for unreasonable delay under the APA. HiFi DNA Tech, LLC v. HHS, No. 07–1511 (D. Conn. Oct. 12, 2007). Following FDA's ruling on the reclassification petition in December 2007, HiFi voluntarily dismissed that suit.

V. THE FDA ORDER

On December 14, 2007, FDA issued a detailed, 14-page Order, in the form of a letter to HiFi's President, denying HiFi's petition for reclassification of the HPV Device from Class III to Class II. AR 491-501. As shown below, FDA evaluated all of the scientific evidence and determined that HiFi's device had not met the statutory criteria for a Class II device. Further, FDA considered the arguments raised by plaintiff and determined that they were without merit. Specifically, FDA determined that there were numerous inadequacies in the data submitted by HiFi, such that the HPV Device's basic performance characteristics, including its clinical sensitivity and specificity, cross-reactivity, and rate of false negative test results, could not be assessed. AR 297-307, 499-504. Even more fundamentally, FDA found that HiFi intends for its device to be used in conjunction with genotyping to confirm its positive test results, but HiFi did not submit any data demonstrating that an HPV genotyping test validated for diagnostic use with cervical cancer even exists. AR 296-308, 500-02. For these reasons, HiFi failed to meet its burden of proving that its HPV Device meets the requirements for reclassification.

May 22, 2007. CDRH relied upon this official filing date and believed that a response was not due until December 18, 2007, which would have been 210 days from the official filing date. The error was discovered only after HiFi filed its original lawsuit in October 2007. FDA ruled on HiFi's reclassification petition on December 14, 2007. AR 493.