

Instructions for Reporting Requirements Under Section 905(j)(1)(A)(ii)

If you are required to register under Section 905(j) and propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, you must submit an abbreviated report to the Secretary indicating your intent.

The abbreviated report must be made and submitted at least 90 days prior to making the introduction or delivery for introduction into interstate commerce, and shall contain the basis for determining that:

1. The tobacco product is modified within the meaning of section 905(j)(3), which states that
 - a. the modification would be a minor modification of a tobacco product that can be sold under this Act;
 - b. a report under Section 905(j) is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and
 - c. an exemption is otherwise appropriate.
2. The tobacco product's modifications are to a product that is commercially marketed and in compliance with the requirements of this Act; and
3. All of the modifications are covered by the exemptions granted pursuant to Section 905(j)(3).

If you need further assistance in completing this abbreviated report, or have any questions, please contact FDA's Center for Tobacco Products Call Center at 1-877-CTP-1373 (1-877-287-1373) or at www.fda.gov/tobaccoproducts. Instructions can also be found at www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence.