"Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products"
(OMB Control Number 0910-0673)

Change Request

September 27, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to reduce the burden based on a recent decision in the United States District Court for the District of Columbia. The court found that a modification to an existing tobacco product's label does not result in a "new tobacco product." (Philip Morris USA Inc. v. United States Food and Drug Administration, No. 15-cv1590 (APM), (D.D.C. Aug. 16, 2016)). As such, products with a modified label are not required to receive premarket authorization. Thus, the numbers will reflect that manufacturers need not submit SE applications for label changes.

The decrease results in minus 518 annual responses and 24,346 hours. Based on these estimates, FDA now estimates that the total burden of this collection is 171,878 (as shown in the chart) and the updated supporting statement attached.

Activity	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	410	1	410	300	123,000
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	250	1	250	90	22,500

Activity	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Product Quantity Change SE Report	264	1	264	87	22,968
Product Quantity Change Bundled SE Report	55	1	55	62	3,410
Totals					0171,878