"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

Mar 4, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to reduce the burden based on new guidance document recommendations which will reduce the time for a manufacturer to submit a Substantial Equivalence (SE) report.

Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be "full" substantial equivalence (SE) reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions," FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report." FDA estimates that it will receive 100 Same Characteristics Se Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 38,075 hours a total reduction of 321,925 hours.

Current 0910-0673

FD&C Act sections	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
905(j)(1)(A)(i) and 910(a	1,000	1	1,000	360	360,000

NEW 0910-0673 burden

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	75	1	75	300	22,500
Product Quantity Change SE Report	125	1	125	87	10,875
Same characteristics SE Report	100	1	100	47	4,700
Totals					38,075

In a conversation with OMB on February 5, 2015, FDA was given concurrence to submit this request. No other changes are being requested.