July 24, 1995

VETERINARY SERVICES MEMORANDUM NO. 565.12

SUBJECT: Animal and Plant Health Inspection Service (APHIS) Policy Change on H5 and H7 Avian Influenza (AI)

TO: State Veterinarians

Director, National Veterinary Services Laboratories

Directors, VS Regions

Director, National Center for Import and Export

Area Veterinarians in Charge

Avian Influenza Working Group

I. PURPOSE

The purpose of this Memorandum is to inform APHIS collaborators and key Veterinary Services employees that there has been a recent policy change detailed in APHIS Veterinary Biologics Memorandum No. 800.85 regarding the production and distribution of AI vaccine.

II. BACKGROUND

Current APHIS policy regarding the control of AI and the related production and distribution of avian influenza vaccines has remained unchanged since the 1983 campaign to eradicate an outbreak of highly pathogenic avian influenza (HPAI) in chickens. (Prior to the 1983 outbreak of HPAI in chickens, APHIS allowed experimental AI vaccines to be prepared from any serotype but restricted such vaccines for use in turkeys only.)

Because the 1983 outbreak of HPAI in chickens was caused by the H5 serotype, APHIS directed that vaccine from any H5 serotype should not be prepared or used unless specifically authorized by Veterinary Services. The purpose of this restriction was to prevent interference with the ongoing control and eradication efforts.

This restriction was subsequently expanded to include vaccine prepared from any of the H7 serotypes. While the production of AI vaccines from serotypes other than H5 and H7 was not restricted, their use was restricted to turkeys.

After analyzing the 1994/95 HPAI situation in Mexico and consulting with the U.S. poultry industry, APHIS has concluded that the restrictions imposed on AI vaccine production and use during the 1983 eradication campaign should be modified to now allow H5 and H7 vaccine to be used as a tool for combating any potential outbreak of HPAI in the United States.

III. POLICY

APHIS will continue to consider HPAI in chickens an exotic disease and will continue to maintain eradication as the preferred response to a domestic

outbreak.

The past restrictions on the availability of AI isolates for use in vaccine production and the production of vaccine for use in chickens have been modified.

AI vaccine may now be prepared from any serotype, including H5 and H7, and may be recommended for use in chickens or turkeys subject to the licensing requirements and restrictions specified in the enclosed copy of Veterinary

Biologics Memorandum No. 800.85.

/s/

Donald W. Luchsinger

Acting Deputy Administrator

Veterinary Services

Enclosure

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ATTACHMENT

VETERINARY BIOLOGICS MEMORANDUM NO. 800.85

Subject: Avian Influenza Vaccines

To: Veterinary Biologics Licensees, Permittees, and Applicants

Director, National Veterinary Services Laboratories

Deputy Director, Veterinary Biologics Field Operations

Deputy Director, Veterinary Biologics

I. PURPOSE

The purpose of this Memorandum is to inform all interested parties of the conditions under which USDA, APHIS, Veterinary Biologics (VB) will consider license applications for Avian Influenza Vaccines. This information is supplemental to the applicable Standard Requirements found in Title 9, Code of Federal Regulations (9 CFR), including but not limited to, Parts 113.200 and 113.300.

II. BACKGROUND

USDA, APHIS, Veterinary Services (VS) considers avian influenza (AI) in chickens to be an exotic disease, and regulates the importation or interstate movement of AI viruses by Permit (9 CFR 122.2). This policy is clarified and updated in the accompanying VS Notice. Therefore, the VS Biologics Notice dated November 21, 1985, is hereby rescinded, and is replaced by the following guideline.

III. PRODUCT MASTER SEED VIRUSES (MSVs)

All applicable Standard Requirements for MSVs must be met, including but not limited to 9 CFR 113.200 and 113.300, with the following additional considerations:

A. VS will continue to regulate all importations or interstate movements of AI viruses by Permit, in accordance with 9 CFR 122.2.

B. MSVs for conventional killed vaccines will be considered for licensure under the following conditions:

1. Only AI viruses of low pathogenicity, obtained from the Diagnostic Virology Laboratory of the National Veterinary Services Laboratories (NVSL), will be eligible for use as MSVs for conventional killed vaccines. Any H type may be obtained from this source.

2. Such isolates must be obtained in accordance with a VS permit. Such permits will be issued with the restriction that the virus be used only for *in vitro* studies. Furthermore, issuance of such a permit may require a facility inspection, at the discretion of VS.

3. Receipt and use of such isolates must also be in accordance with written authorization from the appropriate State officials.

C. Master Seeds for live or inactivated recombinant vaccines, subunit vaccines, or other biotechnology-derived products, will be considered for licensure. Acquisition of AI viruses necessary to construct such seeds must be obtained under VS Permit.

D. Due to the high rate of mutation documented for AI viruses, license applications for conventional modified live AI vaccines will not be considered.

IV. PRODUCT DEVELOPMENT

All applicable Standard Requirements for licensure must be met, including but not limited to 9 CFR 113.200 and 113.300, with the following additional considerations:

A. Products may be developed with a claim for use in either chickens or turkeys, for any H type. All claims for each species, each H type, and each age and route of administration must be supported by the appropriate data.

B. Applications for regularly licensed products must be supported by appropriate vaccination challenge efficacy data. These challenge studies must be conducted under biosafety level 3 (BL3) containment conditions. Prior to the initiation of such a study, the applicant must obtain APHIS approval of the laboratory, study protocol, and challenge virus to be used.

C. Applications for conditionally licensed products will only be considered if the conditions found in 9 CFR 102.6 are met. Furthermore, all applicants or licensees seeking or holding conditional licenses for AI vaccines must work towards eventual regular licensure of these products.

V. PRODUCT LICENSE RESTRICTIONS

A. All licenses for AI vaccines will be issued with the following restrictions:

1. "Distribution in each State shall be limited to authorized recipients designated by proper State officials - under such additional conditions as these authorities may require."

2. "Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials - under such additional conditions as these authorities may require."

B. All AI vaccines for use in chickens, and all H5 and H7 vaccines (for use in either chickens or turkeys) will be licensed with the following additional restriction: "Domestic distribution and use shall be under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program."

VI. PRODUCT LABELING

A. Because of the license restrictions on distribution and use, individual product labels may recommend use of the product in chickens or turkeys, but not both.

B. For licenses carrying the restriction listed in V.B. above, the domestic product labels shall carry the following statement: "This product may only be distributed and used as part of an official USDA animal disease control program."

C. Product labels shall indicate the H type included in the product.

/s/

John H. Payne, Ph.D.

Acting Director

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