BOOSTRIX®
[Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)]

Whooping Cough (Pertussis) Booster Vaccine for Adolescents and Adults

- BOOSTRIX® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)], manufactured by GlaxoSmithKline (GSK), is a booster vaccine approved for use in the U.S. to be given as a single dose to individuals 10-64 years of age to help prevent three serious diseases: tetanus (lockjaw), diphtheria and pertussis (whooping cough).

- BOOSTRIX adds whooping cough protection to the tetanus and diphtheria booster (Td vaccine) already recommended for adults and adolescents. BOOSTRIX offers protection to individuals 10-64 years of age, the broadest age range for any Tdap vaccine.

About Whooping Cough, Diphtheria, Tetanus

- Whooping cough, also known as pertussis, is a serious and highly contagious respiratory disease characterized by severe coughing fits. Whooping cough may lead to complications such as pneumonia or rib fracture in adolescents and adults. The illness may last for more than 100 days and can lead to lost time at work or school.

- Diphtheria is a respiratory disease that affects the tonsils and the throat. It is usually spread from person-to-person when an infected person coughs or sneezes. It can lead to breathing problems, heart problems, paralysis and even death.

- Tetanus (lock jaw) is a bacterial disease which can cause muscle stiffness and spasms, often starting in the muscles of the jaw and neck. Severe tetanus can lead to death. Tetanus enters the body through cuts, scratches or wounds in the skin.

Proven Safety and Immunogenicity

- Clinical trials, involving approximately 4,000 healthy 10-18 year olds who received either one dose of BOOSTRIX or a U.S.-licensed Td vaccine, demonstrated BOOSTRIX to be comparable to the Td vaccine with regard to overall safety and immunogenicity.

- BOOSTRIX has also been thoroughly studied in two clinical trials involving nearly 3,000 U.S. subjects 19-64 years of age. These studies demonstrate the overall safety and immunogenicity of BOOSTRIX in providing booster protection against tetanus, diphtheria and whooping cough in adults.
  - Data show that there was a lower incidence of pain, redness and swelling with administration of BOOSTRIX compared to the other available Tdap vaccine.
  - In another study, BOOSTRIX was given alone or co-administered with Fluarix, an influenza vaccine manufactured by GSK. The study demonstrated that co-administration did not compromise the immunogenicity or safety of either vaccine.

Important Safety Information
In clinical studies, common adverse events were injection-site reactions (pain, redness, swelling, or increase in arm circumference), headache, fatigue, and gastrointestinal symptoms. Severe allergic reaction after a previous dose of BOOSTRIX or encephalopathy within 7 days of a previous pertussis antigen-containing vaccine is a contraindication. The decision to give BOOSTRIX should be based on benefits and risks if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior tetanus toxoid-containing vaccine, or if progressive or unstable neurologic disorders exist. Persons who experienced an Arthus-type hypersensitivity reaction following a previous dose of tetanus toxoid-containing vaccine should not receive BOOSTRIX unless 10 years have elapsed. The prefilled syringes contain dry natural latex rubber that may cause allergic reactions.

GSK: A Worldwide Leader in Vaccines
The approval of BOOSTRIX in adults expands the GSK Vaccines portfolio, making it the only company in the country to offer a full line of vaccines to protect adults from pertussis, hepatitis A & B and flu. GSK markets over 25 vaccines worldwide to prevent potentially life-threatening or crippling illnesses such as hepatitis A, hepatitis B, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio, typhoid, influenza and bacterial meningitis.