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FDA to review Pfizer's meningococcal disease drug

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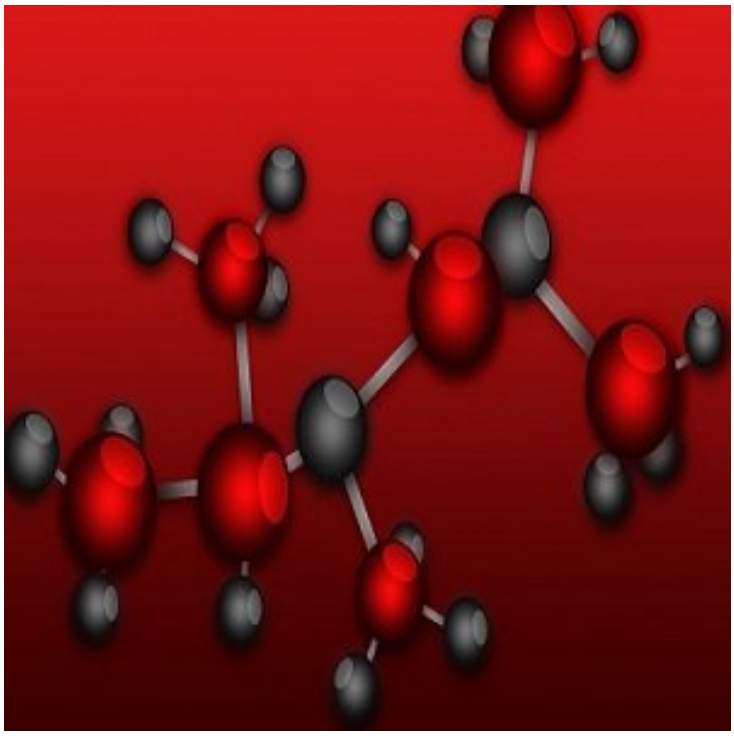

Singapore: Global pharmaceutical firm, Pfizer, has recieved US Food and Drug Administration (FDA) nod for review of Biologics License Application (BLA) for bivalent recombinant LP2086 (rLP2086), the company's vaccine candidate for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroup.

FDA has also granted priority review designation for the BLA, providing an anticipated Prescription Drug User Fee Act (PDUFA) action date of February 14, 2015.

"Pfizer has closely collaborated with the FDA since 2008 to develop our meningococcal B vaccine candidate with the intent to help prevent this devastating disease," said Dr Emilio Emini, senior vice president, Vaccine Research and Development, Pfizer. "Both the acceptance of Pfizer's Biologics License Application and its Priority Review designation, are significant regulatory milestones that underscore the importance of our efforts to expedite the approval and subsequent availability of our meningococcal B vaccine for US adolescents."