U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 92105-1	Date of Issuance: 9/5/19	
NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration	Term of Issuance: Unconditional		
(under FIFRA, as amended)	Name of Pesticide Product: Gonacon Immunocontraceptive Vaccine- EQ		
Name and Address of Registrant (include ZIP Code): Jeff Kemp			
SpayFirst, Inc. P.O. Box 20493 Oklahoma City, OK 73156			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.			
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.			
This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:			
1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.			
 2. Make the following label changes before you release the product for shipment: • Revise the EPA Registration Number to read, "EPA Reg. No. 92105-1." 			
Signature of Approving Official:	Date:		
Sincerely,	9/5/19		
Gene Benbow, Product Manager 7 Invertebrate & Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs			

EPA Form 8570-6

Page 2 of 2 EPA Reg. No. 92105-1 Decision No. 542207

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

• Basic CSF dated 05/21/2018

If you have any questions, please contact Paul Di Salvo by phone at 703-347-0322, or via email at disalvo.paul@epa.gov

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Keep away from humans, domestic animals and pets. Wear protective gloves when handling. If pregnant, do not handle or administer product. Accidental injection may cause infertility in women. Wash all implements used for handling or applying product with detergent and water. Do not use these implements for mixing, holding, or transferring food or feed.

ENVIRONMENTAL HAZARDS: Do not apply this product directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
 - waterproof gloves
 - shoes plus socks

DIRECTIONS FOR USE

USE RESTRICTIONS: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time that the product is applied.

READ THIS LABEL: Read this entire label and follow all use directions and precautions.

IMPORTANT: Do not expose children, pets, or other non-target animals to this product. To help prevent accidents:

1) Keep children out of areas where this product is administered.

- 2) Store product not in use in a location out of reach of children and pets.
- 3) Apply product only according to the directions authorized.
- Dispose of product container and spoiled or unused product as specified in the "STORAGE AND DISPOSAL" section on this label.

GonaCon Immunocontraceptive Vaccine - EQ is used to manage fertility in reproductively mature female wild or feral horses (*Equus caballus*) and burros (*Equus asinus*).

Use caution to prevent accidental self-injection when administering GonaCon Immunocontraceptive Vaccine - EQ to wild or feral horses and burros.

Pregnant women should not be involved in the handling or injection of GonaCon Immunocontraceptive Vaccine - EQ. Do not ingest. Avoid contact with eyes.

Do not apply this product to food or feed.

Applicators: Additional State regulations and/or permitting may apply to the use of this product in wild or feral horses and burros. All applicable State authorities must be contacted prior to use.

GonaCon Immunocontraceptive Vaccine - EQ renders vaccinated reproductively mature female wild or feral horses and burros infertile for a minimum of one year following vaccination.

(See right panel for additional "DIRECTIONS FOR USE")

GONACON

Immunocontraceptive Vaccine – EQ

Alternate Brand Name: GonaCon EQ

For managing fertility in female wild or feral horses (Equus caballus) and burros (Equus asinus)

For use only by employees of Federal agencies, Federally-recognized Indian Tribes, or State agencies responsible for wild or feral horse and burro management, public and private wild or feral horse and burro sanctuaries, research scientists and veterinarians at public and private universities, veterinarians treating wild or feral horse and burro populations, or persons working under their authority.

ACTIVE INGREDIENT

Gonadotropin Releasing Hormone	0.032%
OTHER INGREDIENTS	
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Keep preloaded GonaCon Immunocontraceptive Vaccine - EQ in a refrigerator (36 °F to 45 °F) until ready for use. In the field, keep preloaded GonaCon Immunocontraceptive Vaccine - EQ in a cooler on ice as long as possible prior to use.

PESTICIDE DISPOSAL: If not used within 6 months of manufacture when held under refrigeration (36 °F to 45 °F), or if not maintained on ice in the field, disable and dispose of unused GonaCon Immunocontraceptive Vaccine - EQ material and preloaded syringes as medical waste according to applicable Federal, State, and/or Local regulations.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill container. Disable and dispose of expired material, preloaded syringes or darts, used syringes, darts and needles as medical waste according to applicable Federal, State, and/or Local regulations.

Spay First Inc. P.O. Box 20493 Oklahoma City, OK 73156 EPA Est. No. 92105-CO-1 EPA Reg. No. 92105-1 Net Contents: 2 milliliter (0.066 fl. ounce) Batch Code No.:

DIRECTIONS FOR USE, continued

GonaCon Immunocontraceptive Vaccine - EQ can be administered at any time throughout the year and should not adversely affect an existing pregnancy, but should cause infertility of the vaccinated animal in the subsequent year and possibly longer.

Administer a single vaccination (2 ml) of GonaCon Immunocontraceptive Vaccine - EQ at least two to three months prior to the onset of breeding for full contraceptive effect. If longer contraceptive effect is desired, a second vaccination may be given 90 or more days after the first injection or during the following year with no known adverse health effects to the vaccinated animal. The effects of the vaccine may wear off during the second year or sometimes later and vaccinated females may once again become fertile. However, re-immunization with GonaCon Immunocontraceptive Vaccine - EQ can extend infertility.

There is a chance some vaccinated females will become permanently sterile. Accidental injection of males will result in infertility.

Two-milliliter (2 ml) doses of GonaCon Immunocontraceptive Vaccine - EQ are packaged in pre-loaded, 3-ml plastic syringes.

GonaCon Immunocontraceptive Vaccine - EQ can be administered by hand injection, jab stick or remote delivery (darting). Inject 2.0 ml of GonaCon Immunocontraceptive Vaccine - EQ by intramuscular injection (IM) into a large muscle mass (e.g., rump, neck).

<u>Hand Injection</u>: Inject IM 2 ml GonaCon Immunocontraceptive Vaccine -EQ using the packaged preloaded syringe and a 1.5-inch 18G or 19G stainless steel hypodermic needle.

<u>Jab-Stick Delivery</u>: Transfer 2 ml GonaCon Immunocontraceptive Vaccine - EQ from the preloaded syringe into the jab-stick syringe. Inject IM using a 1.5-inch 14G stainless steel hypodermic needle.

Remote Darting: Recommended dart specifications for this use are a 2 cc dart with a 1.25- or 1.5-inch 14G gelatin barb needle. Transfer 2 ml GonaCon Immunocontraceptive Vaccine - EQ from the preloaded syringe into the dart. Deliver IM using an appropriate projection device.

If remote delivery is used, the applicator must make every attempt to recover all darts. If possible, all darts that are discharged and drop from the horses at the shooting site must be recovered before another darting occurs. In exceptional situations, such as an onset of inclement weather, loss of daylight, applicator safety concerns, or other urgent circumstances, the site of a lost dart may be noted and marked, and recovery efforts made at a later time. Examine all fired darts after recovery to determine if the charge fired and the plunger fully expelled its vaccine content.



A C C E P T E D 09/05/2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92105-1