

Understand What Vaccine Label Claims Mean

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Reprinted from *Cattle Call*, 2007, Vol 12, Iss 1



Vaccines are an essential tool for aiding in the prevention and control of infectious diseases in cattle. There are well over 200 vaccines and vaccine combinations available for

cattle producers. Selecting and using the right vaccines can be daunting, but is an essential part of any successful cattle operation. With all of the choices available, it is important to understand the labeling guidelines that are granted and enforced by the USDA to indicate a product's expected level of protection. The USDA can grant one of five possible levels of protection: 1) Prevention of infection, 2) Prevention of disease, 3) Aid in disease prevention, 4) Aid in disease control 5) Other claims. In each instance, data generated by the vaccine manufacturer must fully support label indications and accurately reflect the expected performance of the product. The decision as to which type of label claim will be granted is based on evaluation by the USDA:APHIS Center for Veterinary Biologicals (CVB), which is the government agency that reviews and grants licenses for veterinary

vaccines. The CVB evaluates the data supplied by the vaccine manufacturer and decides whether the vaccine can be licensed or not. They also determine what type of efficacy claim can appear on vaccine labels and in advertising and promotional materials. Vaccine companies may voluntarily choose a lesser label indication. However, they cannot increase the level of the claims above what the data filed with USDA supports. Following are the 5 label claims that CVB may issue for an approved vaccine (taken directly from USDA:APHIS Veterinary Services Memorandum No. 800.202):

Prevention of infection. A claim that it is intended to prevent infection may be made only for products able to prevent all colonization or replication of the challenge organism in vaccinated and challenged animals. If such a conclusion is supported with a very high degree of confidence by convincing data, a label statement such as "for the prevention of infection with [specific microorganism]" may be used.

Prevention of disease. A claim that it is intended to prevent disease may be made only for products shown to be highly effective in preventing clinical disease in vaccinated and challenged animals. The entire 95% interval estimate of efficacy must be at least

80%. If so, a label statement such as “for the prevention of disease due to [specific microorganism]” may be used.

Aid in disease prevention. A claim that it is intended to aid in disease prevention may be made for products shown to prevent disease in vaccinated and challenged animals by a clinically significant amount which may be less than that required to support a claim of disease prevention. If so, a label statement such as “as an aid in the prevention of disease due to [specific microorganism]” may be used.

Aid in disease control. A claim that it is intended to aid in disease control may be made for products which have been shown to alleviate disease severity, reduce disease duration, or delay disease onset. If so, a label statement such as “as an aid in the control of disease due to [specific microorganism]” or a similar one stating the product’s particular action may be used.

Other 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 the data.

When deciding on a vaccine program for your cattle, we strongly encourage you to consult with your veterinarian who can help you to choose the most effective products and develop the best program for your operation. Furthermore, we encourage you to read the labels of vaccine and become knowledgeable on what they are

indicated for and what their limits are. If you would like to learn more about how animal vaccines are approved, visit <http://www.aphis.usda.gov/vs/cvb/>