

Notice to Readers: FDA Approval of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, (INFANRIX®) for Fifth Consecutive DTaP Vaccine Dose



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On July 8, 2003, the U.S. Food and Drug Administration (FDA) approved the use of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) (INFANRIX[®], SmithKline Beecham Biologicals, Rixensart, Belgium) as a fifth dose for children aged 4--6 years after 4 previous doses of INFANRIX[®]. INFANRIX[®] had been previously approved for the first 4 doses in the DTaP vaccination series. Sufficient data are now available to establish the frequency of adverse events after a fifth dose of INFANRIX[®] at age 4--6 years in children who have received 4 previous doses of INFANRIX[®] (1).

The frequency of local injection site reactions (erythema and swelling) increases with successive doses of INFANRIX[®] (1). In two German studies, 93 and 390 children, respectively, received a fifth dose of INFANRIX[®] at age 4--6 years after 4 previous doses of INFANRIX[®]. Among solicited adverse events, swelling ≥ 5 cm (2 inches) in the injected limb within the 3 days after vaccination was reported in 15% and 20% of the vaccinees, respectively (1). Extensive swelling of the injected limb was reported spontaneously by parents of nine (9.7%) and 25 (6.4%) vaccinees, respectively, in these two studies (1).

The Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, and the American Academy of Family Physicians recommend that children routinely receive a series of 5 doses of vaccine against diphtheria, tetanus, and pertussis before age 7 years. ACIP recommends that the first 4 doses be administered at ages 2, 4, 6, and 15--18 months and the fifth dose at age 4--6 years (2--4).

Data are limited on the safety, immunogenicity, and efficacy of using DTaP vaccines from different manufacturers for successive doses of the DTaP series. ACIP recommends that, whenever feasible, the same brand of DTaP should be used for all doses of the series but that vaccination should not be deferred because the type of DTaP used for previous doses is not available or is unknown. In such situations, any of the available licensed DTaP vaccines can be used to continue or complete the series (3,4).

References

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