UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 13, 2021

Jim E. Warren, PhD
Environmental Protection Specialist/Environmental Toxicologist
USDA-APHIS
1200 Cherry Brook Dr., Suite 100
Little Rock, AR 72211

Subject: Label Amendment – Amendment to allow remote darting of deer
Product Name: GonaCon-Deer
EPA Registration Number: 56228-40
Application Date: 2/5/20
Decision Number: 560605

Dear Dr. Warren:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

with FIFRA section 6. If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043, or via email at lewis.marianne@epa.gov.

Sincerely,

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Keep away from humans, domestic animals and pets. Do not ingest. Avoid contact with eyes. 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

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- chemical resistant gloves made out of: barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinyl chloride ≥ 14 mils, or viton ≥ 14 mils
- shoes plus socks

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. 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.

USE RESTRICTIONS

- Only for use on female deer (1 year of age or older).
- Keep preloaded GonaCon-Deer in a refrigerator (36 °F to 45 °F) until ready to use.
- In the field, keep preloaded GonaCon-Deer in a cooler on ice as long as possible prior to use.
- Do not expose children, pets, or other non-target animals to this product.
- Do not apply this product to food or feed.
- All vaccinated deer must be tagged.
- If pregnant, do not handle or inject GonaCon–Deer.
- GonaCon–Deer is only for use on female deer, which are defined as free-roaming deer, privately or publicly owned, that are capable of doing environmental damage.

(See right panel for additional **DIRECTIONS FOR USE**.)

ACCEPTED
04/13/2021
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 56228-40

RESTRICTED USE PESTICIDE

DUE TO NON-TARGET INJECTION HAZARD

For use only by USDA APHIS Wildlife Services or state wildlife management agency personnel or persons working under their authority. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

GONACON–DEER

*An immunocontraceptive vaccine **only** for use in female white-tailed deer (Odocoileus virginianus).*

ACTIVE INGREDIENT	
Gonadotropin Releasing Hormone	0.032%
OTHER INGREDIENTS	99.968%
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–Deer in a refrigerator (36 °F to 45 °F) until ready for use. In the field, keep preloaded GonaCon–Deer 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–Deer 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, used syringes and needles as medical waste according to applicable Federal, State, and/or Local regulations. All used darts and needles are to be placed in a Sharps container and disposed of as medical waste according to applicable Federal, State and Local regulations.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
4700 River Road, Unit 149
Riverdale, MD 20737-1237
EPA Est. No. 56228-CO-1

Net Contents: 1 milliliter (0.033 fl. ounce)
Batch Code No.: _____

DIRECTIONS FOR USE, continued

- To help prevent accidents:
  1. Keep children out of areas where this product is used.
  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.
  4. Dispose of product container and spoiled or unused product as specified in the **STORAGE AND DISPOSAL** section on this label.
- Caution is required to prevent accidental self-injection when administering GonaCon–Deer to white-tailed deer.
- Applicators should be aware that additional State regulations (including wildlife laws) and permitting may apply to the use of this product. All applicable State authorities must be contacted prior to use.
- GonaCon–Deer is intended to be used in combination with other population management techniques.
- GonaCon–Deer renders a vaccinated female white-tailed deer infertile for a minimum of one year following vaccination.
- GonaCon–Deer should not affect existing pregnancy, but should cause infertility of the vaccinated animal in the subsequent year and possibly longer.

APPLICATION DIRECTIONS

- Administer the first vaccination (1 ml dose) of GonaCon–Deer to female deer by hand injection at least two to three months prior to the onset of rut for full contraceptive effect. You must mark (tag) all vaccinated animals.
- To improve efficacy or if a longer contraceptive effect is desired, a booster vaccination may be administered to marked animals by hand injection or remote darting 90 days or more after the first injection or annually.
- The effects of the vaccine may wear off the second year or sometimes longer, and vaccinated females may once again become fertile. However, re-immunization with GonaCon–Deer can extend infertility. There is a chance some vaccinated females will become permanently sterile.
- Accidental injection of males will result in antler deformities and infertility.
- One-milliliter (1 ml) doses of GonaCon–Deer are packaged in pre-loaded, 3-ml plastic syringes.

Hand Injection Directions: Use the packaged preloaded syringe and a 1.5-inch 18G or 19G stainless steel hypodermic needle. Administer 1 ml of GonaCon–Deer by intramuscular injection into a large muscle mass (e.g., rump, neck).

Remote Darting Directions: Use darts with brightly colored tails to facilitate recovery. The recommended dart specifications for this use are a 2 cc dart with a 1.25- or 1.5-inch 14G gelatin barb needle. Transfer 1 ml of GonaCon–Deer from the preloaded syringe into the dart. Use an appropriate projection device to administer by intramuscular injection into a large muscle mass (e.g., rump, neck).

For remote darting, the applicator must make every attempt to recover all darts. In the event that darts cannot be located due to loss of daylight, onset of inclement weather, applicator safety concerns, or other urgent circumstances, the site of a lost dart needs to be noted and marked, and recovery efforts made as soon as possible.

Syringe Label

Restricted Use Pesticide Syringe #__
GonaCon–Deer
KEEP OUT OF REACH OF CHILDREN
CAUTION: Injection Hazard
Active Ingredient: Gonadotropin Releasing Hormone (0.032%)
See full product label for “DIRECTIONS FOR USE.”
EPA Reg. No. 56228-40; EPA Est. No. 26228-CO-1
Net Contents: 1 ml; Lot: _____; Exp. date: _____