

## SUBCHAPTER E—VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; ORGANISMS AND VECTORS

### PART 101—DEFINITIONS

Sec.

- 101.1 Applicability.
- 101.2 Administrative terminology.
- 101.3 Biological products and related terms.
- 101.4 Labeling terminology.
- 101.5 Testing terminology.
- 101.6 Cell cultures.
- 101.7 Seed organisms.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 8426, Apr. 2, 1973, unless otherwise noted.

#### § 101.1 Applicability.

When used in parts 101 through 117 of this subchapter, the meaning of the words and phrases listed shall be as defined in this part.

#### § 101.2 Administrative terminology.

The following administrative words and phrases shall mean:

*Adjacent herd.* Adjacent herds are herds physically contiguous to the herd of origin; there are no herds between an adjacent herd and the herd of origin.

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

*Animal and Plant Health Inspection Service.* The agency in the Department of Agriculture responsible for administering the Virus-Serum-Toxin Act.

*Biological products.* The term *biological products*, also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term “biological products” includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids,

immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term *analogous products* shall include:

(i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or

(ii) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term *treatment* shall mean the prevention, diagnosis, management, or cure of diseases of animals.

*Department.* The U.S. Department of Agriculture.

*Distributor.* A person who sells, distributes, or otherwise places in channels of trade, one or more biological