DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 1980N-0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule and final order that appeared in the Federal Register of January 5, 2004 (69 FR 255). The document amended the biologics regulations and categorized certain biological products licensed before July 1, 1972, based on their safety, effectiveness, and labeling. The document was published with some typographical errors in the reference section. This document corrects those errors.

DATES: Effective [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-32255, appearing on page 255, in the Federal Register of January 5, 2004, the following corrections are made:

1. On page 265, in the third column, the second reference is corrected to read "Lois M. Joellenbeck, Lee L. Zwanziger, Jane S. Durch, and Brian L. Strom, Editors, Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, Medical Follow-Up Agency, The National Academies Press, "cb041"
Washington, DC, April 2002, http://www.nap.edu/catalog/10310.html (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register)."


4. On page 266, in the first column, the fifth reference is corrected to read "Ivins, B. E.; M. L. M. Pitt; P. F. Fellows; J. W. Farchaus; G. E. Benner; D. M. Waag; S. F. Little; G. W. Anderson, Jr.; P. H. Gibbs; and A. M. Friedlander, 'Comparative Efficacy of Experimental Anthrax Vaccine Candidates Against Inhalation Anthrax in Rhesus Macaques,' Vaccine, 16(11/12):1141–1148, 1998."

5. On page 266, in the first column, the seventh reference is corrected to read "Wright, G. G.; Green, T. W.; and Kanode, Jr., R. G., 'Studies on Immunity in Anthrax: V. Immunizing Activity of Alum-Precipitated Protective Antigen,' Journal of Immunology, 73:387–391, 1954."
6. On page 266, in the first column, the tenth reference is corrected to read "'Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)', September 1998, http://www.fda.gov/cber/gdlns/vaers-1.pdf. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register)."

7. On page 266, in the first column, the eleventh reference is corrected to read "'Estimated Vaccination Coverage With 3+DTP Among Children 19–35 Months of Age by Race/Ethnicity,' and by State and Immunization Action Plan Area—U.S., National Immunization Survey, Q3/2000 - Q2/2001, http://www.cdc.gov/nip/coverage/NIS/00-01/tab19-3dpt_race_iap.htm. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register)."

8. On page 266, in the second column, the twelfth reference is corrected to read "'Protecting Our Kids: What Is Causing the Current Shortage in Childhood Vaccines?—Testimony Before the Committee on Governmental Affairs, United States Senate, June 12, 2002, http://www.cdc.gov/nip/news/testimonies/vac-shortages-walt-6–12–2002.htm. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register)."
Dated: 2/5/04

[Signature]

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-???? Filed ??-??-04; 8:45 am]

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