TEXAS ANIMAL HEALTH COMMISSION

Ernie Morales
Chairman

Bob Hillman, D.V.M.
Executive Director

August 17, 2009

Adam J. Szubin, Esq.
Director
Office of Foreign Assets Control
U.S. Department of the Treasury
Treasury Annex
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

Dear Mr. Szubin:

The Texas Animal Health Commission (TAHC) respectfully requests consideration from the Office of Foreign Assets Control for a license to purchase and import Gavac, an anti-tick vaccine available from Revetmex in Mexico City, Mexico. Unfortunately, Gavac is solely produced in Cuba.

With the assistance of the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and the Agricultural Research Service (ARS), TAHC would like to evaluate the efficacy of Gavac, which was developed to control two tick species that transmit bovine babesiosis to cattle. Bovine babesiosis is a serious disease of cattle that was officially eliminated from the United States in 1943 after decades of systematic eradication efforts to remove the tick vectors. However, reintroduction of both tick species and the potential for the spread of the disease in U.S. cattle have made it critically important for the TAHC to seek alternative resources to mitigate the risk.

Vaccinating cattle against ticks is currently the most promising tick control measure; however, anti-tick vaccines have not been evaluated in the United States. The technology has been evaluated and developed for commercial use in Cuba (Gavac since 1993) and Australia (TickGard in 1994). TickGard has been discontinued and removed completely from the global market; therefore, Gavac is the only commercially available anti-tick vaccine in the world.

When ticks feed on vaccinated cattle blood, the vaccine causes tick gut cells to rupture. The destruction of tick gut cells has a dramatic effect on egg production and viability, including death of adult and immature tick life stages. Research trials from northern Mexico using Gavac against *Boophilus annulatus* (one of the two cattle fever tick species) have shown efficacy of greater than 99 percent, with control measured in failed egg production and lack of successful molts by juvenile ticks. Research trials using Gavac against *B. microplus,* the other cattle fever tick species, have shown approximately 80 percent control.

Additionally, recent research has shown that Gavac is highly effective against chemical- resistant tick populations. When included in an integrated tick control program, Gavac helped to reduce the overall dependency on liquid chemicals. In Cuba, the use of Gavac provided a 60 percent reduction in chemical use in addition to reducing the overall prevalence of babesiosis in cattle, resulting in a cost-benefit savings of $23.40 per animal per year.

Heber Biotec S.A., headquartered in Havana, Cuba, is the only company in the world that manufactures Gavac. The business was formed in 1991 as a specialized biotechnology operation to commercialize products developed by the Center for Genetic Engineering and Biotechnology. Heber Biotec has an open

market for its product portfolio through more than 400 product registrations approved in approximately 45 countries. Additional information on Heber Biotec is available at www.heber-biotec.com and at www.gndp.cigb.edu.cu).

Revetmex is a veterinary pharmaceutical company in Mexico City, Mexico, that is licensed to sell Gavac from Heber Biotec. Revetmex places orders for Gavac to Heber Biotec and sells the product to customers throughout Mexico and other parts of the world. Additional information on Revetmex is available at www.revetmex.com.

Only two acceptable mitigation measures are currently approved by the Texas Administrative Code and implemented by the APHIS Cattle Fever Tick Eradication Program (CFTEP): 1) removing all livestock from tick-quarantined pastures for 6 to 9 months to break the lifecycle of the ticks; or 2) submerging the cattle in vats of Co-Ral, a chemical used to kill ticks and the only chemical approved in the United States for that purpose in cattle.

Vacating pastures is not an effective measure because free-ranging deer are capable of sustaining viable tick populations in the absence of cattle. Additionally, chemical-resistant tick populations commonly found in Mexico are beginning to appear in South Texas. Both tick species are frequently introduced across the Rio Grande into South Texas from Mexico by way of stray and smuggled livestock and free-ranging wildlife, such as white-tailed deer. The number of tick-infested pastures in South Texas has increased dramatically and now includes approximately 1 million acres of quarantined land. Therefore, it is essential that we identify and evaluate all available tick control methods.

If authorized, we plan to purchase a one-time supply of 100 bottles (100 ml each) of Gavac from Revetmex, which will be sufficient to treat approximately 1,000 head of cattle for an 18-month research trial. The cost of each bottle is approximately $150 U.S. dollars and the total purchase amount from Revetmex would be approximately $15,000.

Safety concerns and issues regarding the purity of Gavac will be addressed by APHIS' Center for Veterinary Biologics, which is also the regulatory unit responsible for conducting risk assessments for the importation of foreign vaccines and issuing research evaluation permits. Field and laboratory research will be conducted by TAHC in collaboration with APHIS and ARS veterinarians and scientists under controlled conditions in South Texas to evaluate the overall efficacy of Gavac.

The potential U.S. market for any commercially-available anti-tick vaccines specifically designed for the two cattle fever tick species is extremely small based on the current restricted distribution of the ticks in South Texas along the Rio Grande. If these research efficacy trials are successful with Gavac, then we will consider approaching a U.S. company to develop a limited amount of domestically-produced anti-tick vaccine for TAHC and the CFTEP.

If you have any questions, then please feel free to contact me at bhillman@tahc.state.tx.us, or by telephone at 512-719-0715.

Thank you in advance for your time and consideration.

Sincerely,

Bob Hillman, DVM

Bob Hillman, D.V.M.
Executive Director
Texas Animal Health Commission

cc. Ernie Morales, Chairman, Texas Animal Health Commission
Matt Messenger, Program Director, Cattle Fever Tick Eradication Program