

“Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products”

(OMB Control Number 0910-0749)

Date: October 1, 2014

The Food and Drug Administration/Center for Tobacco Products is submitting this report to comply with the OMB terms of clearance of July 10, 2014.

According to the Notice of Action, FDA will report to OIRA on a quarterly basis beginning October 1, 2014, regarding the progress of meetings with TTB and CBP on whether it would be possible, in light of current legal restrictions on the use of individual taxpayer information, for FDA to rely solely on data received from TTB and CBP and thus eliminate the need for this information collection.

FDA has met with TTB multiple times to discuss the means for the sharing of information that FDA could use to calculate and assess tobacco product user fees. The TTB and FDA have established a recurring working group to continue collaborative discussions on possible options regarding the elimination of FDA’s industry data collection; the FDA has engaged the CBP to establish a similar collaborative working group series.