**United States Department of Agriculture**

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

# VETERINARY SERVICES MEMORANDUM NO. 800.98

**TO:** VS Management Team (VSMT)
Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

**FROM:** John R. Clifford /s/ Andrea M. Morgan 7-25-08
Deputy Administrator
Veterinary Services

**SUBJECT:** Advertising and Promotional Materials

## I. PURPOSE

This memorandum provides guidance concerning advertising and claims which are made about licensed veterinary biological products which are regulated under the Virus-Serum-Toxin Act (21 USC 151, et seq.).

## II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.98 dated June 25, 2008.

## III. BACKGROUND

The regulations in 9 CFR 102.4(b)(3) specify that before the Animal and Plant Health Inspection Service (APHIS) may issue a U.S. Veterinary Biologics Establishment License, applicants must file written assurance with APHIS that the biological products which are licensed to be prepared in the establishment will not be advertised so as to mislead or deceive the purchasers, and that the packages or containers in which the biologics are to be marketed will not bear any statement, design, or device which is false or misleading in any particular. Similarly, an application for a permit to import veterinary biological products must contain information regarding all claims to be made on labels and advertising matter used in connection with or related to the biological product to be imported. Mounted copies of final container labels, carton labels, and enclosures to be used with the imported product must be submitted as provided in part 112 of the regulations.

The Center for Veterinary Biologics (CVB) does not routinely monitor advertising materials that appear in various trade and scientific journals to determine if they contain

statements concerning the product that are false and misleading. However, all reports of alleged false or misleading advertising or claims submitted to CVB are reviewed. Advertising or claims that are found to be false or misleading in any particular will be brought to the attention of the licensee or permittee by written notification as outlined in Section IV of this document. More drastic action may be taken in cases where inappropriate advertising or claims may render a product dangerous or harmful to such an extent that immediate action is necessary.

IV. GUIDELINES

A. Advertising and Claims Based on APHIS Approved Labeling

An advertisement or claim that restates information on APHIS approved labeling and which does not include artwork, pictures, or designs which by implication expand or modify such information as to make it false or misleading is acceptable. An advertisement or claim which misleads by misquoting APHIS requirements or encourages the user to disregard label directions and otherwise use or handle the product in a manner that is inconsistent with approved labeling is considered false and misleading.

B. Advertising Claims Based on APHIS Approved Data

Data which validates protection claims such as prevention of infection, prevention of disease(s), and aid in the prevention of disease(s) are the basis for issuing veterinary biological product licenses and permits. Product advertisements should accurately present the claims reviewed and approved by APHIS.

C. Advertising Claims for Enhanced Performance

Although performance parameters such as increased rate of gain, increased feed efficiency, and increased milk production may be monitored and submitted with data from a host animal protection study, only protection data are considered in the evaluation of a veterinary biological product for licensing purposes. Therefore, advertising veterinary biologics in a manner which, by inferences such as “data on file with USDA,” implies that performance claims have been reviewed and approved by APHIS is considered false and misleading.

D. Advertising Claims Based on Data Taken from Published Literature

APHIS does not review data published in the literature concerning claims for veterinary biologics. For the purposes of licensing product and/or validating claims, only manufacturer submitted data are reviewed. Therefore, product advertisements which feature claims that are based on studies presented in published literature may be considered false and misleading. To preclude the appearance of such, only APHIS approved claims should be used in association with the advertising of veterinary biologics.

E. Advertising Involving Comparison Studies of Competitive Products

APHIS does not consider data resulting from a comparison study with a licensed product in its decision to issue a veterinary biological product license. In addition, APHIS does not review the results of comparative studies of such products published in scientific or trade journals. Therefore, advertising disputes between veterinary biologics manufacturers originating from comparison studies presented in published articles should not be submitted to APHIS for arbitration.

## V. COMPLIANCE PROCEDURES

The regulations in 9 CFR 105.1 specify, in part, that APHIS may suspend or revoke an establishment license, product license, or permit that is being used to facilitate the labeling or advertising of a product so as to mislead the purchaser in any particular. APHIS may take such action if other initiatives designed to gain compliance fail. Other compliance initiatives may consist of the following:

A. Letters of Advice

The Center for Veterinary Biologics-Inspection Compliance (CVB-IC) may send a letter of advice specifying the claim, design, or device that is considered to be false or misleading. Licensees or permittees may be asked to respond to APHIS' findings by supplying information to support continued use of a claim, design, or device or by agreeing to take specific corrective action in regard to claim, design, or device within a specified time frame.

B. Infraction Notice

The CVB-IC may send an infraction notice when the licensee or permittee does not respond to the letter of advice. The infraction notice could cite failure to take the specified corrective action as evidence of willful violation. Such violation could subject the license to suspension or revocation in accordance with 9 CFR 105.1(b).

C. Pre-review of Advertising

APHIS does not normally review each piece of proposed new advertising. Occasionally, however, APHIS may agree to review advertising copy prior to its publication if the licensee is uncertain of the acceptability of a specific claim, design, or device.