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NEWS RELEASE

With U.S. Pharmacopeia's Approval of Chapter <86>, ACC is Positioned to Help More Biotech Companies Reduce Supply Chain Risk and Achieve Sustainability Goals

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On July 26, the U.S. Pharmacopeia (USP) Microbiology Expert Committee approved the inclusion of Chapter <86> *Bacterial Endotoxins Test Using Recombinant Reagents* in the *United States Pharmacopeia–National Formulary,* permitting the use of non-animal-derived reagents for endotoxin testing. With this announcement, pharmaceutical and medical device manufacturers can start transitioning their bacterial endotoxin testing from naturally-sourced BET reagents to recombinant cascade (rCR) and recombinant Factor C (rFC) BET reagents, and begin to integrate this new platform into their quality assurance processes.

"This is a critical milestone in our industry and will have a tremendous positive impact on supply chain robustness and can significantly reduce our reliance on naturally-sourced raw materials enhancing our customers sustainability profiles," said Dr. A.J. Meuse, President and CEO of ACC. "We applaud the USP in establishing rCR and rFC technologies as equally reliable options to ensure the quality and safety in biomanufacturing and are proud to be global leaders for recombinant BET technology during this important transition period."

Since the late 1970s, bacterial endotoxin testing has been based on naturally-sourced Limulus Amebocyte Lysate (LAL), a technology platform pioneered by ACC and adopted by customers worldwide. This traditional method has been the gold standard in Quality Control for pharmaceutical manufacturing, but it relies on horseshoe crab blood as a raw material. With ACC's introduction of PyroSmart NextGen® recombinant Cascade Reagent (rCR) in 2021, non-animal derived BET testing entered a new era with a product featuring greater availability, reliability and robustness as a direct reagent replacement for traditional BET methods. Many QC laboratories were waiting for a formal acceptance within the USP before embarking on a change and incorporating recombinant reagents in their BET QC processes, this announcement by the USP is that acceptance.

PyroSmart NextGen®, a leader among recombinant alternatives to LAL methods, is more reliable and less costly than LAL reagents. Compared to reagents derived from animal products, a supply of synthetic reagents will be less vulnerable to raw material availability with a more sustainable and robust supply chain, helping pharmaceutical and medical device manufacturers respond quickly to emerging threats to human health while decreasing the BET industry's overall impact on the US horseshoe crab population.

ACC looks forward to the possibility of the harmonization of recombinant reagents for bacterial endotoxin testing within the global pharmacopoeias to bring recombinant BET technology into standard practice worldwide.

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About ACC — A Seikagaku Group Company
Specializing in recombinant and traditional chromogenic and turbidimetric reagent technologies, ACC has been a global leader in endotoxin and (1,3)-β-D-glucan detection products and services for 50 years. ACC pioneered modern LAL testing methodology and was the first U.S. FDA-licensed company to manufacture LAL reagents; ACC is today recognized as an international leader in endotoxin detection. Visit www.acciusa.com for more information.

About PyroSmart NextGen® (PSNG)
PyroSmart NextGen® was the first complete recombinant cascade reagent on the market and represents the future of sustainable bacterial endotoxin testing (BET). With the recent approval for the addition of Chapter <86> to the U.S. Pharmacopeia National Formulary, this innovative, sustainable, animal-free solution is positioned to become the new industry standard in BET. PSNG utilizes the same methodology, instrumentation, and software as traditional LAL reagents and seamlessly integrates into existing workflows.

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