Brief Summary of "Not Substantially Equivalent" Determinations

FDA may find a new tobacco product to be NSE either because there is inadequate information submitted, or because FDA finds that the new product has different characteristics and information demonstrates that it raises different questions of public health.

Tobacco products have been found to be not substantially equivalent to specific predicate products due to factors such as inadequate evidence that the proposed predicate products were valid predicates and lack of complete information on the characteristics of the new products and the predicate products. After considering all the evidence, the agency determined that there were differences in characteristics between the new products and the predicate products, and there was not an adequate showing that the new products do not raise different questions of public health requiring a premarket tobacco product application.

The types of deficiencies FDA found in one or more of these are summarized below.

- Predicate

  Insufficient information for FDA to determine whether or not the tobacco product that was referenced as a predicate was predicate-eligible. Specifically, adequate evidence was not provided to demonstrate that the predicate product was commercially marketed in the United States as of February 15, 2007.

- Design Features

  Inadequate information on design features such as ventilation and filter efficiency. This information is needed to understand if any changes in these characteristics are present and, if they are, whether the new product raises different questions of public health.

- Tobacco Type

  Inadequate information on the type of tobacco used in the cigarette. This is a significant deficiency because the type of tobacco can alter the levels of harmful and potentially harmful constituents. This information is needed to understand if any changes in these characteristics are present and, if they are, whether the new product raises different questions of public health.

- Added Toxicants

  Information was provided about the levels of specific ingredients showing they were either present:

(1) at higher levels in the new tobacco product compared to the predicate tobacco product or,
(2) in the new tobacco product when not in the predicate tobacco product.

Some of these ingredients have been shown scientifically to cause both toxicological and dependence concerns. For example, some of these ingredients are listed in the Hazardous Substances Data Bank and have known toxicities. Or some of these ingredients have known toxicities and pharmacological activity. There was not adequate evidence that the changes did not result in the new product not raising different questions of public health.

- Harmful and Potentially Harmful Constituents

  Inadequate information regarding "Harmful and Potentially Harmful Constituents" (HPHCs) in new and/or predicate tobacco products and tobacco smoke. Lacking this information, FDA was not able to determine whether the new product raised different questions of public health.

- Change in Burn Properties

  Inadequate information regarding changes in additives that could change the burning properties of a cigarette. Lacking adequate evidence, FDA was not able to determine whether the new product raised different questions of public health.

- New Characterizing Flavor

  Inadequate information regarding the effect of a new characterizing flavor in smokeless tobacco products on product initiation and cessation. Addition of a new characterizing flavor may cause the new product to raise different questions of public health because initiation may increase and/or cessation may decrease.

  Addition of menthol as a characterizing flavor to a predicate product that does not contain menthol as a characterizing flavor. This causes the new product to raise different questions of public health as it relates to initiation, dependence, and cessation.

- Increase in Free Nicotine

  Inadequate information regarding the effect of increased free nicotine (unprotonated nicotine) in smokeless tobacco products on initiation and cessation. An increase in free nicotine may lead to a higher rate and amount of nicotine absorbed in the body. An increase in free nicotine may cause the new product to raise different questions of public health because initiation may increase and/or cessation may decrease.

- Differences in Tobacco Blend

There were significant differences in the tobacco blends between the predicate and new tobacco products. Tobacco blend differences can result in different levels of harmful and potentially harmful constituents.

- Health Information Summary

  Submitted health information summary does not comply with section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Therefore, a marketing order cannot be issued for the new tobacco product.

- Unique Identification of New Tobacco Product

  There was inadequate information to fully identify the new tobacco product. Specifically, it is unclear what specific product is proposed for commercial marketing in the United States and what FDA should review. Therefore, a marketing order cannot be issued for the new tobacco product.

- Compliance with Section 907

  Lack of statement to comply with section 907 of the FD&C Act, including those under section 907(a) and any promulgated through regulation. Therefore, a marketing order cannot be issued for the new product.

- Change in Ventilation

  Inadequate information regarding the removal of filter ventilation in the new tobacco product. The removal of ventilation can lead to increased harmful and potentially harmful constituent yields.