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Singapore: The US Food and Drug Administration (FDA) has accepted Australia-based CSL Behring's biologics license application for standard review. The application is for a human 4-factor prothrombin complex concentrate (PCC) for the urgent reversal of vitamin K-antagonist therapy (warfarin) in patients with acute major bleeding.

If approved by FDA, the CSL Behring 4-factor PCC would be the first agent of its kind available in the US.

"The acceptance of this application by the FDA of this 4-factor PCC marks an important step toward addressing the urgent unmet need for a rapid and simple way to reverse the effects of warfarin during bleeding emergencies," said Val Romberg, senior vice president, Research and Development at CSL Behring. "This 4-factor PCC has the potential to be a significant new tool in stopping excessive bleeding in patients on warfarin, where fresh frozen plasma is the current standard of care."

The CSL Behring BLA submission is based on results from three prospective Phase III clinical trials that evaluated the safety and efficacy of PCC in patients who required urgent reversal of warfarin therapy.