Proposed § 1150.5(a): This proposed paragraph describes when and in what manner domestic manufacturers and importers of FDA-regulated tobacco products would be required to submit information to FDA. The cost and hourly burden for this proposed section is covered under proposed § 1150.5(b).

Proposed § 1150.5(b)(1) and (b)(2): These proposed paragraphs describe the information that domestic manufacturers and importers of FDA-regulated tobacco products would be required to provide monthly. Under proposed § 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 proposed § 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. Proposed § 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 (proposed Form FDA 3852) The cost and hourly burden for this section also contains burden from proposed § 1150.5(a) and from proposed Form FDA 3852.

Proposed Form FDA 3852: This proposed form captures the monthly identification and removal information that domestic manufacturers and importers of FDA-regulated tobacco product would be required to submit under proposed § 1150.5(b)(1) and (b)(2). The form also directs manufacturers and importers to attach supporting documentation required by proposed § 1150.5(b)(3) (described below). Thus, the burden for this form is covered under proposed § 1150.5(b).

The information captured by § 1150.5(a), (b)(1), (b)(2), and proposed Form FDA 3852 is necessary to provide FDA with the information needed to calculate the user fee to be assessed and collected from each domestic manufacturer and importer.

Proposed § 1150.5(b)(3): This proposed paragraph requires that domestic manufacturers and importers of FDA-regulated tobacco products provide monthly certified copies of the returns or forms related to the removal of tobacco products into domestic commerce and the payment of excise taxes. These reports and forms are referred by reference to the applicable Internal Revenue Code Authority. Because the specific names of reports and forms may change over time, FDA does not name reports or forms in the proposed rule. FDA intends to specify the form names in FDA's quarterly notification of assessments to domestic manufacturers and importers and on its Web site (http://www.fda.gov/TobaccoProduct). Currently the forms are: TTB Form 5220.6; TTB Form 5210.5; TTB 5000.24; and CBP Form 7501.

Proposed § 1150.15(a)

This proposed section requires domestic manufacturers and importers submit any dispute in writing within 45 days of the date of the assessment notification. If FDA determines there was an error in the amount of the assessment, FDA would refund the amount that was incorrectly assessed. This allows adequate time to detect a dispute and prepare a written submission to FDA. The notification of assessment would provide information regarding where to send a dispute and when it needs to be sent.