Information request on electronic smoking devices' regulation _ Resposta EUA

Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>

Seg, 11/01/2021 12:39

Para: Isabella Radd Pires da Silva <isabella.radd@anvisa.gov.br>
Cc: Gloria Maria de Oliveira Latuf <Gloria.Latuf@anvisa.gov.br>

Isabela, bom dia.

Recebemos a resposta do FDA.

Att.,
Stefania

De: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Enviado: sexta-feira, 8 de janeiro de 2021 14:24
Para: Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>
Assunto: ENC: Information request on electronic smoking devices' regulation.

Prezada Stefania.

Espero que tenha tido boas festas e desejo um feliz ano novo.

Encaminho resposta recebida da FDA sobre a regulamentação de dispositivos eletrônicos para fumar.

Cordialmente,
Felipe Dias

De: CTP-StakeholderRelations <CTP-StakeholderRelations@fda.hhs.gov>
Enviado: sexta-feira, 8 de janeiro de 2021 14:14
Para: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Cc: CTP-OCD-Intl <CTP-OCD-Intl@fda.hhs.gov>; AskCTP <AskCTP@fda.hhs.gov>
Assunto: RE: Information request on electronic smoking devices' regulation.

Dear Members of the International Affairs Office:

Thank you for your e-mail dated December 2, 2020, to the U.S. Food and Drug Administration's (FDA or the Agency) Center for Tobacco Products (CTP) concerning U.S. regulation of noncombustible tobacco products. We appreciate your interest in FDA's regulatory efforts.

In response to your specific questions:

1. **Are ENDS, ENNDS and HTP authorized in your country? If so, through which health legislation/standard are they authorized?**

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), enacted in 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C) to grant authority to the FDA to regulate tobacco products. This new authority gave FDA comprehensive tools, including a thorough science-based regulation of the manufacturing, marketing, and distribution of tobacco products, to protect the public from the harmful effects of tobacco use.

As defined in the TCA, "new tobacco products" – any product not commercially marketed in the United States as of February 15, 2007, or the modification of a tobacco product where the modified product was

commercially marketed in the United States after February 15, 2007 – may not be legally marketed in the United States without a tobacco product marketing order from the FDA. This requirement applies to all FDA-regulated tobacco products, including electronic nicotine delivery systems (ENDS) and heated tobacco products (HTPs).

One pathway to market is via submission and FDA authorization of a premarket tobacco product application (PMTA).

To receive a marketing order under the PMTA pathway, an applicant must provide scientific data that demonstrates a product is appropriate for the protection of the public health. In order to reach such a decision and to authorize marketing, FDA considers, among other things:

- Risks and benefits to the *U.S. population* as a whole, including people who would use the proposed new tobacco product as well as nonusers;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;
- Whether people who currently do not use any tobacco products (including former users) would be more or less likely to begin using tobacco products if the new product were available; and
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.

FDA's evaluation also includes reviewing a tobacco product's components, ingredients, additives and health risks.

If a product receives an order authorizing marketing, there are postmarket reporting requirements. Applicants must establish and maintain records and make reports that FDA requires as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing granted order.

FDA announced on April 30, 2019, the Agency had authorized the marketing of one heated tobacco system, Philip Morris Products S.A.'s IQOS "Tobacco Heating System," through the PMTA pathway.[1] On December 7, 2020, FDA issued a marketing order to Philip Morris Products S.A. authorizing the sale of the IQOS 3 System Holder and Charger. This is the first "supplemental" PMTA received by FDA. Such applications seek authorization to modify a tobacco product that previously received a marketing order via the PMTA pathway. To date, no electronic nicotine delivery system (ENDS) product has received a marketing order from FDA. FDA's premarket tobacco product marketing orders can be found at https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.

2. **Can these products be marketed with the claim that they pose reduced risks to users' health? If so, which risks are reduced, and which scientific evidence supported this decision?**

As defined in the TCA, a modified risk tobacco product (MRTP) is "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed products." In order to receive authorization to market a tobacco product as modified risk in the United States, an MRTP application must be submitted to the FDA. The MRTP application process is separate from the above described PMTA pathway. An order authorizing the marketing of an MRTP refers to a specific product, not an entire class of tobacco products.

An MRTP application must, among other things, demonstrate that the product will or is expected to benefit the health of the *U.S. population* as a whole. In order to reach a decision to authorize marketing of a proposed MRTP, FDA must consider, pursuant to the TCA:

- the relative health risks to individuals of the tobacco product that is the subject of the application;
- the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;
- the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved as medical products

to treat nicotine dependence; and

- comments, data, and information submitted by interested persons.[2]

If a product receives a modified risk order, there are postmarket reporting requirements. Applicants are required to conduct surveillance and postmarket studies to determine the impact of the modified risk order on consumer perception, behavior, and health, to allow FDA to review the accuracy of the determinations upon which the modified risk order was based.[3]

An FDA order permitting marketing of an MRTP is valid only for the fixed time period specified in the order and is not permanent. To continue marketing an MRTP after the set term, the company may submit a new MRTP application for FDA to determine that the product still satisfies the requirements set forth in the Tobacco Control Act.[4]

FDA authorized the marketing of the IQOS "Tobacco Heating System" as modified risk tobacco products on July 7, 2020. These products received "exposure modification" orders, which permit 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 U.S. population. The MRTP application also requested "risk modification" orders, which would have allowed for marketing of the product using claims regarding its health risks; however, the FDA determined that the evidence did not support issuing risk modification orders at this time. The findings FDA made with respect to the MRTP application for the IQOS Tobacco Heating System do not apply to all heated tobacco products.[5] FDA's modified risk orders can be found at https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders.

3. **If the products can be marketed with the claim that they reduce risks, how is this information disclosed by the health authority? Are risk-reduced products subject to the same regulation as conventional smoking products (fees, advertising and indoor use prohibition)?**

FDA distributes an announcement when a modified risk order is issued. This information is also available on the FDA website.

In general, FDA regulates tobacco products by product type, such as cigarettes, smokeless tobacco, and ENDS. Due to your interest in ENDS and heated tobacco products, the table below outlines several FDA statutory and regulatory requirements and their applicability to ENDS and heated tobacco products. This information is provided as a general overview and does not represent an exhaustive list.

	Electronic Nicotine Delivery Systems	**Heated Tobacco Products**
Requirement		
Tobacco registration and product listing	Applies to every person who owns or operates any domestic establishment engaged in manufacturing tobacco products	
Submit data and pay tobacco user fees	Does not apply	Applies[6]
Submit ingredient listing	Applies to every domestic manufacturer and importer	
Apply to market a new tobacco product	Every manufacturer and importer with a product not commercially marketed in the U.S. as of February 15, 2007 must submit an application and obtain FDA authorization before marketing a "new tobacco product"[7]	
Submit quantities of harmful and potentially harmful constituents (HPHCs) in tobacco and tobacco smoke	FDA has proposed changes to the list of HPHCs to reflect the addition of deemed products, e.g. ENDS[8]	Applies[9]
Include required warning statements on packages and	Applies	Applies

advertisements		
Submit a modified risk tobacco product (MRTP) application	Applies to all domestic tobacco product manufacturers, importers, and distributors who would like to sell or distribute a "modified risk tobacco product"	

Please note, certain laws, e.g. excise taxes and indoor air restrictions, may be issued by state and local governments.

4. **If the products can be marketed with the reduced risks to users' health claim, does this information appear on the product label? If so, are there regulations to define how this information should be displayed on the label?**

A MRTP application requires sample product labels and labeling. Copies of each package label variation (including inserts and onserts) that is proposed to be used for the modified risk tobacco product should be provided in an application.

5. **Are there any records of non-compliance with the health legislation/standard by the Tobacco Industry? If so, in which aspects?**

Below is a list of Warning Letters FDA has issued to various firms for marketing unauthorized modified risk tobacco products:

- ***JUUL Labs Inc. (JUUL)*** – In September 2019, FDA issued a Warning Letter to *JUUL Labs Inc.* for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers. The Warning Letter stated that FDA has determined that JUUL marketed its products as modified risk tobacco products (MRTP) without an appropriate FDA order in effect. FDA also sent an additional letter to the company expressing concern and requesting documents and information about several issues regarding JUUL's outreach and marketing practices.

  The warning letter identified several statements, including statements discussed in testimony from a July 2019 Congressional hearing on JUUL. FDA is concerned these statements and representations may convey that switching to JUUL is a safer alternative to cigarettes, in that using JUUL products poses less risk or is less harmful than cigarettes. According to that testimony, a JUUL representative speaking with students at his presentation in a school stated that:
  - JUUL "was much safer than cigarettes" and that "FDA would approve it any day."
  - JUUL was "totally safe."
  - A student "…should mention JUUL to his [nicotine-addicted] friend…because that's a safer alternative than smoking cigarettes, and it would be better for the kid to use."
  - "FDA was about to come out and say it [JUUL] was 99% safer than cigarettes…and that…would happen very soon…."

- **Eonsmoke, LLC** – In October 2019, FDA issued a Warning Letter to *EonSmoke, LLC*, for engaging in labeling, advertising, and/or other activities directed to consumers that explicitly and/or implicitly presented ENDS products sold or distributed by the company as having a lower risk of tobacco-related disease or as less harmful than other commercially marketed tobacco products.
  - For example, the company's website (https://www.eonsmoke.com) included the claim: "Eonsmoke electronic cigarettes provide you with a premium vaping experience without the thousands of harmful chemicals and additives often found in tobacco cigarettes." These types of claims require review by the agency through the modified risk tobacco product pathway, which requires the company to submit evidence to support its claims.

- **StemStix, Inc. –** In June 2020, FDA issued a Warning Letter to StemStix, Inc. for, among other violations, marketing unauthorized modified risk tobacco products. FDA's review of the firm website https://www.mystemjuice.com and Instagram https://www.instagram.com/stemjuice, revealed the sale and distribution of e-liquid product described as presenting a lower risk of tobacco-related disease or being less harmful than one or more other commercially marketed tobacco products, containing a reduced level of a substance or presenting a reduced exposure to a substance, or not containing or being free of a substance. Examples of these claims include:
  - "STEMJUICE is the least toxic vape on the market"
  - "Lose the toxic chemicals, not the flavor"
  - "#STEMJUICE is Made in the USA us [sic] We removed toxic chemicals to give you a cleaner vape experience…Revitalize your lungs with STEMJUICE."
  - "We replaced the bad stuff with the good"

- "Breathe easy, with STEMJUICE" followed by "MADE WITHOUT…Aldehyde, Formaldehyde, Diacetyl, Propylene Glycol, Hydrogen Cyanide, Vitamin E Acetate"
- "We use plant stem cell extracts from fresh green apples grown in Switzerland, providing a natural source for our e-juices. These are not only safe to include in e-juices, but can even improve your lung vitality."
- "Our e-liquid has undergone tests with the Food and Drug Administration, ensuring its quality and safety. We gave [sic] begun the PMTA process, so you can be assured that our product is safe for consumption and use."

- **Cool Clouds Distribution, Inc. d/b/a Puff Bar & HQD Tech USA LLC** – In July 2020, FDA's Warning Letters to *Cool Clouds Distribution (d/b/a Puff Bar)* and *HQD Tech USA LLC* included charges for marketing unauthorized modified risk tobacco products. The website https://puffbar.com includes a number of MRTP claims, including:
  - "Made from medical-grade soaked cotton with 5% salt nicotine and flavoring, the Puff Bar heats liquid to product vapor without burning carcinogens."
  - "Smoking isn't cheap, so we want a product that motivates you not just for health reasons."
  - "Value is important because smoking cigarettes is not cheap habit. Making the switch shouldn't only be a health-conscious decision but a budget-friendly one as well."
  - "Quit smoking today with Puff Bar. Over 24 options to choose from. Traditional cigarettes contain a laundry list of chemicals that are proven harmful. There is still more research to be done on the negative effects of vaping, but we believe it is the healthier alternative and adults should have that choice. Plus you won't smell like an ash tray."

  The website, https://hqdtechusa.com included the following claims regarding ENDS products:
  - "Vaping is used as (sic) safer and healthier alternative to smoking."
  - "The Rosy has two separate departments for the battery and juice, which certain physicians believe decreases turbulence and consumption of harmful metals, including aluminum, lithium, cranium [sic], and others."

- **Pretty Women UK LTD T/A Coil2oil and Mad Kingdom Liquids** – In September 2020, FDA reviewed the website and Instagram account associated with the firm Pretty Women UK LTD T/A Coil2oil and Mad Kingdom Liquids, and uncovered a number of MRTP violations involving claims such as:
  - "The vape device works by heating a liquid which is made of nicotine, propylene glycol, or vegetable glycerine and different flavourings. . . . This vapour is safer than the smoke because smoke is made by burning tobacco but vapor is made by heating E-liquid.
  - "Vaping devices have been designed by keeping in mind the normal tobacco smokers, so that it would be easy for you to trick the brain. It is used in a similar way as the normal cigarettes but is free of the majority toxic chemicals found in normal cigarettes. Vaping is safer than normal tobacco smoking. It is a great alternative to tobacco. If you want to get rid of the bad habit of smoking tobacco, then you should choose a vaping device without any doubt and Coil2Oil is helping millions to achieve this goal."

Warning letters issued by the FDA Center for Tobacco Products can be found at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters. The Compliance Check Inspections of Tobacco Product Retailers database can be found here https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

Thank you, again, for contacting the FDA with your questions. The regulatory framework FDA has established for tobacco products is specific to the United States and is not designed to inform frameworks in other countries nor does the FDA advise countries on tobacco product regulation. If you have any further questions, please feel free to contact the FDA Center for Tobacco Products at CTP-OCD-Intl@fda.hhs.gov.

Sincerely,

Stakeholder Relations Office

Center for Tobacco Products
Office of the Center Director
U.S. Food and Drug Administration
CTP-StakeholderRelations@fda.hhs.gov
For international matters: CTP-OCD-Intl@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Footnotes:

[1] FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway. FDA. https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

2 Modified Risk Tobacco Products. FDA. https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products.

3 See supra note 2.

4 See supra note 2.

5 FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information. FDA. https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information.

6 While non-combusted cigarettes may be referred to as "heat-not-burn" or "heated" tobacco products, they meet the definition of a cigarette in the Federal Food, Drug and Cosmetic Act.

7 In the preamble to the deeming rule, FDA established a compliance policy providing additional time during which FDA does not intend to enforce the premarket authorization requirements for newly deemed, finished tobacco products that were on the U.S. market on August 8, 2016.

8 When the Agency established the HPHC established list in 2012, the tobacco products that were subject to its authorities under the FD&C Act were limited to cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco products. Since then, however, the FDA's tobacco product authorities were extended under the Deeming Rule to all products, including components and parts (but excluding accessories of deemed products) that meet the statutory definition of tobacco product, including electronic nicotine delivery systems (ENDS). Therefore, the Agency is considering revising the HPHC established list to reflect the current range of tobacco products now subject to the Agency's tobacco product authorities as well as the Agency's growing scientific expertise with respect to all tobacco products.

9 See supra note 6.

From: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Sent: Wednesday, December 2, 2020 3:26 PM
To: AskCTP <AskCTP@fda.hhs.gov>[redacted]
Subject: Information request on electronic smoking devices' regulation.

Dear Sir/Madam,

We hope this message finds you well.

The import, marketing and advertisement of electronic smoking devices (ESDs) [1] are prohibited in Brazil by ANVISA's Resolution nº 46/2009. These prohibitions are based in the precautionary principle and in the absence of scientific evidence on safety and efficacy of these products.

Almost ten years after the publication of the Resolution and aiming to discuss ESDs related issues based on current scientific knowledge, in 2019, ANVISA started a regulatory process to assess the current regulation[2]. In order to achieve this objective, the Agency is conducting a survey and an assessment of updated scientific evidences without conflict of interest on these devices.

Among the issues to be scientifically evaluated, the Tobacco Industry claims that these devices reduce the health risks to users when compared to cigarettes and other conventional

tobacco products.

Therefore, we would like to rely on the support of Global Tobacco Regulator Forum (GTRF) members to clarify the following questions:

1- *Are ENDS, ENNDS and HTP authorized in your country? If so, through which health legislation/standard are they authorized?*

2- *Can these products be marketed with the claim that they pose reduced risks to users' health? If so, which risks are reduced, and which scientific evidence supported this decision?*

3- *If the products can be marketed with the claim that they reduce risks, how is this information disclosed by the health authority? Are risk-reduced products subject to the same regulation as conventional smoking products (fees, advertising and indoor use prohibition)?*

4- *If the products can be marketed with the reduced risks to users' health claim, does this information appear on the product label? If so, are there regulations to define how this information should be displayed on the label?*

5- *Are there any records of non-compliance with the health legislation/standard by the Tobacco Industry? If so, in which aspects?*

We would appreciate if you could provide this and any other information that you consider relevant. We strongly believe that the reported experiences will be of great value to the current discussions in Brazil.

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[1] Electronic Nicotine Delivery Systems (ENDS) Electronic Non-Nicotine Delivery Systems (ENNDS) and Heated Tobacco Products (HTP)

[2] Regulatory Process: http://portal.anvisa.gov.br/tabaco/cigarro-eletronico

Best Regards,
International Affairs Office
Brazilian Health Regulatory Agency - ANVISA

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[1] FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway. FDA. https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

[2] Modified Risk Tobacco Products. FDA. https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products.

[3] See supra note 2.

[4] See supra note 2.

[5] FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information. FDA. https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information.

[6] While non-combusted cigarettes may be referred to as “heat-not-burn” or “heated” tobacco products, they meet the definition of a cigarette in the Federal Food, Drug and Cosmetic Act.

[7] In the preamble to the deeming rule, FDA established a compliance policy providing additional time during which FDA does not intend to enforce the premarket authorization requirements for newly deemed, finished tobacco products that were on the U.S. market on August 8, 2016.

[8] When the Agency established the HPHC established list in 2012, the tobacco products that were subject to its authorities under the FD&C Act were limited to cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco products. Since then, however, the FDA's tobacco product authorities were extended under the Deeming Rule to all products, including components and parts (but excluding accessories of deemed products) that meet the statutory definition of tobacco product, including electronic nicotine delivery systems (ENDS). Therefore, the Agency is considering revising the HPHC established list to reflect the current range of tobacco products now subject to the Agency's tobacco product authorities as well as the Agency's growing scientific expertise with respect to all tobacco products.

[9] See supra note 6.