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SPAULDING CLINICAL OFFERS AN EXPERT RESPONSE TO THE BURNING QUESTION: IS YOUR SUNSCREEN SAFE?

Contract Research Organization Behind Maximum Usage Trials Reported in FDA Paper on Active Ingredient Absorption Offers an Opportunity to Get a Jump on Product Testing

WEST BEND, Wis. (May 14, 2019) – Spaulding Clinical Research, the contract research organization tapped by the U.S. Food and Drug Administration to conduct a study on the absorption of active ingredients in sunscreen into the bloodstream, announced today that it is now available to design and execute Maximum Usage Trials (MUsTs) for sunscreen and sunscreen-containing products. The company, which has conducted numerous MUsTs for the pharmaceutical industry, collaborated with the FDA on the design and execution of the sunscreen trial that helped confirm the long-held suspicion about absorption. It has set up a website, www.keepsunscreensafe.com, to provide an overview of the trial, access to the report published in the May 6 issue of *The Journal of the American Medical Association (JAMA)*, as well as details on its innovative, industry-leading research services and contact information for companies interested in testing their products.

The *JAMA* article, "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," covers the first of a two-part Maximum Usage Trial focused on absorption of the active ingredients in four commercially available sunscreens. In this first stage, sunscreen products were applied to 24 healthy volunteers and blood was drawn at regular intervals, providing concrete evidence that the four ingredients – avobenzone, oxybenzone, octocrylene and ecamsule – all were absorbed into the bloodstream. The report drew two important conclusions: Further research is needed to determine the clinical significance of the findings; and individuals should not refrain from using sunscreen based on the results to date.

The FDA's final MUsT Guidance for conducting trials was released on May 9, 2019. According to Cassandra Erato, MSN, ACNP, Chief Operating Officer of Spaulding, however, many producers of sunscreen, sunscreen's active ingredients and products containing sunscreen have not had to conduct such complex trials as the guidance recommends. Spaulding has the capability to design and execute MUsTs for all prescription pharmaceutical and over-the-counter health and beauty products, Erato said, and now has pioneered the process specifically for testing sunscreen.

"We conducted an extensive clinical trial, going beyond what was summarized in the *JAMA* report," she said. "The two-part FDA-designed study includes nearly 1,000 full-body applications and more than 2,300 blood samples drawn from a total of 72 test subjects. This experience, our resources and facilities and our close work with the FDA in every

stage of the process have given us unparalleled expertise in designing and executing trials to help companies comply with the requirements in the OTC Sunscreen Guidance for Industry."

Producers who proactively carry out MUsTs before they are required to do so may also save themselves some time and money in the long run, Erato added. The *JAMA* report notes that "the FDA sunscreen guidance and the proposed rule for OTC sunscreen monograph products note that some non-clinical toxicology studies (i.e., systemic carcinogenicity and additional developmental and reproductive studies) may be waived if results of an adequately conducted human pharmacokinetic Maximum Usage Trial show a steady-state blood level less than 0.5 ng/mL and an adequately conducted toxicology assessment does not reveal any potential safety concerns."
"Right now, there's a bit of the fear of the unknown and a bit of the fear of the known," said Erato. "We've already been approached by companies worried about how to validate their products. We want to tell them, 'We can help you. This is a complex trial, but we know the design protocols and can work hand-in-hand with you to figure this out.'"

For more information on the sunscreen trials, to download the *JAMA* article or to explore conducting a MUsT on your product, visit www.KeepSunscreenSafe.com.

About Spaulding Clinical Research, LLC: Spaulding Clinical Research is a global contract research organization (CRO) based in West Bend, Wisc., providing Phase I – IV drug development services to the biotechnology and pharmaceutical companies. Founded in 2007, Spaulding Clinical operates a 200-bed Clinical Pharmacology Unit, Cardiac Core Laboratory, Clinical Laboratory and provides full Biometrics/Scientific Affairs services. For more information, visit www.spauldingclinical.com or contact us at (262) 334-6020 or info@spauldingclinical.com.

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