The U.S. Food and Drug Administration recently approved Menhibrix, a combination vaccine for infants and children ages 6 weeks through 18 months, for prevention of invasive disease caused by Neisseria meningitidis serogroups C and Y and Haemophilus influenzae type b.

Diseases caused by the bacteria Neisseria meningitidis (meningococcal disease) and Haemophilus influenzae type b (Hib disease) can be life-threatening. These bacteria can infect the bloodstream causing sepsis, and the lining that surrounds the brain and spinal cord causing meningitis. In young children, Neisseria meningitidis and Haemophilus influenzae type b are important causes of bacterial meningitis.

Without vaccination, children younger than two years are susceptible to these serious illnesses. Meningococcal and Hib diseases are particularly dangerous because both diseases often progress rapidly and can cause death or serious, long-lasting health consequences such as blindness, mental retardation, or amputations. Early symptoms for both diseases often are difficult to distinguish from other common childhood illnesses.

“With the approval of Menhibrix, there is now a combination vaccine that can be used to prevent potentially life-threatening Hib disease and two types of meningococcal disease in children. It is the first meningococcal vaccine that can be given starting as young as six weeks of age,” said Karen Midthun, M.D., director of the FDA’s Center for Biologics Evaluation and Research.

The effectiveness of Menhibrix was based on immune responses in several hundred U.S. infants and toddlers vaccinated with Menhibrix. For the Hib component of the vaccine, immune responses in infants and toddlers following vaccination with Menhibrix were comparable to immune responses in infants and toddlers who received an FDA-approved vaccine against invasive Hib disease.

For the meningococcal component, study results showed that the vaccine produces antibodies in the blood at levels that are considered to be predictive of protection against invasive meningococcal disease caused by serogroups C and Y.

The safety of Menhibrix was evaluated in about 7,500 infants and toddlers in the U.S., Mexico and Australia. Common adverse reactions reported after administration of Menhibrix were pain, redness and swelling at the injection site, irritability and fever.

Menhibrix is given as a four-dose series at 2, 4, 6 and 12 through 15 months of age. The first dose may be given as early as 6 weeks of age. The fourth dose may be given as late as 18 months of age.

Menhibrix is manufactured by GlaxoSmithKline Biologicals, based in Rixensart, Belgium.

SOURCE: FDA