



Food and Drug Administration
1401 Rockville Pike
Rockville, Maryland 20852

Memorandum

*Rec'd 3/3/05
JLB*

Date March 3, 2005

From Supervisory Regulatory Counsel, Regulations and Policy Staff, Office of the Center Director, Center for Biologics Evaluation and Research

Subject Memorandum regarding Adverse Events Following Anthrax Vaccine Reported to the Vaccine Adverse Event Reporting System

To Division of Dockets Management (HFA-305)

Please replace in Docket No. 1980N-0208 the 12/20/2004 version of the memorandum referenced above with the 12/22/2004 version. The 12/22/2004 memorandum is part of reference seven in the proposed rule and proposed order, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review (69 FR 78281, December 29, 2004). Reference seven of the proposed rule and proposed order reads, "Reports and evaluation of reports of adverse events following administration of anthrax vaccine received by the Federal Vaccine Adverse Event Reporting System (VAERS) through November 2004."


Kathleen Swisher

80N-0208

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