

United States Department of Agriculture
Animal and Plant Health Inspection Service

Directive 6910.1 12/15/93

DIAGNOSTIC TEST KITS - LICENSING AND APPROVAL PROCEDURES

1. PURPOSE

This Directive describes the procedure for coordinating the licensing and approval processes for diagnostic products intended for use in Cooperative State/Federal/Industry Animal Disease Control and Eradication Programs (Control Programs).

2. REPLACEMENT HIGHLIGHTS

This Directive replaces APHIS Directive 6910.1, dated 3/14/91.

3. AUTHORITIES AND REFERENCES

- a. The Virus-Serum-Toxin Act, 21 U.S.C. 151-159, as amended by Section 1768 (a-f), Food Security Act of 1985, P.L. 99-198.
- b. Title 9, Code of Federal Regulations, Parts 101-118.
- c. Animal health statutes applicable to control and eradication programs, 21 U.S.C. 111-112a, 115, 117, 120, 121, 123-126, 134b-134f, 137b-137f.
- d. Title 9, Code of Federal Regulations, Parts 70-85.

4. DEFINITIONS

- a. Licensed diagnostic product means any product that is produced under license granted by the Secretary of Agriculture in accordance with provisions of the Virus-Serum-Toxin Act of March 4, 1913, and any subsequent amendment with indications for use in the diagnosis of disease or making a determination of susceptibility to and/or exposure to potential disease causing agents in animals.
- b. Official or approved test means any licensed diagnostic test which is used for regulating the interstate or international movement of animals in conjunction with Animal Disease Programs as provided in 9 CFR, Parts 70-85.
- c. Conditional license means a U.S. Veterinary Biological Product License issued under an expedited procedure

which ensures purity, safety, and a reasonable expectation of efficacy.

- d. Restricted license means a U.S. Veterinary Biological Product License issued with restrictions on the use of the product.

5. BACKGROUND

In many instances, official or approved tests are conducted using products licensed by the U.S. Department of Agriculture (USDA) under the Virus-Serum-Toxin Act of 1913 as amended by the Food Security Act of 1985.

In such cases, a USDA Veterinary Biological Product License has been issued for the product and then the product has been subject to an approval process where further field evaluation has been conducted in accordance with requirements prescribed by the Veterinary Services Operational Support Staff (VSOSS) responsible for administering the applicable animal disease eradication or control program.

After assessing the performance of the product in comprehensive tests done under field conditions, VSOSS would make a recommendation to the Administrator to approve or withhold approval to use the product in conducting official tests. If approved, a rulemaking notice was published in the Federal Register informing the public of a proposal to approve the test conducted with the product for official program use.

6. POLICY

The Administrator, APHIS, has the authority to prescribe requirements for the approval of diagnostic tests used in Control Programs, thereby becoming official or approved tests.

By declaring a particular diagnostic procedure to be an official or approved test, regulatory officials will be able to use standardized diagnostic procedures to determine an animal's disease status for the purpose of regulating the interstate and/or international movement of animals subject to animal disease control and/or eradication programs.

7. RESPONSIBILITIES

The Veterinary Biologics Staff (VBS) will coordinate the licensing/approval process. This includes reviewing all data submitted in support of a USDA Veterinary Biological Product License and coordinating the development of data needed to evaluate the efficacy of the product for use in

Control Programs.

8. LICENSING/APPROVAL PROCESS

a. The applicant will submit a USDA Veterinary Biological Product License application and supporting data to Veterinary Biologics. VSOSS will be informed of receipt of the application. The data will be evaluated for clinical and biometric significance. Upon approval of supporting data and completion of satisfactory confirmatory tests on prelicensing serials that indicate acceptability of the product for routine diagnostic purposes, a restricted license or a conditional license will be issued, whichever is appropriate.

b. Either license will allow the applicant to produce and market the product for diagnosis for unofficial purposes. However, the label will specify that the product cannot be used to determine the disease status of an animal for interstate or international movement or for use in Control Programs.

c. Concurrently, VSOSS will be informed that the test has been granted a restricted license and is eligible for further evaluation to determine if it is satisfactory for use as an official test in Control Programs. From its review of the application and supporting data, VSOSS will be asked to make its recommendations for studies needed for evaluation of the product before licensing for program purposes, including selecting laboratories and/or States to serve as cooperators.

The applicant will be informed of the recommendations and must arrange for an evaluation of the product under field conditions in accordance with requirements specified by VSOSS. The field studies will be coordinated with the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the United States Animal Health Association (USAHA) when necessary, and the National Veterinary Services Laboratories (NVSL). The purpose of this evaluation is to:

- (1) Provide an opportunity for potential users to gain experience with the product, and
- (2) Allow cooperators the opportunity to determine with a greater degree of confidence that the product performs according to label claims and will

yield consistent and reproducible results in
different laboratories under varied and
prescribed field conditions.

d. Data developed by the cooperating laboratories and any recommendations regarding the application, performance, and/or appropriateness of the product will be forwarded to the appropriate diagnostic laboratory at NVSL. NVSL and the AAVLD, in collaboration with VSOSS and Veterinary Biologics, will review all data relative to the efficacy of the product's use in the applicable Control Programs.

e. Following this review, Veterinary Biologics will inform the firm that the test data are either acceptable or unacceptable for this purpose and how they should proceed.

f. If data from these studies is found acceptable, an outline change providing for the new indications and a new label which includes a statement indicating that the product is approved for official use as a test in the specified Control Program will be filed, and a regular license will be issued for the product. This regular license will replace the restricted or conditional license previously issued.

g. VSOSS will prepare a notice for publication in the Federal Register to inform interested persons that the product has been licensed with indications for its use in Control Programs.

h. If data from these studies is unacceptable, problem areas will be identified and possible solutions offered to the license applicant.

i. Once the product has been approved for use in control and/or eradication programs, it cannot be altered, modified, or the components changed without the written approval of VBS and VSOSS. Changes made without this approval may result in withdrawal of the product from official use.

9. INQUIRIES

Any questions regarding this Directive should be directed to Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection.

/s/ Lonnie J. King /s/
Acting Administrator