DIAGNOSTIC TEST KIT – 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 12/15/93.

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 (CFR), 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, CFR Parts 70-85.

4. DEFINITIONS

a. Licensed diagnostic product. 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. 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. 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. 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 March 4, 1913, as amended by the Food Security Act of 1985.

In such cases, a USDA Veterinary Biological Product License is issued for the product and then the product was subject to an approval process where further field evaluation is conducted in accordance with requirements prescribed by the National Center for Animal Health Programs Team (NCAHP), 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, NCAHP makes a recommendation to the Administrator to approve or withhold approval to use the product in conducting official tests. If approved, a rulemaking notice is 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 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 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 Center for Veterinary Biologics (CVB) will coordinate the licensing/approval process. This includes reviewing all data submitted in support of USDA Veterinary Biological Product Licenses 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 CVB. NCAHP will be informed of the 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 a restricted or a conditional 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, NCAHP 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, NCAHP 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 NCAHP. The field studies will be coordinated with the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the United States Animal Health Association (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 NCAHP and CVB, will review all data relative to the efficacy of the product's use in the applicable Control Programs.

e. Following this review, CVB 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 are 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 Programs 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. NCAHP will prepare a notice for publication in the Federal Register to inform interested persons that the product was licensed with indications for its use in Control Programs.

h. If data from these studies are unacceptable, problem areas will be identified and possible solutions offered to the licensed 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 from CVB or NCAHP. 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 the Center for Veterinary Biologics - Policy Evaluation and Licensing, Veterinary Services, at 301-734-8245.

/s/
W. Ron DeHaven
Administrator