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BUSINESS WIRE

PharmChem receives FDA market approval for PharmChek sweat patch

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MENLO PARK, Calif.—(BUSINESS WIRE)—July 16, 1995—PharmChem Laboratories Inc. (NASDAQ:PCHM) of Menlo Park, Calif. announced it received market approval from the U.S. Food and Drug Administration (FDA) for its PharmChek sweat patch drug testing system for detecting the use of cocaine, opiates (including heroin), and amphetamines (including methamphetamine). This approval permits PharmChem to introduce PharmChek in all its markets, including for medical use in drug treatment and workplace drug testing programs.

Jay Whitney, PharmChem's president and CEO, stated, "I am extremely pleased to receive FDA clearance to market PharmChek for these three drugs. This clearance supports our ongoing program to introduce this exciting new drug detection technology, which we believe provides a much more cost effective way to detect and deter the use of illegal drugs and alcohol," Whitney said.

"PharmChek is a band-aid type patch device which is worn for a week or more and, when tested in the laboratory, detects the use of illegal drugs while the patch was worn. The tamper-evident design of the patch permits it to be applied to persons providing continuous monitoring of illegal drug use," Whitney explained.

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company in Bethlehem, Penn. In 1992, PharmChem acquired the exclusive worldwide marketing rights for the sweat patch technology for use in testing for drugs of abuse and alcohol.

"PharmChem initiated a pilot program using PharmChek with the Michigan Department of Corrections in December of 1994 and announced the preliminary results of this pilot program earlier this month. We are currently working with other criminal justice agencies to initiate additional pilot programs using the sweat patch and to demonstrate full forensic defensibility of PharmChek results in legal proceedings. This FDA clearance permits us to also initiate pilot programs with public and private employers in employee assistance drug treatment and return-to-work programs. The consequences of a positive drug test are very serious. As a result, PharmChem remains committed to ensuring that the accuracy, reliability and forensic defensibility of the sweat patch are carefully demonstrated before it is marketed," Whitney said.

"This FDA clearance applies to the detection of cocaine, opiates and amphetamines use with the sweat patch. We are currently working to obtain FDA clearance for two additional drugs — marijuana and PCP," Whitney commented.

"PharmChem hopes to gain initial acceptance of PharmChek in the criminal justice and drug treatment markets during 1995. Also, we plan to continue developing other applications of the sweat patch. These other applications include one to continuously monitor the use of alcohol while the patch is worn and one that permits the detection of illegal drug use after the patch has been worn for only 20-30 minutes. This later application is designed as a less costly replacement for urine drug testing in the workplace. We plan to submit these applications for FDA clearance once trials are completed later this year or early next year and to introduce them to the market upon FDA clearance," Whitney stated.

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Fort Worth, Texas, and London.

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