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U.S. Pharmacopeia

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Comments Regarding Proposed Chapter 86: Bacterial Endotoxins Test Using Recombinant Reagents

As members of the Horseshoe Crab Recovery Coalition, we are writing to express our support for the adoption of Chapter 86, and to suggest several ways to strengthen the proposal to expedite industry use of recombinant agents in endotoxin testing.

The use of horseshoe crabs for biomedical purposes has exploded in recent years. Nearly a million crabs are now being bled each year for this purpose. It is estimated that up to 30 percent die during the process, meaning that hundreds of thousands of preventable deaths could be avoided with greater use of synthetic reagents.

With that in mind, we applaud the work of the Microbiology Expert Committee in developing this new proposal. It would provide a reliable and sustainable source for endotoxin testing material that does not use the blood of a wild animal. Further, based on real-world evidence with medicines already on the market, the recombinant agents have been shown to be as good as, or better, than traditional testing using limulus amebocyte lysate (LAL).

Our coalition consists of approximately 50 healthcare, conservation, and business organizations with international constituencies. We base our advocacy on healthcare needs and sound science in addition to conservation and animal protection interests.

While the new recommendation is an important step forward, our coalition believes that several actions could strengthen it further.

First, we believe there is a need for a bridge between Chapters 85 and 86 that would clearly position the recombinant tests on level footing with LAL, removing all obstacles to using the recombinant reagents in testing existing medicines as well as newly marketed products.

Second, with USP joining compendial organizations in Europe, Japan, and other nations in recognizing the new recombinant reagents, there is a need to move rapidly toward harmonization to establish a common global testing standard. We urge the USP to take a lead in this effort.

Finally, we would encourage the USP to expedite the process of adopting the new chapter to facilitate earlier adoption by companies that want to convert to recombinant reagents prior to November 2024.

One leading biopharmaceutical manufacturer, Eli Lilly, now uses rFC in eight of its manufacturing sites and for all its injectable products. Several other companies have announced their intent to transition once the USP includes recombinants as compendial methods. Granting compendial status would expedite this process by removing multiple barriers to greater adoption of an important scientific advance.

We urge the USP to act with sound science, conservation and the 3R principles in mind in adopting Chapter 86 with a bridge to the existing Chapter 85.

Signed,

American Bird Conservancy
American Littoral Society
Audubon Mid-Atlantic
Audubon South Carolina
Birds Georgia (formerly Georgia Audubon)
Center for Biological Diversity
Charleston Natural History Society
Delaware Audubon
Delaware Riverkeeper Network
Defenders of Wildlife
Forest Keeper
Humane Society of the United States
League of Women Voters of New Jersey
Maryland Ornithological Society
National Audubon Society
National Wildlife Federation
North Carolina Wildlife Federation
New Jersey Audubon
New York City Audubon
Physicians Committee for Responsible Medicine
Return the Favor
Revive and Restore
Save Coastal Wildlife
Shark River Cleanup Coalition
Wetlands Institute
Wildlife Restoration Partnerships