

“Tobacco User Fees”
(OMB Control Number 0910-0749)

Date: December, 31, 2015

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 continues to meet with the Alcohol and Tobacco Tax and Trade Bureau (TTB) to discuss the feasibility of eliminating the need of the subject data collection from the tobacco industry via a data sharing agreement which the FDA could utilize TTB information to verify, calculate and assess tobacco product user fees.

The Customs and Border Protection (CBP) and TTB have informed FDA that they participate in the Border Interagency Executive Council (BIEC); the BIEC has directed that each agency review all of their current data collection requirements for streamlining. CTP continues to express interest in participating in discussions regarding the data streamline effort between the TTB and CBP, as the FDA relies on both Agencies' information to fully support the Tobacco User Fee program.

The aforementioned discussions have led to the identification and further awareness of the legal restrictions that are outlined in the Internal Revenue Code law(s), specifically section 6103, which would not allow for the complete utilization of data received from the TTB and CBP to implement FDA's Tobacco User Fee Program.

Section 6103(o)(1)(A) states that “returns and return information with respect to taxes imposed by subtitle E (relating to taxes on alcohol, tobacco, and firearms) shall be open to inspection by or disclosure to officers and employees of a Federal agency whose official duties require such inspection or disclosure”; this section enables the FDA to receive return information from TTB, though FDA is limited in its ability to use and further disclosure of the return information received because the restrictions of Section 6103(p)(4) apply. Specifically Section 6103(p)(4)(F) states that “ upon completion of use of such returns or return information— (i) in the case of an agency, body, or commission described in subsection (d), (i)(3)(B)(i), (k)(10), or (l)(6), (7), (8), (9), or (16), any appropriate State officer (as defined in section 6104(c)), or any other person described in subsection (k)(10) or subsection (l)(10), (16), (18), (19), or (20) return to the Secretary such returns or return information (along with any copies made therefrom) or make such returns or return information undisclosable in any manner and furnish a written report to

the Secretary describing such manner.” Therefore, return and return information received from TTb could not be used for purposes of legal enforcement or punishment.