovative tobacco products that have been developed or are being developed that enable smokers to move away from combustible cigarettes, which have been documented since the 1960s to be deadly, to products that are far less harmful.

To help more Americans wean themselves off cigarettes and move to a far less risky tobacco product that has been proven to reduce or eliminate the toxins contained in combustible tobacco products, we urge the FDA to quickly issue a MRTP marketing order for the IQOS 3. Doing so will enable more smokers to have more products to choose from that will help them to stop smoking, while also knowing the product has been reviewed by the FDA and stated claims about harm reduction are valid.

Sincerely,