

## §610.19

the applicable provisions of §§211.188 and 211.194 of this chapter.

(Approved by the Office of Management and Budget under control number 0910-0139)

[38 FR 32056, Nov. 20, 1973, as amended at 51 FR 44453, Dec. 10, 1986; 55 FR 11013, Mar. 26, 1990]

### §610.19 Status of specific products; Group A streptococcus.

The presence of Group A streptococcus organisms and derivatives of Group A streptococcus in Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency" may induce dangerous tissue reactions in humans. Available data demonstrate that they are unsafe as ingredients in products for human use. Group A streptococcus organisms and derivatives of Group A streptococcus are prohibited from Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency." Any Bacterial Vaccine or Bacterial Antigen with "No U.S. Standard of Potency" containing Group A streptococcus organisms or derivatives of Group A streptococcus in interstate commerce is in violation of section 351 of the Public Health Service Act (42 U.S.C. 262).

[44 FR 1549, Jan. 5, 1979]

## Subpart C—Standard Preparations and Limits of Potency

### §610.20 Standard preparations.

Standard preparations made available by the Center for Biologics Evaluation and Research shall be applied in testing, as follows:

(a) *Potency standards.* Potency standards shall be applied in testing for potency all forms of the following:

#### ANTIBODIES

Botulism Antitoxin, Type A.  
Botulism Antitoxin, Type B.  
Botulism Antitoxin, Type E.  
Diphtheria Antitoxin.  
Histolyticus Antitoxin.  
Oedematiens Antitoxin.  
Perfringens Antitoxin.  
Antipertussis Serum.  
Antirabies Serum.  
Sordellii Antitoxin.  
Staphylococcus Antitoxin.  
Tetanus Antitoxin.  
Vibriion Septique Antitoxin.

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#### ANTIGENS

Cholera Vaccine, Inaba serotype.  
Cholera Vaccine, Ogawa serotype.  
Diphtheria Toxin for Schick Test.  
Pertussis Vaccine.  
Tuberculin, Old.  
Tuberculin, Purified Protein Derivative.  
Typhoid Vaccine.

#### BLOOD DERIVATIVE

Thrombin.

(b) *Opacity standard.* The U.S. Opacity Standard shall be applied in estimating the bacterial concentration of all bacterial vaccines. The assigned value of the standard when observed visually is 10 units. The assigned value of the standard when observed with a photometer is (1) 10 units when the wavelength of the filter is 530 millimicrons, (2) 10.6 units when the wavelength of the filter is 650 millimicrons, and (3) 9 units when the wavelength of the filter is 420 millimicrons.

[38 FR 32056, Nov. 20, 1973, as amended at 41 FR 10429, Mar. 11, 1976; 41 FR 18295, May 3, 1976; 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

### §610.21 Limits of potency.

The potency of the following products shall be not less than that set forth below and products dispensed in the dried state shall represent liquid products having the stated limitations.

#### ANTIBODIES

Diphtheria Antitoxin, 500 units per milliliter.  
Tetanus Antitoxin, 400 units per milliliter.  
Tetanus Immune Globulin (Human), 50 units of tetanus antitoxin per milliliter.

#### ANTIGENS

Cholera Vaccine, 8 units each of Inaba and Ogawa serotype antigens per milliliter.  
Pertussis Vaccine, 12 units per total human immunizing dose.  
Typhoid Vaccine, 8 units per milliliter.

[41 FR 10429, Mar. 11, 1976, as amended at 41 FR 18295, May 3, 1976]

## Subpart D—Mycoplasma

### §610.30 Test for Mycoplasma.

Except as provided otherwise in this subchapter, prior to clarification or filtration in the case of live virus vaccines produced from in vitro living cell cultures, and prior to inactivation in