

**“Potential Tobacco Product Violations Reporting Form”
(OMB Control Number 0910-0716)**

Change Request (83-C)

October 18, 2013

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to comply with the OMB terms of clearance of July, 30, 2012 which stated “Before seeking re-approval of this collection, FDA should submit a formal telephone script as a non-substantive change to this collection”.

According to the NOA “OMB understands that telephone call screeners will request exactly the same information that is collected through the equivalent paper form”. The telephone script does not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR. The call operator will first offer the caller the option of submitting his or her report online, using the *external* web form before they record any information.

FDA does not believe adding the telephone script will change any cost or hourly burden in the existing ICR.