

CHAPTER 6

BIOLOGICAL PRODUCTS FOR DIAGNOSTIC OR THERAPEUTIC PURPOSES

Authority

N.J.S.A. 4:1-11, 4:5-104, and 4:5-108.

Source and Effective Date

Effective: October 26, 2017.
See: 49 N.J.R. 3588(a).

Chapter Expiration Date

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, expires on October 26, 2024.

Chapter Historical Note

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was filed and became effective prior to September 1, 1969.

Pursuant to Executive Order No. 66(1978), Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was readopted as R.1983 d.453, effective September 29, 1983. See: 15 N.J.R. 1205(b), 15 N.J.R. 1754(c).

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was repealed and Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was adopted as new rules by R.1985 d.448, effective September 3, 1985. See: 17 N.J.R. 1617(a), 17 N.J.R. 2102(a). Pursuant to Executive Order No. 66(1978), Chapter 6 expired on September 3, 1990.

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was adopted as new rules by R.1995 d.83, effective February 6, 1995. See: 26 N.J.R. 3784(a), 27 N.J.R. 481(a). Pursuant to Executive Order No. 66(1978), Chapter 6 expired on February 6, 2000.

Pursuant to Executive Order No. 66(1978), Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was adopted as new rules by R.2000 d.225, effective June 5, 2000. See: 32 N.J.R. 734(a), 32 N.J.R. 2045(b).

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was readopted as R.2005 d.325, effective August 26, 2005. See: 37 N.J.R. 2162(a), 37 N.J.R. 3809(a).

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was readopted as R.2011 d.071, effective January 28, 2011. See: 42 N.J.R. 1933(a), 43 N.J.R. 389(a).

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was scheduled to expire on January 28, 2018. See: 43 N.J.R. 1203(a).

Chapter 6, Biological Products for Diagnostic or Therapeutic Purposes, was readopted, effective October 26, 2017. See: Source and Effective Date.

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SUBCHAPTER 1. BIOLOGICAL LICENSING

2:6-1.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Accredited veterinarian” means any licensed Doctor of Veterinary Medicine who has fulfilled the requirements for Federal and State accreditation, pursuant to 9 C.F.R. §§ 160.1 et seq. in the State of New Jersey.

“Biological product” or “biologic,” “biological” and “biological drug” mean any product utilizing virus (whether active or inactive) or any molecular part thereof, bacteria or any genetic equivalent thereof, or toxin as its basic component, or any product derived from the serum of any other animal, in the diagnosis (diagnostic biologic) or prevention (prophylactic biologic) of animal disease. This includes any and all products covered by the Animal Virus, Serum, and Toxin Act, 21 U.S.C. §§ 151 et seq., and the regulations issues pursuant thereto, 9 C.F.R. §§ 101.1 et seq.

“Diagnostic biologic” means a preparation of bacterial, viral or parasitic agents, products, factions, serums, or fractions of serums utilized to determine experience with a disease causing agent.

“Director” means the Director, Division of Animal Health, New Jersey Department of Agriculture.

“Distribution” means the preparation, sale, barter, exchange, or giving away of any regulated product.

“Domestic animal” means any and all animals other than humans.

“Licensed veterinarian” means a Doctor of Veterinary Medicine licensed by the New Jersey Board of Veterinary Medical Examiners, pursuant to N.J.S.A. 45:16-1 et seq., and the rules issued pursuant thereto, N.J.A.C. 13:44, to practice veterinary medicine, surgery, and dentistry in the State of New Jersey.

“Person” means any individual, corporation, institution or partnership.

“Prophylactic biologic” means any and all vaccines or toxoids used to initiate immunity against disease in domestic animals.

2:6-1.2 Distribution of biologics

(a) Unless otherwise stated, all United States Department of Agriculture (U.S.D.A.) licensed biologics may be distributed and used according to the terms of this chapter.

(b) No U.S.D.A. unlicensed or conditionally licensed biologic or diagnostic biologic shall be distributed without the written permission from the Director.

2:6-1.3 Procedure for State license or permit

(a) License or written permission to distribute, use, sell, or give away a biological product unlicensed by or conditionally licensed by the USDA shall be granted by the Director upon a showing to the Director's satisfaction in writing of:

1. The purpose, purity, safety, potency and efficacy of the product;
2. The procedures to insure (a)1 above;
3. Reporting procedures to track the product; and
4. The credibility and reliability of the person applying for the license, based on their credentials and past performance in handling these materials.

(b) License or written permission to distribute, use, sell, or give away a biological product shall be granted by the Director for more than one biological product upon a showing, to the satisfaction of the Director in writing, of the need for scientific research or testing.

2:6-1.4 Use of biological products, diagnostic biologics and prophylactic biologics

(a) Only U.S.D.A. licensed biological products or those biological products authorized in accordance with N.J.A.C. 2:6-1.2 or 1.3 shall be used in New Jersey.

(b) The use of biologic products is subject to the following restrictions:

1. Brucella Abortus and contagious ecthyma vaccines shall be administered only by accredited veterinarians; and

2. Diagnostic biologics for the following diseases are limited to use by the New Jersey Department of Agriculture, Division of Animal Health only, unless specific written permission is granted by the Director, for in vitro diagnosis of:

- i. Anaplasmosis;
- ii. Avian Influenza;
- iii. Brucellosis;
- iv. Equine Infectious Anemia;
- v. Equine Viral Arteritis;
- vi. Paratuberculosis (Johne's Disease);
- vii. Pseudorabies; or
- viii. Pullorum.

(c) Exceptions to (b)2 above may be granted by the Director to other government agencies who may be cooperating with the New Jersey Department of Agriculture, or where in the opinion of the Director, there is an emergent situation requiring immediate action.

2:6-1.5 Revocation of license or permission to distribute or use

(a) A license or permission to distribute or use any biological product may be revoked by the Director when there has been a violation of State or Federal laws, rules or regulations, or where the public health, welfare or safety shall warrant such revocation, subject to notice and opportunity to be heard.

(b) Any hearing to be conducted under this section shall be so conducted pursuant to N.J.A.C. 2:1-3.4 and the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.