In June, the U.S. Pharmacopeia (USP) approved a new chapter providing guidelines for bacterial endotoxin testing that will allow the pharmaceutical industry to move away from traditional assays that depend on horseshoe crab blood in favor of more sustainable testing solutions that use recombinant technology. On November 1, the USP Microbiology Expert Committee published the final text of Chapter 86, which removes a critical barrier for the industry that has hampered use of synthetic alternatives to LAL (Limulus amebocyte lysate) and TAL (Tachypleus amebocyte lysate), reagents derived from horseshoe crabs.

We are writing to request your participation in an important survey that will track industry progress in transitioning toward synthetic endotoxin testing solutions. As one of the 50 largest pharmaceutical companies in the world, your company's survey results will be published publicly as part of the Sustainability Scorecard for Endotoxin Testing. The Sustainability Scorecard measures, tracks, and highlights the positive efforts being made by companies that are in the process of transitioning to sustainable synthetic alternatives for endotoxin testing in vaccines and injectable biologics.

The survey asks questions about your company's endotoxin testing methodologies and your plans to transition to synthetic alternatives. Each question is weighted. The total number of points that your company earns on the survey corresponds to a sustainability rating. Your total points and sustainability rating will appear on the Sustainability Scorecard with other pharmaceutical companies. The more points, the higher your rating.

The Scorecard will be updated periodically to allow companies to increase their score and highlight their progress as they move along the continuum to full adoption of synthetic alternatives.

Now more than ever, there is a growing need to scale up resources for endotoxin reagents without relying on an animal-derived product (given the rapid increase in injectable medications and vaccines). The American horseshoe crab is already listed by the International Union for the Conservation of Nature as a Vulnerable species, while the Asian tri-spined horseshoe crab is now considered Endangered. About 1.1 million American horseshoe crabs are bled every year for biomedical purposes, and it is estimated that up to 30 percent of the animals die during this process.

Companies are beginning to make the switch.

A search of public records indicates that at least six global pharmaceutical companies, including Eli Lilly, Pfizer, BMS, Sanofi, Roche/Genentech, and Takeda, have begun or announced plans to transition from the traditional LAL test to recombinant Bacterial Endotoxin Testing (rBET) solutions. Others, such as AstraZeneca and GSK, have committed to substantially reducing their use of horseshoe crab blood in the coming years.

The Sustainability Scorecard is a joint initiative from a coalition of pharmaceutical companies and conservation groups including Revive & Restore, the Horseshoe Crab Recovery Coalition (HCRC), and the Center for Biological Diversity.

We kindly request that a company representative complete the secure survey by February 1, 2025. Survey results, including your company's sustainability rating, will be available to the public at www.pharmascore.org beginning in February.

Your input will help us track industry progress in transitioning toward a more sustainable and reliable method of endotoxin testing that does not compromise the safety of patients that depend on the life-saving products you provide.

Thank you in advance for your consideration. We look forward to highlighting your leadership in this area.