

FDA approves GSK meningococcal vaccine

15 June 2012 | News | By BioSpectrum Bureau

FDA approves GSK meningococcal vaccine



Singapore: The US Food and Drug Administration (FDA) has approved GlaxoSmithKline's vaccine MenHibrix (meningococcal groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine).

MenHibrix is a vaccine indicated to prevent invasive disease caused by *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b. MenHibrix is approved for use in children aged six weeks through 18 months.

"All of us at GSK Vaccines look at today's approval as a good day for infants, toddlers and healthcare providers," said Dr Leonard Friedland, vice president, head, Clinical and Medical Affairs, North America Vaccine Development, GSK Vaccines. "MenHibrix gives healthcare providers the option of combining Hib immunization with meningococcal C and Y immunization without increasing the number of shots for infants and toddlers."

The basis for FDA approval of MenHibrix included data that GSK submitted from clinical trials conducted in the US, Mexico, Australia, Belgium and Germany over seven years in which 7,521 infants and toddlers received at least one dose of Men.