UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 19, 2015

David S. Reinhold
Chief
Environmental and Risk Analysis Services
USDA-APHIS
4700 River Road
Riverdale, MD 20737

Subject: Label and CSF Amendment – Calculation corrections on CSF and subsequent label changes
Product Name: GonaCon Immunocontraceptive Vaccine
EPA Registration Number: 56228-40
Application Date: 7/22/2015, 11/2/2015
Decision Numbers: 508907, 510841

Dear Mr. Reinhold:

The amended label and CSFs referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following CSFs:

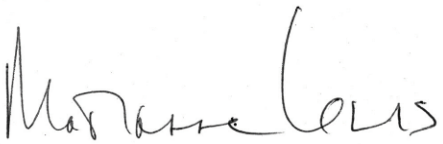
- Basic CSF dated 07/22/2015
- Alternate CSF 1 dated 07/22/2015

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 Jacquelyn Marchese by phone at 703-347-0559, or via email at marchese.jacquelyn@epa.gov.

Sincerely,



Marianne Lewis,
Acting Product Manager 07
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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
- gloves
- shoes plus socks

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.

4) Dispose of product container and spoiled or unused product as specified in the "STORAGE AND DISPOSAL" section on this label.

GonaCon Immunocontraceptive Vaccine (GonaCon) is for use in female white-tailed deer 1 year of age or older.

Caution is required to prevent accidental self-injection when administering GonaCon to white-tailed deer.

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

Do not apply this product to food or feed.

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.

(See right panel for DIRECTIONS FOR USE)

RESTRICTED USE PESTICIDE

DUE TO NON-TARGET INJECTION HAZARD

For use by USDA APHIS Wildlife Services or state wildlife management agency personnel or persons working under their authority.

GONACON IMMUNOCONTRACEPTIVE VACCINE

Immunocontraceptive vaccine for use in white-tailed deer (Odocoileus virginianus)

ACTIVE INGREDIENT

Mammalian 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 Immunocontraceptive Vaccine in a refrigerator (36 °F to 45 °F) until ready for use. In the field, keep preloaded GonaCon Immunocontraceptive Vaccine 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 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.

DIRECTIONS FOR USE

GonaCon is intended to be used in combination with other population management techniques.

GonaCon renders a vaccinated female white-tailed deer infertile for a minimum of one year following vaccination.

GonaCon should not affect existing pregnancy, but should cause infertility of the vaccinated animal in the subsequent year and possibly longer.

Administer a single vaccination (1 ml) of GonaCon at least two to three months prior to the onset of rut for full contraceptive effect.

If longer contraceptive effect is desired, a second vaccination may be given 30 to 60 days after the first injection or during the following year with no known adverse health effects to the vaccinated animal. Mark vaccinated animals to ensure that they are not unintentionally reinjected.

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 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 are packaged in pre-loaded, 3-ml plastic syringes.

GonaCon must be administered by hand injection. Inject each female with 1.0 ml of GonaCon, using an 18- or 19-gauge stainless steel hypodermic needle, by intramuscular injection into a large muscle mass.

Syringes must be individually labeled with the following language:

Restricted Use: Injection Hazard
CAUTION
GonaCon Immunocontraceptive Vaccine
Active Ingredient: Gonadotropin Releasing Hormone (0.032%)
KEEP OUT OF REACH OF CHILDREN
EPA Reg. No. 56228-40, EPA Est. No. 56228-CO-1
See Full Product Label for Application Instructions.
Vaccine expires 6 months from: _____

ACCEPTED
Nov 19, 2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 56228-40

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
Riverdale, MD 20737-1237
EPA Est. No. 56228-CO-1
EPA Reg. No. 56228-40
Net Contents: 1 milliliter (0.033 fl. ounce)
Batch Code No.: _____

Revised 11-16-15