



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

1. SmithKline Beecham Biologicals. INFANRIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) Prescribing information. SmithKline Beecham Biologicals, Rixensart, Belgium, July 2003.
2. CDC. Recommended childhood immunization schedule—United States, 2003. MMWR 2003;52: Q1-Q4.
3. CDC. Pertussis vaccination: use of acellular pertussis vaccine among infants and young children—recommendations of the Advisory Committee on Immunization Practices. MMWR 1997;46(No. RR-7).
4. CDC. Use of diphtheria toxoid-tetanus toxoid-acellular pertussis vaccine as a five-dose series; supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000; 49(No. RR-13).

Recommended Adult Immunization Schedule—United States, 2003-2004

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IN JUNE 2003, THE ADVISORY COMMITTEE on Immunization Practices (ACIP) approved the revised Adult Immunization Schedule for 2003-2004. The for-

mat has been revised to better represent the schedule's two components, by age group and by medical condition (Figures 1 and 2) and better indicate how the footnotes apply to both figures.

Revisions to the schedule and footnotes include (1) additional information regarding use of tetanus-diphtheria toxoids as prophylaxis in wound management; (2) clarification regarding the number of doses of the measles component of the measles-mumps-rubella vaccine; (3) guidance regarding the use of intranasally administered, live, attenuated influenza vaccine for healthy persons aged 5-49 years; (4) recommendations regarding administering influenza vaccination to pregnant women with or without pre-existing chronic diseases or conditions; and (5) added information regarding influenza and consideration of *Haemophilus influenzae* type b vaccine for asplenic persons.

Two measures initiated by the Centers for Medicare and Medicaid Services (CMS) are expected to increase vaccination among Medicare and Medicaid beneficiaries. First, in 2002, CMS enacted a new regulation allowing for the use of standing orders at Medicare- and Medicaid-participating hospitals, long-term-care facilities, and home-health agencies to deliver influenza and pneumococcal vaccinations¹ as recommended by ACIP² and the Task Force on Community Preventive Services.³ Second, CMS increased reimbursement rates for administering hepatitis, influenza, and pneumococcal vaccines from a national average of \$3.98 in 2002 to \$7.72 in 2003.⁴ In addition, expansion of the National Committee for Quality Assurance's Health Plan Employer Data and Information Set to include quality indicators on influenza vaccinations for persons aged 50-64 years in 2001 and pneumococcal vaccinations for persons aged ≥ 65 years in 2002 might improve vaccination-delivery services at managed-care organizations.^{5,6}