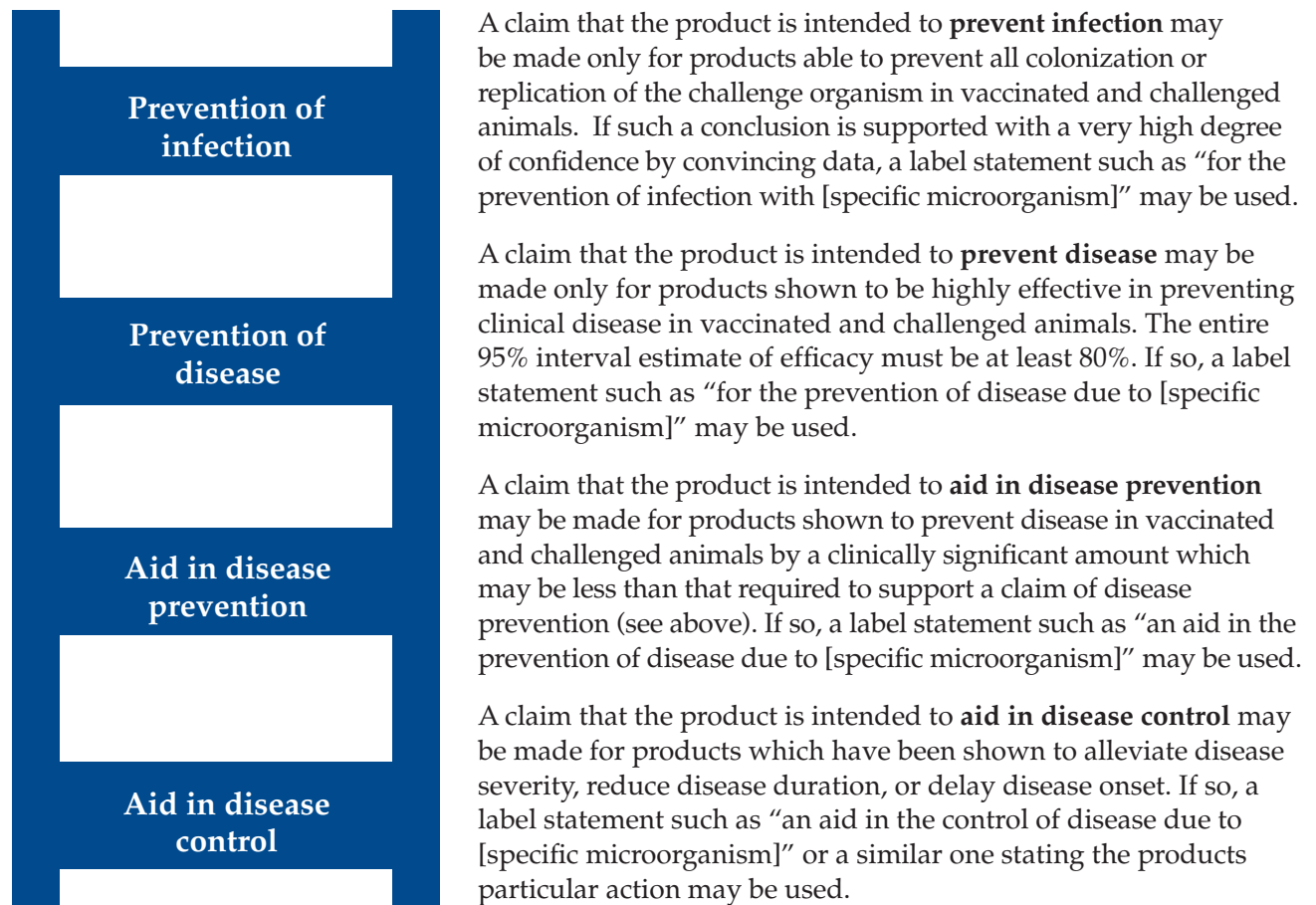


Level of Protection Label Claims

What are they and what do they mean?

There has been a lot of talk recently concerning label claims for vaccines, especially label claims as they relate to protection against BVD virus. The label claims for a product must be supported with data that accurately reflects the expected performance by the product. Depending on the strength of the data, USDA-APHIS may grant a vaccine one of label claims listed below.



Other Label Claims

Products with beneficial effects other than direct disease control, such as the control of infectiousness through the reduction of pathogen shedding, may make such claims if the size of the effect is clinically significant and well supported by data.

Information taken from Veterinary Services Memorandum No. 800.202, June 14, 2002

Vaccine Claims for Protection of the Fetus against Bovine Virus Diarrhea Virus

Bovine virus diarrhea virus (BVDV) can result in a multitude of reproductive problems in cattle including abortion, stillbirths, congenital anomalies, persistently infected calves, and unthrifty, stunted calves. The Center for Veterinary Biologics has published a notice that clarifies the type of data required to support various label claims against the reproductive effects of BVDV.

Label claims for BVDV reproductive effects have been divided into claims for fetal protection and claims for abortion (due to maternal or fetal causes). The claims must be type-specific (BVDV Type 1 or Type 2) and must be supported by acceptable data as outlined in Veterinary Services Memorandum 800.202.

Categories of Claims for BVDV Reproductive Effects¹

1. **“Aids in the prevention of abortion”:**
 - a. Supported by studies in which abortions occur in an acceptable proportion of the non-vaccinated control cattle
 - b. Must utilize challenge strains that routinely cause abortion
 - c. Field studies, using natural exposure to BVDV, may be performed
2. **“Aids in the prevention of persistently infected calves”:**
 - a. Challenge pregnant cattle at 75-90 days of gestation
 - b. Perform virus isolation procedures on tissues from all fetuses on, or after, 150 days of gestation
 - c. Fetuses from which BVDV is isolated are considered to be persistently infected
3. **“Aids in the prevention of fetal infection” or “Aids in the prevention of fetal infection, including persistently infected calves”:**
 - a. May be supported by data to support the claim for “aids in the prevention of persistently infected calves” AND,
 - b. Must challenge a separate group of pregnant cattle at ~180 days of gestation and evaluate the fetuses (or calves) at, or after, ≥ 220 days of gestation.
 - c. Serology and virus isolation procedures must be performed.
 - d. Fetuses (or calves) are considered to be protected from infection if they are BVDV negative and seronegative for BVDV antibodies.

¹Information taken from Center for Veterinary Biologics Notice No. 02-19, Sept. 5, 2002