§ 1150.5(a), 1150.5(b)(1) and (b)(2), and Form FDA 3852

§ 1150.5(a): This section describes when and in what manner domestic manufacturers and importers of FDA-regulated tobacco products would be required to submit information to FDA. FDA will use the information submitted under this section and any other available information, as FDA determines appropriate, to make tobacco product user fee assessments. The cost and hourly burden for this section is covered under § 1150.5(b).

§ 1150.5(b)(1) and (b)(2): These sections describe the information that domestic manufacturers and importers of FDA-regulated tobacco products would be required to provide monthly. Under § 1150.5(b)(1), each domestic manufacturer and importer would submit identifying information, including its name and address, contact name and telephone number, an email address and postal address for FDA notifications, Alcohol and Tobacco Tax and Trade Bureau (TTB) permit number, and Employer Identification Number. Under § 1150.5(b)(2), the manufacturer and importer would submit information regarding the total amount of tobacco products, by class, removed into domestic commerce in the prior month and the Federal excise taxes paid, by class, for those removals. § 1150.5(b)(2) would require monthly reports from all domestic manufacturers and importers, and, as is currently required by USDA, entities that had no removals subject to tax during the reporting period would be required to report that they had no removals. This type and frequency of reporting would be almost identical to what USDA currently collects on its CCC-974 form. Moreover, FDA intends to make available to domestic manufacturers and importers a form similar to the USDA CCC-974 form with minor changes reflecting that this information would be submitted to FDA instead of USDA (Form FDA 3852) The cost and hourly burden for this section also contains burden from § 1150.5(a) and from Form FDA 3852.

Form FDA 3852: This form captures the monthly identification and removal information that domestic manufacturers and importers of FDA-regulated tobacco product would be required to submit under § 1150.5(b)(1) and (b)(2).