Brief Summary of "Refusal-to-File" Determinations

FDA may refuse to file a new tobacco product application (PMTA) due to the application missing one or more items required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The following items are required by the FD&C Act to be in a PMTA:

- Full reports of all information, published or known to, or which should reasonably be known to you, concerning investigations which have been made to show the health risks of this new tobacco product and whether this product presents less risk than other tobacco products per Section 910(b)(1)(A) of the FD&C Act.
- A full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of your tobacco product per section 910(b)(1)(B) of the FD&C Act.
- A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of your new tobacco product per Section 910(b)(1)(C) of the FD&C Act.
- Information to demonstrate that your product either fully complies with any applicable tobacco product standards, or justifies any deviation from such standard per Section 910(b)(1)(D) of the FD&C Act.
- Specimens of proposed labeling for your new tobacco product per Section 910(b)(1)(F) of the FD&C Act.

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

- 910(b)(1)(B)

  An insufficient listing of the ingredients and additives. A lack of full statement of properties. Only four properties were provided, which was not a full statement of the properties.

- 910(b)(1)(C):

  Lack of a full description of the methods and controls used in the manufacture, processing, packing, and installation of the new product. Failure to provide any description of the methods used, or the manufacturing process, for each component.

- 910(b)(1)(D)

  Lack of a reference to the artificial or natural characterizing flavor ban in section 907(a)(1)(A).

- 910(b)(1)(F)

A specimen of the proposed labeling was either not provided for the new product or the specimen provided was not submitted in a manner that would permit review:

- Visible text is not legible
- Submitted specimen is not reproduced in color
- Some products appear to lack any label specimen
- Not possible to verify that labeling submitted for each product