United States Animal Health Association
2019 Resolution
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RESOLUTION NUMBER: 27 **APPROVED**

SUBJECT MATTER: Q-Fever (*Coxiella burnetii*) Vaccine

BACKGROUND INFORMATION:

Q-Fever is a zoonotic disease caused by the bacterium *Coxiella burnetii*. Coxiella infection is found in many species in many countries of the world, including the United States (US). The disease is a major cause of abortion in sheep and goats, which results in significant economic losses to producers, but also results in significant risk of transmission to human beings. Exposure to the products of abortion or raw milk products either directly or through environmental contamination poses a significant public health risk, as demonstrated by the large-scale 2005-2011 Q-fever epidemic (human and goat) in the Netherlands.

Currently there is no vaccine available in the US to prevent *Coxiella burnetii* infection or abortion in sheep and goats. Such a vaccine is available in Europe. The availability/approval of a safe and effective sheep and goat vaccine for *Coxiella burneiti* in the US would serve to safeguard human health and prevent production losses due to this potentially devastating disease. Humans not in direct contact with aborting animals also face some risk of indirect environmental exposure, so effective vaccination of sheep and goats could play a key role in minimizing human exposure. Additionally, the availability and approval of a safe and effective human vaccine would provide protection for those with occupational risk of exposure to *Coxiella burnetii*.

The United States Animal Health Association approved Resolutions on this matter in 2013 and 2014. Despite willingness of United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Center for Veterinary Biologics to work with companies to approve vaccines in the US, no companies have come forward requesting approval and challenges remain for approval of import of effective vaccines, especially given the select agent listing of this agent, which requires Biological Safety Level (BSL)-3 facilities for research. Continued work toward import of vaccines as well as development of strategies for domestic production of *Coxiella burnetii* vaccines which would prevent the disease as well as the shedding of the organism are vital to reducing the impact of Coxiella infections in animals and man through a One Health approach. There is a need for development of animal models of placental accumulation and shedding of *C. burnetii* to facilitate rapid screening and testing of vaccine candidates. Specifically, we recognize the need for the construction of a mouse model of placental accumulation utilizing BSL-2-approved Nine Mile phase II clone 4 (RSA 439) *C. burnetii* to facilitate rapid screening of vaccine and treatment candidates in low cost environment. These will support the development of a full virulence (phase I) model of *C. burnetii* placental accumulation and

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shedding to test vaccine and treatment candidates in preparation for efficacy testing in ruminant livestock.

RESOLUTION:

The United States Animal Health Association (USAHA) encourages the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB) to continue to work to facilitate the licensure or importation of a safe and effective Q-Fever (*Coxiella burnetii*) vaccine for sheep and goats.

In addition, USAHA urges the USDA, Agricultural Research Service (ARS) to continue development of research models that could lead to the development of vaccines in the United States; the development of tests for accumulation and shedding of *Coxiella burnetii;* and identification of genetic tools for improved control of Coxiella infections, including reduced shedding. USDA-ARS should pursue vaccine candidates that can be cost-effectively produced in a Biological Safety Level-2 facility.

INTERIM RESPONSE:

USDA, APHIS, VS, recognizes the concerns of the USAHA and appreciates the opportunity to respond. VS CVB stands ready to evaluate any requests for either a domestic license, or for a permit to import the vaccine from outside of the United States. To date, CVB has not received any applications for either a license, or a permit to import vaccine.