

“Tobacco Product Establishment Registration and Submission of Certain Health Information”
(OMB Control Number 0910-0650)

Change Request (83-C)

July 7, 2016

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to include a revised version of the associated Registration and Listing guidance. OMB has concurred with the submission of this change request.

We are seeking OMB’s approval for the use of a change request to account for decreased PRA estimates due to the guidance revisions. The revisions to the guidance reiterate information that was already included in the deeming final rule preamble. There are no substantive changes being made in the revised guidance. The intent of the compliance policy change driving the PRA adjustment is to harmonize our enforcement discretion policy for originally regulated products with the policy for newly deemed products.

In the revised guidance that would apply to both originally regulated and newly deemed tobacco products, we are revising the enforcement discretion policy to state that FDA intends to enforce these requirements for finished tobacco products only. Thus, the enforcement discretion policy now would apply to all tobacco products in the same way. This change in compliance policy lessens the burden on industry since we will not be expecting such submissions from components or parts for further manufacturing.

The Deeming PRA estimates did not include this lessening in burden because this change in policy affects the products originally regulated by FDA rather than the newly deemed products. In addition, we had not finalized our thinking on this policy until after the deeming rule published.

Based on the new compliance policy, FDA estimates 15 fewer respondents and a decrease of 444 hours and 200 responses for the registration and product listing and ingredient listing collections. We have re-estimated Table 3.--Estimated Annual Reporting Burden on page 11 (below).



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Revision supporting s