

Animal and Plant Health Inspection

Service

Veterinary Services

1400 Independence Ave, SW

Washington, DC 20250

**VETERINARY SERVICES MEMORANDUM NO. 800.95** 

**TO:** Veterinary Services Leadership Team

Directors, Center for Veterinary Biologics

Biologics Licensees, Permittees, and Applicants

**FROM:** John R. Clifford /s/ Jack Shere September 2, 2015

**Deputy Administrator** 

**SUBJECT:** GB Texas Newcastle Disease Challenge Virus

#### I. PURPOSE

This memorandum informs all interested parties of a change in the status of the GB Texas Newcastle disease challenge virus, and the effect of this change on licensees, permittees, and applicants currently using or planning to obtain this strain of Newcastle disease virus (NDV) for any purpose.

### II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.95 dated June 25, 2008.

#### III. BACKGROUND

The GB Texas strain of NDV is a neurotropic, velogenic virus commonly used as a challenge virus in efficacy and potency testing of Newcastle disease vaccines, and in research. Since 1996, this NDV strain was subject to regulation under title 9, *Code of Federal Regulations* part 82 (9 CFR 82) as an Exotic Newcastle Disease strain, but could be obtained by holders of a valid United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors issued by Veterinary Services, National Import Export Services . A Final Rule published March 18, 2005, has since clarified that all strains of velogenic NDV would be regulated as select agents and subject to the requirements of the Agricultural Bioterrorism Protection Act of 2002 and 9 CFR 121: Possession, Use, and Transfer of Biological Agents and Toxins. The GB Texas strain of NDV may be obtained from the National Veterinary Services Laboratories, effective the date of this notice.

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# IV. ACTION

As a result of the clarification of the status of this NDV strain as a select agent, entities interested in obtaining, maintaining, using, or transferring the GB Texas strain of NDV must now register with the Animal and Plant Health Inspection Service and meet the requirements set forth in 9 CFR, part 121. Information concerning the select agent registration process and the regulations in 9 CFR, part 121 may be obtained from the Agricultural Select Agent Program by telephone at (301) 851-3300 (select option 3) or through the Agriculture Select Agent Services web site.

## V. IMPLEMENTATION

This action is effective immediately.