

Microbiology Devices Panel Meeting

June 13, 2013

The Microbiology Devices Panel met on June 13, 2013 to discuss and make recommendations regarding the possible reclassification of rapid influenza detection devices, currently regulated as Class I, to Class II. The Panel discussed an FDA proposal for a new Class II regulation with specific Special Controls designed to ensure safety and effectiveness of these devices throughout their Total Product Life Cycle (TPLC). As these devices are the most broadly used tests to aid in the diagnosis of an influenza infection, especially in physician offices and outpatient clinics, their quality and reliability is crucial for proper patient management, for surveillance and for infection control. The discussion focused on (1) the minimum performance criteria that should be required for clearance of the rapid influenza detection devices; (2) what is the appropriate reference method to be used for evaluation of clinical performance; (3) the need for annual post-market reactivity testing of device performance due to the continuous genetic changes of seasonal influenza viruses and, how to communicate the ability of previously cleared rapid influenza detection devices to detect novel influenza virus strains; and (4) a provision for testing when a new influenza strain with a potential to become a public health emergency emerges.

Two guest speakers presented information and data in support of the FDA proposal. Dr. Julie Villaneuva from the U.S. Centers for Disease Control and Prevention (CDC) addressed the public health challenges associated with influenza. Dr. Kirsten St. George from Wadsworth Center, New York State Department of Health speaking on behalf of the Association of Public Health Laboratories (APHL) provided data on the usage of the rapid tests in medical practice and the problems for laboratorians and physicians associated with their inadequate clinical performance.

The Panel members had a very robust discussion about the specificity and sensitivity of the currently FDA cleared rapid influenza detection devices and the use of viral culture vs. molecular methods as a comparator in the evaluation of the clinical performance validation of these tests. Much of the discussion was focused on the proposed Special Control that would require the manufacturers to conduct annual analytical performance testing with contemporary strains of influenza virus. The Panel members recommended that the results of such testing become publicly available to inform physicians, laboratorians and other health care providers to enable them to choose the most appropriate rapid influenza tests in preparation for the next flu season. The Panel's consensus was that General Controls alone are not sufficient and that Special Controls are needed to provide a reasonable assurance of safety and effectiveness of rapid influenza detection devices. The Panel unanimously agreed that there is sufficient information to reclassify rapid influenza detection devices from Class I to Class II with Special Controls to provide reasonable assurance of the safety and effectiveness of the rapid influenza detection devices. The Panel agreed that the four Special Controls proposed by FDA are appropriate to include in a new regulation for rapid influenza detection devices currently regulated as Class I devices under 21 CFR 866.3330. Additionally, the Panel members agreed that the Special Controls for the respiratory viral panel multiplex nucleic acid assay regulation (21 CFR 866.3980) should be amended to add an annual performance monitoring requirement for any of these devices with influenza related intended use or indications for use claims.

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