



Brief Summary of the Clinical Chemistry and Clinical Toxicology Devices Panel Meeting – April 25, 2013

Introduction:

The Clinical Chemistry and Clinical Toxicity Devices Panel met on April 25, 2013, to discuss and make recommendations on information related to the classification of three diagnostic devices. In Session I, the panel made recommendations on the appropriate regulatory classification for the diagnostic devices known as methotrexate test systems. During Session II, the panel made recommendations on the appropriate regulatory classification for diagnostic devices known as phencyclidine (PCP) test systems. During Session III, the panel made recommendations on the appropriate regulatory classification for diagnostic devices known as isoniazid test strips. These types of devices are considered pre-Amendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective.

Session I - Methotrexate Test Systems

Methotrexate test systems are currently regulated under the heading of “Enzyme Immunoassay, Methotrexate” (product code LAO) as unclassified devices under the 510(k) premarket notification authority. Methotrexate test systems are for the quantitative measurement of methotrexate. Methotrexate concentrations are used to monitor levels of methotrexate to ensure appropriate drug therapy. The FDA presented the relevant regulatory background, a scientific review of the available literature on methotrexate and the use of methotrexate test systems, and a discussion of the risks and mitigations associated with this type of device.

The panel had a robust conversation regarding key risks to health due to potential false positive and false negative methotrexate test system results. Based on their knowledge and expertise, the panel identified additional risks to health with regards to methotrexate test systems, including concerns regarding potential cross reactivity and assay specificity.

Overall, the panel agreed that Class II (special controls) is an appropriate recommended classification. The panel suggested special controls that may address or mitigate the identified risks to health, including labeling describing cross reactivity with metabolites and concomitant drugs and analytical performance across the measuring range of the device. The panel had a split consensus regarding the recommendation that statements be required in the laboratory test report for this assay describing the potential for overestimation of methotrexate concentration due to metabolite cross reactivity.

Session II - PCP Test Systems

PCP test systems are currently regulated under the heading of “Enzyme Immunoassay, Phencyclidine” (product code LCM), and “Radioimmunoassay, Phencyclidine” (product code LCL), as unclassified devices under the 510(k) premarket notification authority. PCP test systems are for the qualitative detection of PCP in human specimens. The FDA presented the relevant regulatory background, a scientific review of the available literature on PCP test systems, and a discussion of the risks and mitigations associated with this type of device.

The panel had a robust conversation regarding key risks to health due to potential false positive and false negative PCP test system results. Based on their knowledge and expertise, the panel identified the following additional risks to health. The panel discussed the varying impact of false positives or false negative results in the different settings in which these tests are used (e.g., clinical laboratories, emergency departments, and in over the counter settings). The importance of confirmation of screening results was discussed, and the panel was concerned that positive screening results are often not confirmed, even in the clinical setting. The impact of cross reactivity with structurally similar compounds on the reliability and accuracy of these was also discussed.

The panel unanimously recommended that the appropriate classification for PCP test systems is Class II (special controls). The panel suggested special controls that may address or mitigate the identified risks to health, including labeling describing cross reactivity with metabolites and other interferents, and labeling in plain language to ensure more consumer-friendly communication of drug testing issues.

Session III - Isoniazid Test Strips

Isoniazid test strips are currently regulated under the heading of “Strip, Test Isoniazid” (product code MIG) as unclassified devices under the 510(k) premarket notification authority. Isoniazid test strips are a qualitative assay used to detect isonicotinic acid and its metabolites in urine to determine patient compliance with prescribed isoniazid medication. The FDA presented the relevant regulatory background, a scientific review of the available literature on isoniazid and the use of isoniazid test strips, and a discussion of the risks and mitigations associated with this type of device. The panelists in consensus identified no additional risks to health they felt had been omitted with regards to isoniazid test strips than were presented by the FDA.

The panel had a split consensus regarding the appropriate classification of isoniazid test strips. The majority of panel members recommended a Class II classification. They suggested special controls including robust analytical performance standards. A minority of panelists recommended a Class I classification, and that general controls were sufficient to provide a reasonable assurance of safety and effectiveness for these devices. This minority based their recommendation, in part, on the lack of reported safety issues for devices of this type.

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