

Food and Drug Administration

(Docket No. 78D-04381)

Adsorbed Diphtheria and Tetanus Toxoids;
Availability of Guideline

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The agency announces the availability of a guideline for interpretation of potency test results for all forms of adsorbed diphtheria and tetanus toxoids.

ADDRESS: Written comments may be submitted to the hearing Clerk (HFA-305 Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Iris Hyman, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20014. 301-448-1306.

SUPPLEMENTARY INFORMATION: The guideline prepared by the Bureau of Biologics covers potency tests performed on all forms of adsorbed diphtheria and tetanus toxoids, including Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, Diphtheria and Tetanus Toxoid Adsorbed, Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use), and Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. Adsorbed toxoids are the insoluble, precipitated form of the soluble, parent toxoid. Both forms are used in the prevention of the diseases diphtheria and tetanus.

Currently, the only guidelines controlling these products are minimum requirements, each of which gives slightly different wording for the potency tests performed on all forms of the adsorbed toxoids. This has led to confusion and to a variety of interpretations by manufacturers. The new guideline is intended to clarify the definition of a valid potency test endpoint to ensure standardization of performance and reporting of potency test results on protocols for release. Because of the brevity of the guideline it is reproduced in this notice, as follows:

Biological Products

GUIDELINE FOR INTERPRETATION OF POTENCY TEST RESULTS FOR ALL FORMS OF ADSORBED DIPHThERIA AND TETANUS TOXOIDS

For a valid potency test, each control animal must die in less than 96 hours. For the lot to pass, each test animal must survive for more than 96 hours at the minimum unit level required.

Copies of the guideline are being furnished to all licensed manufacturers of adsorbed tetanus and diphtheria toxoids. Other persons interested in obtaining copies of the minimum requirements, as amended, and guideline may contact the office of the Hearing Clerk, Food and Drug Administration, at the above address.

* * * * *

(FR Doc. 79-11451 Filed 4-12-79; 8:45 am)