Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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New Vaccine Approval – Dengue Tetravalent Vaccine, Live
(Dengvaxia)

Dengue disease is a major global public health concern and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands.

On May 1, 2019, the FDA approved Dengvaxia for the prevention of dengue disease caused by all dengue virus serotypes (1, 2, 3 and 4) in people ages 9 through 16 who have laboratory-confirmed previous dengue infection and who live in endemic areas.

Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown.

Health care professionals should evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.

The safety and effectiveness of the vaccine was determined in three randomized, placebo-controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America and the Asia Pacific region.