

**“Tobacco Health Document Submission”
(OMB Control Number 0910-0654)**

Change Request (83-C)

November 17, 2016

The Food and Drug Administration (FDA) is submitting this nonmaterial/non-substantive change request (83-C) to include a revised version of the associated Tobacco Health Document submission guidance. OMB was previously notified of this change request submission.

FDA is revising this guidance to reflect our authority over newly deemed products and to help industry comply with the health document submission requirements. The general compliance date for health documents submission is February 8, 2017.

In the revised guidance, FDA intends to enforce the requirement to submit health documents with respect to finished tobacco products only (previously regulated and newly deemed products), which is in line with the compliance policy for newly deemed products explained in the deeming rule.

In the revised draft guidance, we will be requesting health documents for newly regulated tobacco products that were developed between June 22, 2009 and December 31, 2009 (this is the same date range that FDA applied to previously regulated tobacco products).



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Document Submission