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## ***FDA Statement***

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Statement  
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### **FDA Issues Final Rule and Final Order Regarding Safety and Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine**

To complete the review of the safety and effectiveness of certain bacterial vaccines and toxoids licensed before July, 1972, FDA today issued a final rule and order that makes final determinations concerning the safety and effectiveness of such products and amends certain biologics regulations. The final order states FDA's conclusion that the licensed anthrax vaccine, Anthrax Vaccine Adsorbed, is safe and effective for the prevention of anthrax disease - regardless of the route of exposure.

The process of finalizing this rule and order has taken considerable time, as is true with all such documents. Although a District of Columbia Federal Court issued an injunction regarding the anthrax vaccine and its legal status as an approved product recently, FDA made its determinations regarding the anthrax vaccine, as reflected in the final order, long before the court's ruling.

Expert panels were assigned the task of reviewing information on biological products that were licensed under the Public Health Service Act before 1972 when the responsibility for licensing biological products was moved from the National Institutes of Health to the FDA. Based upon their review of the available data, the Expert Panel recommended that the anthrax vaccine, originally licensed in 1970, be classified as a Category I product, meaning that it was safe and effective as it was labeled. The panel recommended that it continue to be licensed on the basis of the evidence of its safety and effectiveness. These findings were originally published in the *Federal Register* on December 13, 1985.

FDA agreed with the Expert Panel's general recommendation categorizing the vaccine at that time and continues to support that conclusion in this final rule and order.

FDA's final order states that the efficacy analysis in the controlled clinical trial demonstrating the efficacy of the vaccine includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease. Although there were too few inhalation anthrax cases to support an independent statistical analysis, due to the rarity of this method of exposure during the period of time that the study was performed, FDA noted in the final rule that all of the cases of inhalation anthrax that occurred were in unvaccinated individuals. Therefore, the FDA-approved labeling for the anthrax vaccine does not specify the route of exposure, and the vaccine is indicated for active immunization against *Bacillus anthracis*, independent of the route of exposure. (<http://www.fda.gov/cber/products/biopava0131021.htm>)

Also, the Institute of Medicine recently conducted an independent review of the licensed anthrax vaccine (<http://www.nap.edu/books/0309083095/html/>) and concluded that it was a safe and effective vaccine to protect humans against anthrax, including inhalation anthrax. The Expert Panel that reviewed the licensed anthrax vaccine and other bacterial vaccines and toxoids that had been licensed before 1972 also, as part of its review, classified these products into one of the following categories: Category I - safe, effective and not misbranded; Category II - unsafe, ineffective or misbranded; or Category III - insufficient information, further testing required. The FDA focused its resources initially in addressing those products in category II and III because these posed the greatest potential public health harm. FDA has been working on removing such products from the market and updating the labeling of other products based on the Agency's determinations after the panels' recommendations.

More information about the Panel's report and FDA's conclusions regarding the anthrax vaccine and other products under review can be found soon at

<http://www.accessdata.fda.gov/scripts/oc/ohrms/advisdisplay.cfm>.

A recent ruling by a United States District Court for the District of Columbia gave the opinion that the anthrax vaccine should be classified as "investigational" with regard to protecting against inhalation anthrax. Today's final rule and order make it clear that FDA does not regard the approved anthrax vaccine as "investigational" for protection against inhalation anthrax. FDA's final determination of the safety and effectiveness of the anthrax vaccine, independent of route of exposure, as well as its conclusions regarding the Expert Panel's report, being announced today in the final order, are relevant and should be considered in any further litigation in this matter.

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