VACCINE SAFETY -DEFINITION

Safety, as defined in the biologics regulation, is:

"the relative freedom from harmful effect to the persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." (21 CFR 600.3).



Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases