United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-19

Subject: Vaccine Claims for Protection of the Fetus Against Bovine Virus Diarrhea Virus

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) policy concerning vaccine claims for protection against the reproductive effects of bovine virus diarrhea virus.

II. BACKGROUND

Infection with bovine virus diarrhea virus (BVDV) can cause a wide array of reproductive sequelae, including abortion, persistently infected calves, unthrifty or stunted calves, and congenital anomalies. This notice clarifies the type of data that are needed to support various label claims against reproductive effects of BVDV.

III. POLICY

Label claims for BVDV reproductive effects will be divided into claims for fetal protection and claims for abortion (which may be due to maternal, as well as fetal, causes). The claims will be type-specific (i.e., BVDV Type 1 or Type 2). Each claim must be directly supported by acceptable data; see Veterinary Services Memorandum 800.202 for additional guidance. Three categories have been identified:

"Aids in the prevention of abortion:" Must be supported by studies in which abortions occur in an acceptable proportion of the nonvaccinated control cattle. Since many strains of BVDV do not routinely cause abortion, appropriate challenge strains must be used. Alternatively, acceptable field studies, using natural exposure to BVDV, may be performed.

"Aids in the prevention of persistently infected calves:" May be supported by challenging pregnant cattle at 75-90 days of gestation and performing virus isolation procedures on tissues from all fetuses on, or after, 150 days of gestation. Those fetuses from which BVDV is isolated are considered to be persistently infected.

"Aids in the prevention of fetal infection" or "Aids in the prevention of fetal infection, including persistently infected calves:" May be supported by generating data to support the claim for "aids in the prevention of persistently infected calves" AND challenging a separate group of pregnant cattle at approximately 180 days of gestation and evaluating the fetuses (or calves) at, or after, ≥220 days of gestation. Serology and virus isolation procedures must be performed. Fetuses (or calves) are considered to be protected from infection if they are BVDV negative and seronegative for BVDV antibodies.

Product labels should not be more specific than what can be supported by the filed data (e.g., should not make a specific label claim for congenital anomalies if the efficacy study did not produce calves with congenital anomalies in the nonvaccinated control group).

Promotional materials for BVDV products with reproductive claims should be appropriate for the label claim. Products with claims for persistently infected calves or fetal infection should not be promoted as being effective against abortion or fetal loss. Promotional materials for products with claims for fetal infection may discuss the possible sequelae of fetal infection (e.g., congenital anomalies, unthrifty calves) but should not imply that protection against these conditions has been directly proven unless supported by acceptable data.

III. ACTION

Labels and promotional materials for previously licensed products should be amended, as necessary, to follow these guidelines.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics