NEW JERSEY REGISTER

VOLUME 42, ISSUE 17

ISSUE DATE: SEPTEMBER 7, 2010

RULE PROPOSALS

AGRICULTURE
DIVISION OF ANIMAL HEALTH

42 N.J.R. 1933(a)

Proposed Readoption: N.J.A.C. 2:6

Click here to view Interested Persons Statement

Biological Products for Diagnostic or Therapeutic Purposes

Authorized By: State Board of Agriculture, Douglas H. Fisher, Secretary.

Authority: N.J.S.A. 4:5-104 et seq.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2010-198.

Submit written comments by November 6, 2010 to:
Dr. Nancy E. Halpern
NJDA/Division of Animal Health
PO Box 330
Trenton, NJ 08625

The agency proposal follows:

Summary

Pursuant to N.J.S.A. 52:14B-5.1, the rules in this chapter are scheduled to expire August 26, 2010. In accordance with N.J.S.A. 52:14B-5.1c, the submission of this notice of proposal to the Office of Administrative Law extends that expiration date 180 days to February 22, 2011. The Department of Agriculture has reviewed these rules and has found

them to be necessary, reasonable and proper for the purposes for which they were promulgated.

The rules proposed for readoption regulate the sale and use of biologics in New Jersey. Biologics are complex products with variable applications and effects that have the potential for misuse. The probable results of their misuse can maintain or spread disease, complicate the diagnostic process and fail to provide effective disease protection.

The rules do not apply to drugs or chemicals, including antibiotic preparations.

These rules exempt individual registration of most Federally licensed manufacturers or products, and limit the use and distribution of unlicensed or conditionally licensed products. These Department of Agriculture rules will help insure that only those biologics that have been licensed by the U.S. Department of Agriculture (USDA) or by the Director of the Division of Animal Health in the New Jersey Department of Agriculture will be used or sold. The rules contain the definitions used (N.J.A.C. 2:6-1.1), distribution restrictions (N.J.A.C. 2:6-1.2), procedures for State license or permit (N.J.A.C. 2:6-1.3), restrictions on the use of biologics (N.J.A.C. 2:6-1.4) and revocation of State license or permit (N.J.A.C. 2:6-1.5).

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The rules proposed for readoption affect veterinarians, livestock owners and poultrymen by protecting these individuals from the ineffective use of vaccines, serums, antigens and diagnostic agents to determine, prevent and treat animal disease. The risks of not readopting these rules include the use of unlicensed or conditionally licensed biologics, which could result in the maintenance and spread of infection in livestock, misdiagnosis and mistreatment of disease entities. In addition, the rules will protect human health by restricting exposure to disease-causing organisms. Therefore, these rules, which are proposed for readoption, without amendments, will continue to have a positive social impact.

Economic Impact

Diagnosis, prevention and treatment of animal disease, to include the use of proper veterinary biologics, prevents the illness and death of livestock and poultry, and as a consequence, increases the economic return of animal agriculture products to farmers and stakeholders. Healthy animals also allow New Jersey farmers the opportunity to compete more effectively in the national and international marketplace for the distribution and sale of animal agriculture products. Therefore, the rules proposed for readoption will result in a positive economic impact.

Federal Standards Statement

Executive Order No. 27 (1994) and P.L. 1995, c. 65 require State agencies that adopt, readopt or amend State rules that exceed any Federal standards or requirements to include in the rulemaking document a comparison with Federal law. Biologics are either licensed or conditionally licensed by the Food and Drug Administration (FDA) (Public Health Services Act, Section 351 42 U.S.C. §242) or by the USDA pursuant to 9 CFR 101 through 123. States may then impose additional restrictions upon the availability of some biologics based on disease prevalence and eradication in each state. For biologics that are licensed by the FDA or USDA, New Jersey imposes no additional standards. Only those biologics that are conditionally licensed are required to have additional reporting and recordkeeping as discussed more fully in the Regulatory Flexibility Analysis as set forth below. However, since this is explicitly permitted by the Federal government, these rules are not exceeding any Federal standards and therefore, no Federal standards analysis is necessary.

Jobs Impact

The rules proposed for readoption will not result in the generation or loss of jobs in the State.

Agriculture Industry Impact

The rules proposed for readoption will have a positive impact on the agriculture industry, in particular the livestock industry, since they [page=1934] minimize the introduction and/or spread of disease to New Jersey livestock.

Regulatory Flexibility Analysis

While most farmers are small businesses as that term is defined by the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., the rules proposed for readoption do not impose any new or increased recordkeeping and/or other compliance requirements beyond those already mandated by the authorizing statutes. There are no recordkeeping or reporting requirements for those persons utilizing USDA licensed biological products. There are reporting and recordkeeping requirements for those persons seeking the Department's permission to administer unlicensed or conditionally licensed biologicals in order to protect both animal and human health. Any person seeking to utilize unlicensed or conditionally licensed biologicals must demonstrate, in writing, the purpose, purity, safety, potency and efficacy of the product; the procedures to ensure same; the reporting procedures used to track the product and the credentials and past performance of the person administering the product. The Division director will then issue a license or written permission to utilize these products upon a showing that the there is a need for scientific research or testing.

The restriction of the distribution of unlicensed or conditionally licensed biologics will have a minimum impact upon the farmers in this State. Professional services would be required in those instances where the unlicensed or conditionally licensed biologics were used on livestock. In these cases, the additional cost to the farmer would vary depending on the number of animals involved, vaccination protocol and fees charged by the individual's veterinarian.

The rules permit individuals to acquire and use biologic products, in accordance with this chapter. Because the rules are concerned with the control of disease and the public welfare, no lessening of, or exemption from, these requirements is provided based on business size.

Smart Growth Impact

The rules proposed for readoption will have no impact on the achievement of smart growth or implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The rules proposed for readoption will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules limit the use and distribution of unlicensed or conditionally licensed biologic products in New Jersey.

Smart Growth Development Impact

The rules proposed for readoption will have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in house production in Planning Areas 1 or 2 within designated centers under the State Development and Redevelopment Plan in New Jersey because the rules limit the use and distribution of unlicensed or conditionally licensed biologic products in New Jersey.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 2:6.