

§ 1150.15(a)

This 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.