

U.S. Food and Drug Administration
Center for Tobacco Products
“Premarket Tobacco Product Applications and Recordkeeping Requirements”
(OMB Control Number 0910-0879)

Change Request - April 2022

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to revise FDA Form 4057b to allow for products containing non tobacco derived nicotine to submit PMTA applications. Effective April 14, 2022, Section 201(rr) of the Federal Food, Drug, and Cosmetic Act now applies to “any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption”. Additionally, we have incorporated other edits in the form to improve the data quality obtained. Currently, we do not have an estimate on the impact to our burden estimates. Once FDA has more data, we will submit another ICR to OMB to adjust our numbers (if necessary).

Redline Documents

FDA form 4057b Form detail changes:

Changes are marked in red and change column describes the nature of the change.



Change
Request_4 057b Detail

Supporting Statement A



0879 PMTA Final
Rule SS Tracked 3.31.