USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Legislative and Public Affairs

Freedom of Information

4700 River Road
Unit 50
Riverdale, MD
20737-1232

SEP 29 2011

Debbie Coffey

Dear Ms. Coffey:

This is in response to your August 10, 2011, Freedom of Information Act (FOIA) request for all permits, experimental use permits or letters of investigational exemptions for the use of GonaCon, SpayVac, and field spaying between the USDA and other agencies for the time period of January, 2000 to present. Your request was received in this office on August 11, 2011, and assigned case number FOIA 11-747. We apologize for the delay in processing your request.

The Office of Wildlife Services conducted thorough searches of their files and located one page which is being released in full. Please note there was a regulatory transition from the Food and Drug Administration (FDA) to the Environmental Protection Agency (EPA). The FDA initially provided regulatory oversight of contraceptive vaccines, such as GonaCon (GnRH), for use in wildlife and feral animals. Subsequently, in 2006, FDA and EPA determined jointly that EPA was better suited to administer regulatory authority for these uses (free ranging wildlife and feral animals).

Prior to 2006, research involving GonaCon was conducted under an FDA Investigational New Animal Drug (INAD) application (1998). In 2006, APHIS requested, and FDA agreed to maintain the INAD to ensure regulatory oversight of on-going studies. The INAD was terminated in early 2010 when these studies were completed. GonaCon studies begun after the 2006 regulatory transition were conducted under EPA regulatory oversight. EPA typically requires an Experimental Use Permit (EUP) for field applications greater than 10 acres. Targeted applications of contraceptive vaccine to larger animal species maintained in fenced paddocks or corrals greater than 10 acres in size, have thus far been exempt from the 10-acre rule.

Please be advised that there were two pages of responsive records which originated and were referred to the EPA. The responsive records were directed to the following contact/address for processing:

Environmental Protection Agency
Larry F. Gottesman
National FOIA Officer
Mail Code 2822T
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

In addition, two responsive records were found and referred to FDA for their review and direct response to you. The responsive records were directed to the following contact/address:

FOIA Officer
Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
12420 Parklawn Drive
Elem - 1029
Rockville, MD 20857

APHIS also conducted research of SpayVac (PZP) for use in horses, which is a product of ImmunoVaccine Technologies (IVT). APHIS does not receive regulatory authorization records for products developed by another company or agency.

The immunocontraceptive research studies in horses covered by the FOIA request are summarized below.

1) FDA regulated (INAD) studies of GonaCon and SpayVac in horses-
a. Nevada Department of Agriculture/NWRC Study—Carson City Penal Facility:
- This was a fenced facility. No additional permit was necessary to use the contraceptives
- SpayVac (IVT Product)
-GonaCon was shipped under the Investigational New Animal Application # 10006

b. University of Nevada Study:
- Any necessary state permits would have been obtained by the University of Nevada
-GonaCon was shipped under the Investigational New Animal Application # 10006
-SpayVac vaccine and modified PZP vaccine (IVT products)

2) EPA regulated (EUP) studies of GonaCon in horses -
a. Theodore Roosevelt National Park Study:
- GonaCon used on horse in TRNP was authorized by EPA under EUP-40

Wildlife Services-National Wildlife Research Center (NWRC) did not field spaying. SpayVac is not a NWRC product, thus we do not have any documents on it.

You may appeal our full release and no records determination. If you choose to appeal, your appeal must be in writing and must be sent within 45 days of the date of this letter to:

Administrator
Animal and Plant Health Inspection Service
Ag Box 3401
Washington, DC 20250-3401

Please refer to FOIA 11-747 in your appeal letter and add the words "FOIA Appeal" to the front of the envelope. To assist the Administrator in reviewing your appeal, provide specific reasons why you believe modification of the determination is warranted.

Because the cost to process your request was less than $25.00, the fee has been waived. If you have any questions, please contact Mr. Robbie Perry of my staff at (301) 734-8696.

Sincerely,

Tonya Woods
Director
Freedom of Information & Privacy Act
Legislative and Public Affairs

Enclosure