



The FDA's Premarket Review of Tobacco Products Fails to Fully Protect Public Health

The Family Smoking Prevention and Tobacco Control Act gives the U.S. Food and Drug Administration (FDA) unprecedented authority to regulate tobacco products.¹ One of the most powerful tools available to the FDA under the Act is the power to decide whether or not a new tobacco product can be introduced to the market.² In theory, this gatekeeping role should allow the agency to prevent those products with the most potential to harm public health from ever reaching retail store shelves.

However, the FDA's implementation of this authority has not maximized the potential to protect public health. Most significantly, the FDA is prioritizing the introduction of new tobacco products over the removal of potentially non-compliant products from the market. This problem is mostly hidden from public view but has enormous public health implications. This fact sheet will explain the processes for authorizing the marketing of new products and provide information on FDA's actions to date.

FDA Authority over New Products

The Tobacco Control Act creates three pathways by which the tobacco industry can receive FDA authorization to put additional products on the market: 1) Premarket Tobacco Product Applications, 2) Substantial Equivalence Applications³, and 3) Exemptions from Substantial Equivalence Applications. Each pathway has its own review process.

1) Premarket Tobacco Product Applications (PMTA)

The "Premarket Tobacco Product Application" or "PMTA" pathway for new products is what most would imagine when they learn that the FDA has the authority to decide whether or not new products can enter the market. The pathway is intended to be the primary process for new tobacco products to enter the market. This pathway should be used for any products that were not commercially marketed as of February 15, 2007, and are not substantially equivalent to products that were on the market as of that date. An application should be denied by the FDA if: 1) the product does not appropriately protect public health,⁴ considering the product's impact on initiation and cessation;⁵ 2) the manufacturing process for the product does not meet established standards;⁶ 3) the labeling of the product is false or misleading;⁷ or 4) the product does not meet a product standard set by the FDA.⁸

2) *Substantial Equivalence (SE)*

The “Substantial Equivalence” or “SE” pathway is the review process for new products that are similar to products already on the market. This process is intended to be used for products that have the same characteristics as products marketed as of February 15, 2007,⁹ or that have different characteristics that do not raise different questions of public health.¹⁰

This product pathway requires a comparison between an existing product, which the FDA calls a predicate product, and the new product. If the FDA finds that the existing product was commercially marketed (not test marketed) in the United States on February 15, 2007, it can be named as a predicate product on this type of application.¹¹ A product that is authorized for sale under this pathway can also serve as a predicate product on another application even if the authorized product was not on the market until after February 15, 2007, as long as the authorized product is compliant with any product standards established by the FDA.¹²

This pathway has two subsets. Applications filed by March 22, 2011 for products on the market by that date are called “Provisional” because the products can remain on the market provisionally until the FDA has assessed the merits of the application. Products for which a “Regular” application was filed after March 22, 2011, cannot be marketed until the FDA issues an order authorizing the sale.

3) *Substantial Equivalence Exemption (SE Exemption)*

The third method the industry can use to seek FDA authorization to market a new product is to file a request for exemption from Substantial Equivalence stating that, for example,¹³ a new product is so similar to a predicate product (described above) that the difference between the two is minor and the submission of a full report demonstrating substantial equivalence is not necessary to protect public health.¹⁴ The Tobacco Control Act provides an example of a product that might be exempt from the SE report process: a product that is only different from an existing product because an additive was deleted or added or where the level of an existing additive was increased or decreased.¹⁵

Figure 1: Premarket Review Pathways

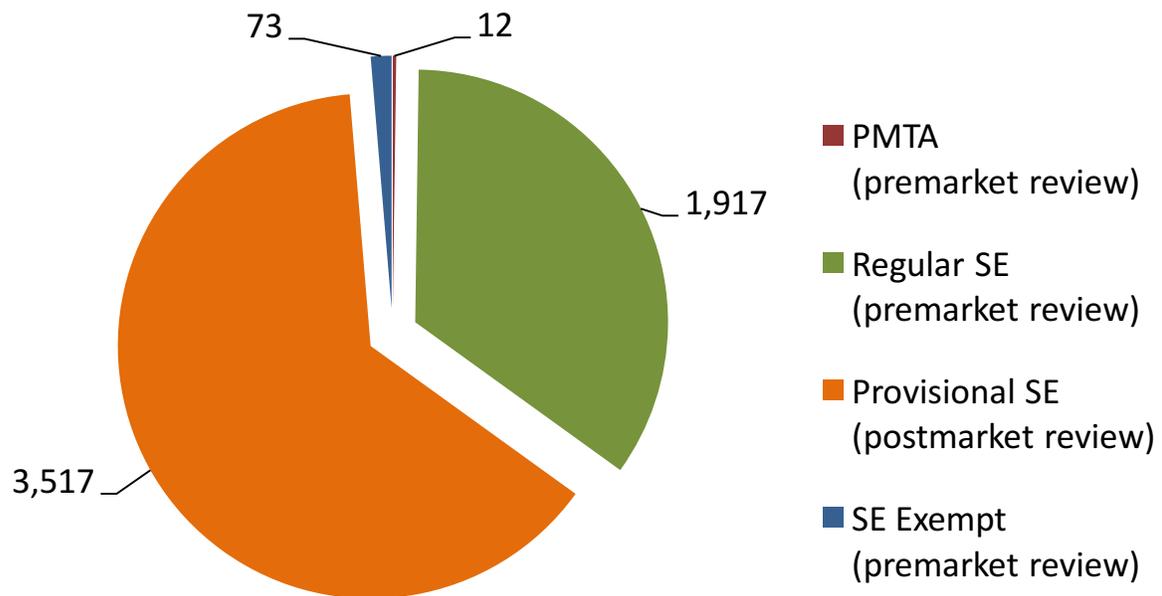
	Pathway 1: Premarket Tobacco Product Applications (PMTA)	Pathway 2a: Provisional Substantial Equivalence (Provisional SE)	Pathway 2b: Regular Substantial Equivalence (Regular SE)	Pathway 3: Substantial Equivalence Exemption (SE Exemption)
Application contains:	Analysis of one product that has never been previously marketed	Analysis of the similarities and differences of: 1) a product that was introduced to the market between 2/15/2007 and 3/22/2011; and 2) a predicate product	Analysis of the similarities and differences of: 1) a product that has never been previously marketed; and 2) a predicate product	Analysis of the similarities and differences of: 1) a product that has never been previously marketed and 2) a predicate product
Eligible Predicate Products:	N/A	A product that was marketed on 2/15/2007*	A product that was marketed on 2/15/2007, or a product authorized through the SE pathway (Provisional or Regular)	A product that was marketed on 2/15/2007, or a product authorized through the SE pathway (Provisional or Regular)
Product can be authorized if:	Manufacturer demonstrates that permitting the new product to be marketed would be appropriate for the protection of the public health taking into account risks and benefits to users and nonusers, rates of cessation, and rates of initiation	Manufacturer demonstrates that: 1) the new product has the same characteristics as its predicate, or 2) any differences in the characteristics of the new and predicate products do not raise different questions of public health	Manufacturer demonstrates that: 1) the new product has the same characteristics as its predicate or 2) any differences in the characteristics of the new and predicate products do not raise different questions of public health	Manufacturer demonstrates that: 1) a predicate product has only been subject to a minor modification, 2) a full SE report is not necessary to ensure that permitting the new product to be marketed would be appropriate for the protection of the public health, and 3) an exemption is otherwise appropriate
Marketing status:	Cannot be sold until authorized by the FDA	Allowed to be sold until removed by the FDA	Cannot be sold until authorized by the FDA	Cannot be sold until authorized by the FDA

*Products authorized through the SE pathway are also eligible predicate products for this pathway. However, because no SE authorizations were issued before 3/22/2011, when the Provisional SE applications were due, all applications necessarily used products that were marketed on 2/15/2007 as their predicates.

Industry Exploitation of Premarket Review

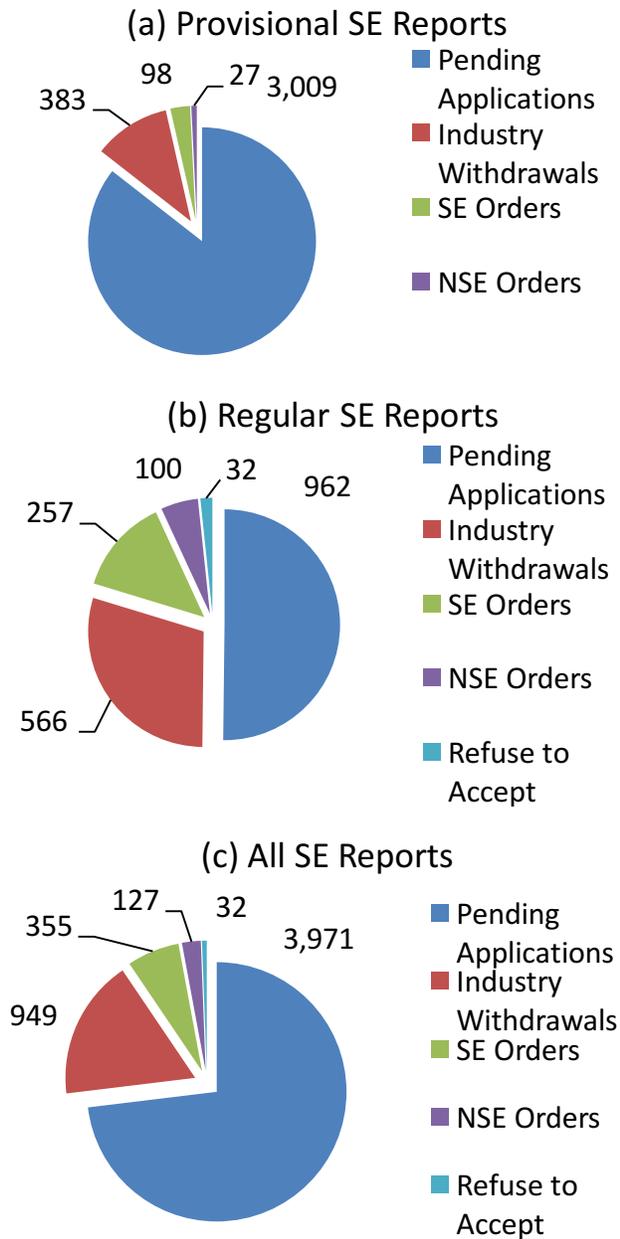
Products to be introduced through Pathways 1, 2b, and 3 in Figure 1 must all receive authorization from the FDA *before* they can be introduced to the market. These products are subject to true premarket review. However, products introduced through Pathway 2a, Provisional SE products, can stay on the market so long as they were introduced by March 22, 2011 and an SE report was filed by that date. These products may stay on the market until the FDA orders them to be removed and so they are only subject to postmarket review.¹⁶

Figure 2: Premarket Submissions to the FDA



With its sophisticated knowledge of the Tobacco Control Act, the tobacco industry seized the opportunity to maximize the number of products on the market. The industry flooded the FDA with Provisional SE reports just before the March 22, 2011 deadline, submitting a total of 3,517 Provisional SE applications.¹⁷ This stands in stark contrast to the 1,917 Regular SE reports filed after March 22, 2011,¹⁸ and only 85 total product applications under the pathways that are entirely subject to premarket review (12 PMTAs and 73 SE Exemption requests).¹⁹ This means that of the 5,519 applications that the FDA has received, two-thirds are for products that are subject only to postmarket review.²⁰ Figure 2 above illustrates how the tobacco industry has used Provisional SE products to avoid premarket review for most new products.

Figure 3: Status of Premarket Submissions to the FDA



Given the FDA’s mandate to protect public health, one would expect the agency to take swift action to mitigate the harm caused by the tobacco industry’s exploitation of the premarket review process. By quickly acting on all of the Provisional SE reports that the industry filed, the FDA could remove any non-compliant products from the market before they cause even greater harm. The FDA has instead prioritized the review of Regular SE reports, those for products that are subject to true premarket review. This priority is allowing the tobacco industry to continue marketing unauthorized Provisional SE products as well as introducing new products through the Regular SE pathway.

The figure on the left shows the various actions that the FDA has taken on Provisional and Regular SE reports as well as both groups combined. An SE order provides authorization to market a product while an NSE order prevents a Regular SE product from entering the market and removes a Provisional SE product from the market. The FDA may also “Refuse to Accept” reports that are deficient, denying a product access to the market.

Fixing the Problem

The FDA could improve the premarket review process by taking a few simple steps. The agency’s first action should be to reverse its review priority and begin acting on Provisional SE reports that represent

products that are currently on the market, have not been reviewed by the agency, and may be out of compliance with federal regulations. Only after all of these reports have been reviewed should the agency begin its review of products that have not yet been introduced to the market.

For more in-depth information on the FDA’s review of tobacco product marketing applications, see the Consortium’s [FDA Premarket Review of Tobacco Products](http://www.fda.gov/premarket-review-of-tobacco-products) webpage with other resources on this topic.

Last updated: May 2016

Notes

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387).

² 21 U.S.C. § 387j.

³ For the Substantial Equivalence pathway, the FDA uses the term “report” rather than “application.”

⁴ 21 U.S.C. § 387j(c)(2)(A).

⁵ 21 U.S.C. § 387j(c)(4).

⁶ 21 U.S.C. § 387j(c)(2)(B).

⁷ 21 U.S.C. § 387j(c)(2)(C).

⁸ 21 U.S.C. § 387j(c)(2)(D).

⁹ 21 U.S.C. § 387j(a)(3)(A)(i).

¹⁰ 21 U.S.C. § 387j(a)(3)(A)(ii).

¹¹ 21 U.S.C. § 387e(j)(1)(A)(i).

¹² 21 U.S.C. § 387e(j)(1)(A)(i).

¹³ An applicant may also indicate that a report “is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health,” or that “an exemption is otherwise appropriate.” 21 U.S.C. § 387e(j)(3)(A)(ii)-(iii).

¹⁴ 21 U.S.C. § 387e(j)(3).

¹⁵ 21 U.S.C. § 387e(j)(3).

¹⁶ The term “postmarket review” as it is used here is a contrasting term to “premarket review.” It is not intended to capture any of the FDA’s authority with respect to postmarket surveillance.

¹⁷ U.S. FOOD AND DRUG ADMIN., Cumulative Number of Provisional Substantial Equivalence (SE) reports received since Program Inception,

<http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-provisional-SE-reports&fy=all> (last visited January 8, 2016).

¹⁸ U.S. FOOD AND DRUG ADMIN., Cumulative Number of Regular Substantial Equivalence (SE) reports received since Program Inception,

<http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OS-regular-SE-reports&fy=all> (last visited January 8, 2016).

¹⁹ U.S. FOOD AND DRUG ADMIN., Total number of product submission received or filed in the month (1),

<http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all> (last visited January 8, 2016).

²⁰ *Id.*