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REGULATORY REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICES – FDA

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ABSTRACT

The FDA has been instrumental in enforcing essential documents and laws related to tobacco product regulations, even though tobacco use is the primary cause of one in five US deaths. The Family Smoking Prevention and Tobacco Control Act passed in 2009, marked the beginning of a comprehensive public health initiative. The FDA has the power to regulate tobacco products, which are the country's highest avoidable cause of death. However, this regulation presents new opportunities and challenges for public health professionals in academia, research, government, and advocacy. On August 23, the FDA released a regulation restricting the sale and distribution of cigarettes and smokeless tobacco products to underage individuals, marking the most extensive program ever implemented to reduce teen tobacco consumption. The FDA's jurisdiction over these products is based on the investigation that led to its assertion of its jurisdiction over these products and the policy considerations that shaped the final rule.

Keywords: FDA, Smokeless Tobacco Products, Act, Guidance, Jurisdiction

INTRODUCTION:

The regulations governing the production, advertising, distribution, and retailing of tobacco products are enforced by the **Food and Drug Administration (FDA)**, an

organization under the Department of **Health and Human Services (HHS)**. The Tobacco Center of the FDA Items (CTP) was created by the 2009 Family Smoking

Prevention and Tobacco Control Act. The Federal Food and Drug Administration, TCA, and others revised the Cosmetic Act (FFDCA), adding a new chapter IX ("tobacco products"). This chapter discussed the use of tobacco in cigarettes, including smokeless, roll-your-own, and tobacco.

The **Tobacco Products Scientific Advisory Committee** (TPSAC) offers advice on any topic addressed under FFDCA chapter IX, including issues related to tobacco control. A wide variety of backgrounds and expertise are represented by the twelve elected members of the TPSAC [1].

A set of rules, as described in **21 C.F.R. Part 1120**, is enforced against producers of tobacco goods. These regulations include the following:

- Establishing controls to prevent or minimize specific risks in the design and development of tobacco products;
- Ensuring that tobacco products, both finished and in bulk, are manufactured by established specifications;
- Minimizing the likelihood of producing and distributing non-compliant tobacco products.

Except for other tobacco products that it determines fall within the definition of a tobacco product and are thus governed by FDC Act chapter IX, the FDA maintains wide regulatory power over them. In 2016, the FDA expanded its regulatory powers to include all tobacco products, including

ENDS, that were not previously covered by the FFDCA by utilizing this jurisdiction to produce rules.

The FDA must get permission before a company can lawfully distribute or sell a new tobacco product in the US. Premarket tobacco product applications (PMTA), large equivalency applications, and exemption from major equivalence requests are the three routes a new tobacco product might take to enter the market.

A new tobacco product must demonstrate that it would be **"appropriate for the protection of the public health"** and that it would make it less probable for both existing users and non-users to start using tobacco products to be allowed for distribution.

When compared to a **"predicate"** product, a new tobacco product may be deemed **"substantially equivalent"** if it can be shown that the two products share features or if the products have distinct features, that the products do not create different public health issues.

It can be easy to avoid proving substantial equivalency for a changed tobacco product by adding, removing, or changing the amount of an already-existing tobacco component [3].

The FDA regulates tobacco products differently than it does medical items (such as prescription medications and medical equipment) since tobacco products have no

proven health benefits. Tobacco product producers are subject to the same manufacturer regulations as apply to makers of medical devices. These regulations cover premarket review and user fee collection. Tobacco product manufacturers, on the other hand, often have to meet a threshold "appropriate for the protection of public health," rather than the standard safety and efficacy requirements that medical product manufacturers must fulfil to obtain FDA regulatory premarket approval. Due to the health risks associated with tobacco

products, legislation about tobacco makers, importers, distributors, and retailers apply [1].

The FDA can control the production, promotion, retailing, and distribution of **tobacco products under Section 901 of the FFCA**. Any part, accessory, or component that is packaged with a tobacco product is considered a tobacco product, as is any object made of tobacco intended for ingestion by humans [1].

REGULATIONS: [7]

Table 1: Shows the regulations for the Tobacco Product

SI No.	Regulations	Issued Date
01.	Requirements for Tobacco Product Manufacturing Practice	03/10/23
02.	Tobacco Product Standard for Menthol in Cigarettes	05/04/22
03.	Premarket Tobacco Applications and Recordkeeping Requirements	10/05/21
04.	Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	10/05/21

GUIDANCE DOCUMENTS: [8]

Table 2: Shows the Guidance Documents for the Tobacco Product

SI No.	Guidance Documents	Issued Date
01	Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions	10/17/23
02	Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	08/31/23
03	Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	03/31/23
04	FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements	03/17/23
05	Health Document Submission Requirements for Tobacco Products	03/31/23

Objectives:

- To contend with the **evolving scenario** of Tobacco Product Manufacturing in the US.
- To understand the **current Regulation and Guidance documents** for tobacco products in the US.

- To provide an **outline of the approval process** for tobacco products in the US.

Advantages of Tobacco:

- Increase Neurotransmitters
- Have Antidepressant Properties
- Increase Brain Waves
- Help in Weight and Insulin Control
- Possess Neuroprotective Properties

Disadvantages of Tobacco:

- **Cancer:** Smoking is a major contributor to lung, throat, oral, and bladder cancers.
- **Heart disease:** stroke, and other cardiovascular conditions can be brought on by smoking [4].
- **Respiratory conditions:** Smoking can lead to emphysema, chronic bronchitis, and other conditions affecting the lungs [5].
- **Immune system issues:** It is more difficult for the body to fight off illnesses when smoking since it lowers immunity [5].

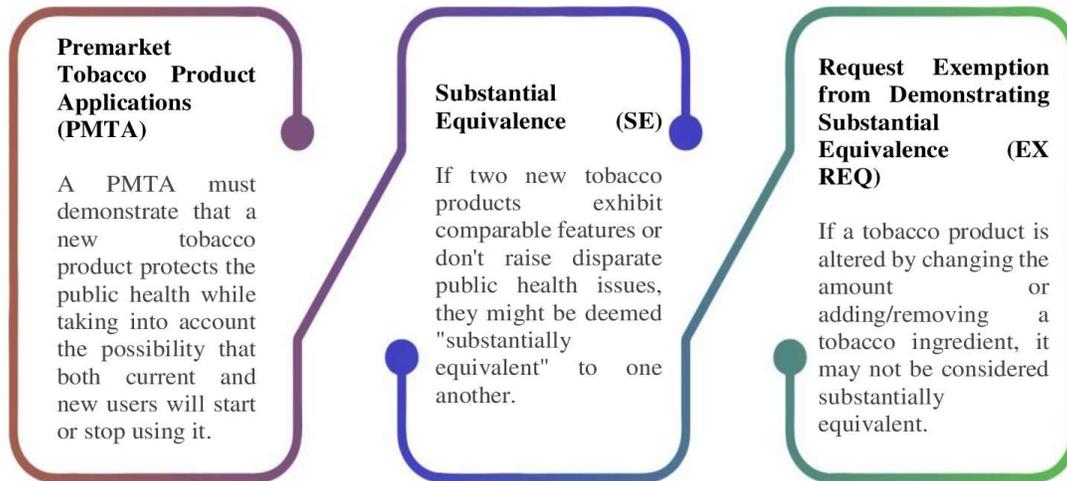
- **Fertility issues:** Smoking can affect a person's ability to conceive in both men and women [4].

RESULTS & DISCUSSIONS:

Introduce a new tobacco product to the market

An organization needs FDA approval and to file a marketing application before releasing a new tobacco product into the market. Any product that was not commercially accessible in the United States on February 15, 2007, or any tobacco product that underwent alterations before being commercially distributed in the United States, is considered a "new tobacco product". The FDA's scientists closely examine these new products and their applications to determine whether or not they offer enough proof that the cutting-edge tobacco product complies with relevant regulatory requirements. The sale of new tobacco products without the necessary premarket approval may result in FDA enforcement action. They are also getting unlawful advertising.

There are three pathways to market for new tobacco products:[6]



According to the **Federal Food, Drug, and Cosmetic Act section 910(b)**, any person may file a **premarket tobacco product application (PMTA)** for any new tobacco product requesting an FDA marketing order. Scientific evidence that a product is suitable for public health protection must be provided by a PMTA. According to section **910(c)(4)**, the FDA takes into account the following factors among others to decide and approve marketing:

- Those who presently use tobacco products would most likely stop

if the recommended new product were made available.

- If the new product were made available, those who don't now use tobacco products may start using them.
- The entire population, which includes both users and non-users, will benefit from and be at risk from the new tobacco product that is being suggested.
- The new tobacco product under consideration would both benefit and endanger the whole public, including non-users [7].

PMTA Review Process



Figure 2: Shows the PMTA review process

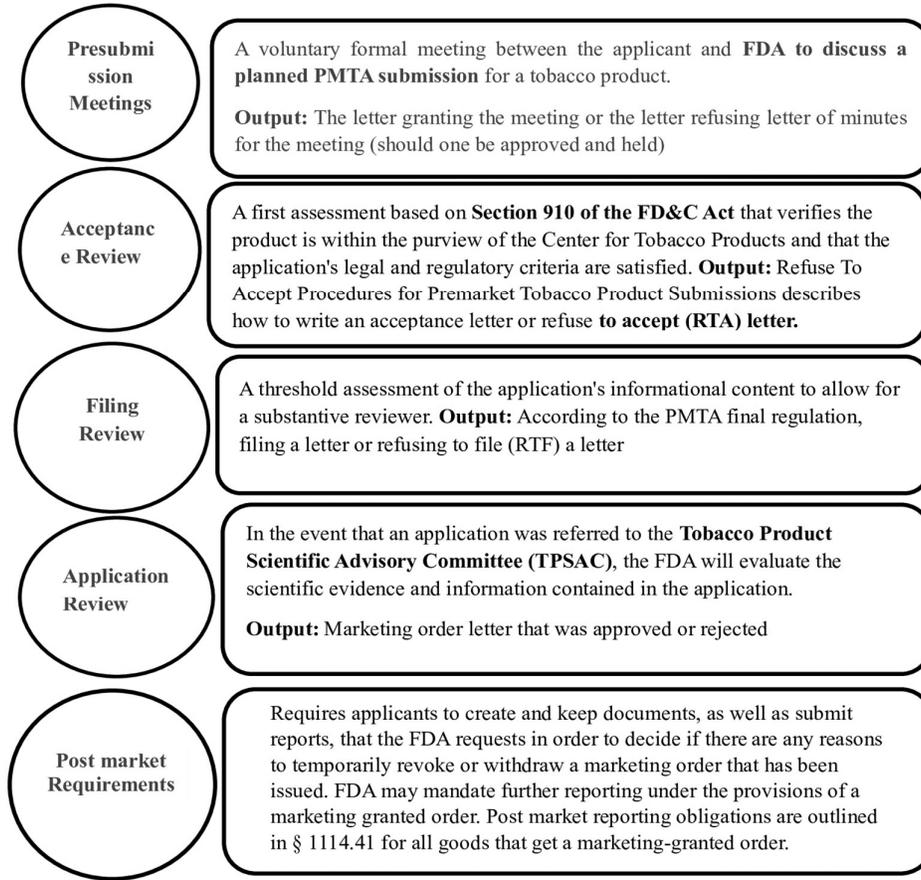


Figure 3: Shows that the pathway of PMTA

SE Review Process



Figure 4: shows the SE review process

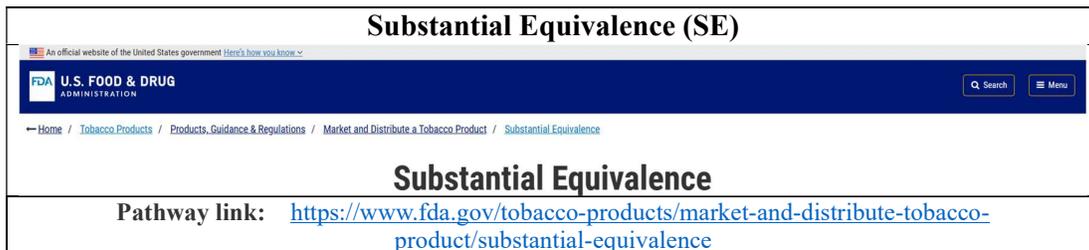
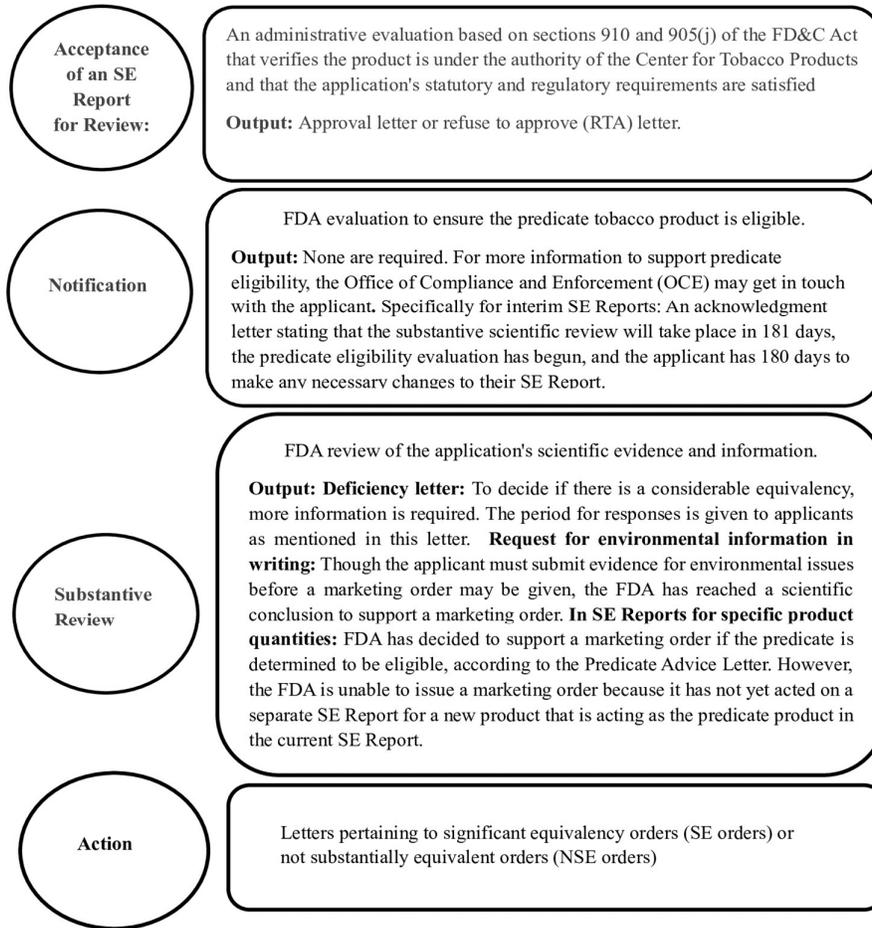


Figure 5: Substantial Equivalence Pathway

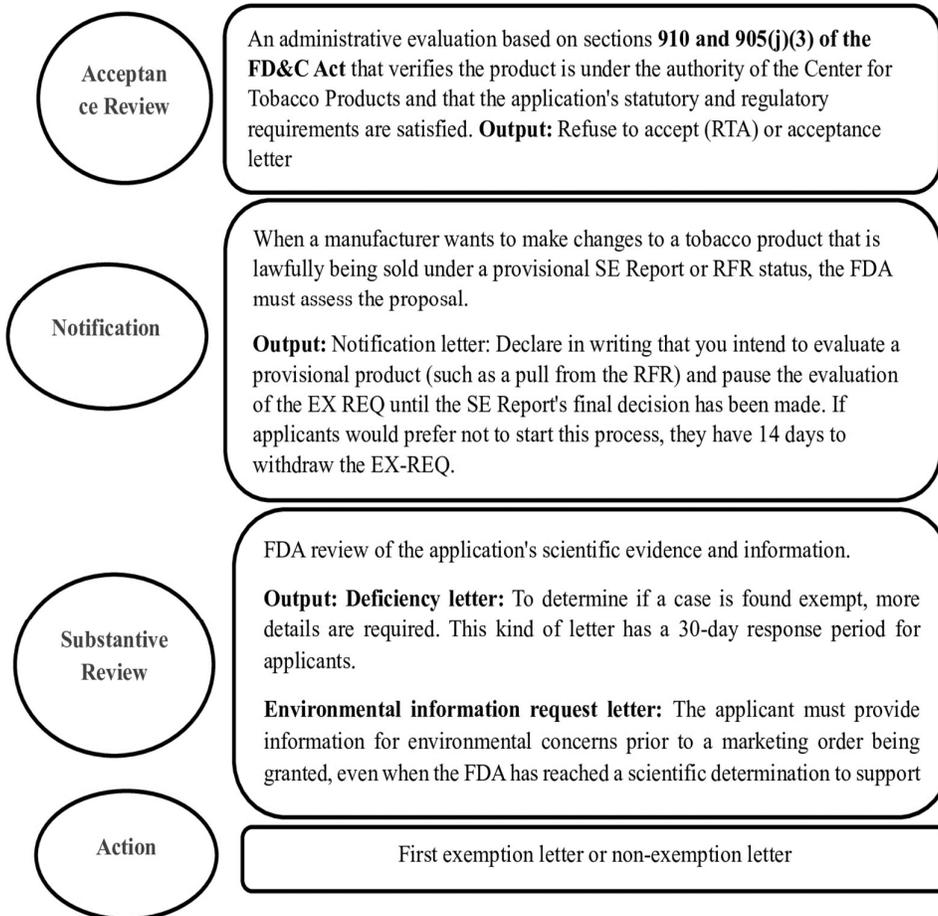
In Exemption from Substantial Equivalence (EX REQ) it has two types

- Step-1: EX REQ review process
- Step-2: Abbreviated Report Review Process

EX REQ Review Process



Figure 6: shows that the review process of EX-REQ



Abbreviated Report Review Process (Step Two of the EX REQ process)



Figure 7: shows the review process of the Abbreviated report review process of EX-REQ

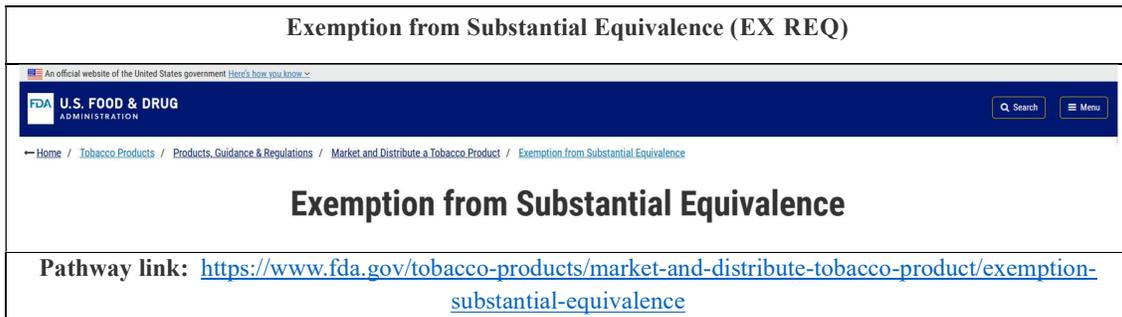
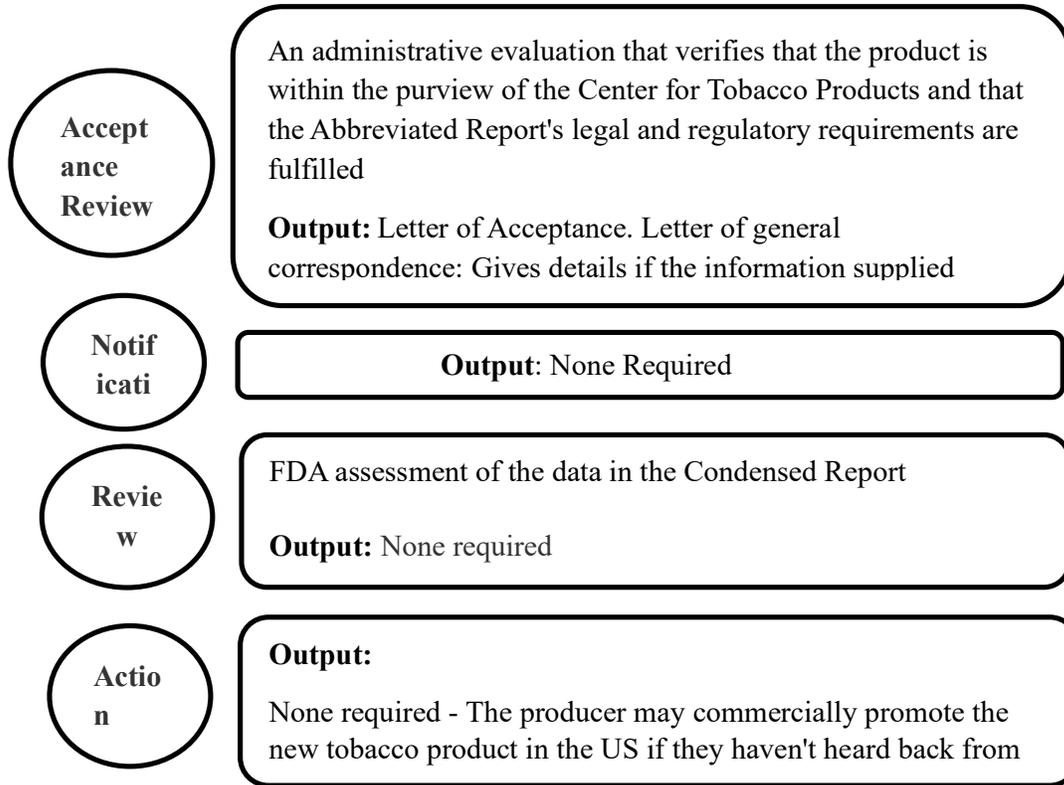


Figure 8: shows the Exemption from Substantial Equivalence (EX REQ) pathway Newly Approved Tobacco Product by U.S. FDA In the Year 2023

Table 3: shows the newly approved tobacco product by the U.S. FDA

Sl.No	Manufacturer	Product Name and Order Letter	Product Category	Date Issued
01	Philip Morris Products S.A.	Marlboro Sienna Heat Sticks	Heated Tobacco Product (HTP)	1/26/2023
02	Philip Morris Products S.A.	Marlboro Bronze Heat Sticks	Heated Tobacco Product (HTP)	1/26/2023
03	Philip Morris Products S.A.	Marlboro Amber Heat Sticks	Heated Tobacco Product (HTP)	1/26/2023

Checklist: <https://www.fda.gov/tobacco-products/manufacturing/electronic-submissions-tobacco-products>

CONCLUSION:

Despite being the most avoidable cause of disease and death in the US, there are a variety of advanced burning, non-combustible, and electronic tobacco products on the market. Tobacco-related morbidity and mortality in the US can be decreased by implementing comprehensive, evidence-based, population-level interventions together with targeted tactics and tobacco product legislation. Targeted interventions are also necessary as part of an all-encompassing strategy to reach the subpopulations that use tobacco products the most, which may differ depending on the kind of product. Any tobacco product hurts biological systems when used, including e-cigarettes, hookahs, non-cigarette combustible tobacco, and smokeless tobacco. However, the amount of harmful and potentially harmful ingredients that are exposed to varying degrees depends on the product, increasing the risk of cardiovascular disease associated with use. Longitudinal studies on the relationship between e-cigarette usage and cardiovascular disease are desperately needed. These goods have the potential to create dependency since they contain nicotine.

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CONFLICT OF INTEREST:

The authors declared that there is no conflict of interest

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