

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 201 and 610**

[Docket No. 1980N-0208]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 5, 2004 (69 FR 255), a final rule and final order (January 2004 final rule and final order) amending the biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and

Toxoids with Standards of Potency. On January 8, 2004 (69 FR 1320), a correction document was published to correct the effective date from "January 4, 2003", to "January 4, 2005." On February 13, 2004 (69 FR 7114), FDA issued a correction document to correct typographical errors in the reference section of the January 2004 final rule and final order.

On October 27, 2004, the United States District Court for the District of Columbia (the Court) issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. Because the January 2004 final rule and final order were vacated by the Court, FDA is withdrawing the January 2004 final rule and final order.

In a proposed rule and proposed order published concurrently with this document, FDA is providing notice and an opportunity to comment on the

Bacterial Vaccine and Toxoids efficacy review.

DATES: The final rule and final order published at 69 FR 255 (January 5, 2004), is withdrawn as of December 29, 2004.

FOR FURTHER INFORMATION CONTACT:

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AUTHORITY: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the final rule and final order published on January 5, 2004 (69 FR 255) is withdrawn.

Dated: December 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-28459 Filed 12-23-04; 11:16 am]

BILLING CODE 4160-01-S