S6228-40 C 09-29-2009 C

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
56228-40	SEP 29 2009

Term of Issuance: Conditional

Name of Pesticide Product: GonaCon Immunocontraceptive Vaccine

Name and Address of Registrant (include ZIP Code):

U.S. Department of Agriculture, Animal and Plant Health Inspection Service
Environmental Services, Unit 149
4700 River Road
Riverdale, MD 20737

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/reregistered 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 conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.

2. Make the following label change before you release the product for shipment revise the EPA Registration Number to read, "EPA Reg. No. 56228-40."

Signature of Approving Official:

John Hebert, Product Manager
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date: SEP 29 2009

EPA Form 8570-6

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.
4. Submit the following conditional data requirements within 12 months of the date of this letter:
    - Guideline 830.1700 - Preliminary analysis and validation of the method of analysis of the formulation
    - Guideline 830.1750 - Certified limits (basic and alternate CSFs)

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

John Hebert
Product Manager
Insecticide-Rodenticide Branch
Registration Division (7505P)

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 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.

GonaCon™ Immunocontraceptive Vaccine 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™ immunocontraceptive vaccine 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	0.03%
OTHER INGREDIENTS	99.97%
TOTAL	100.00%

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

ACCEPTED
With COMMENTS
In EPA Letter Dated:
SEP 29 2009
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-ID-1
EPA Reg. No. 56228-xx
Net Contents: 1 milliliter (0.033 fl. ounce)
Batch Code No.: _____

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-mililiter (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 Hazards
CAUTION
GonaCon Immunocontraceptive Vaccine
Active Ingredient: Gonadotropin Releasing Hormone (0.03%)
KEEP OUT OF REACH OF CHILDREN
EPA Reg. No. 56228-xx, EPA Est. No. 26228-ID-1
See Full Product Label for Application Instructions.
Vaccine expires 6 months from: _____

STORAGE AND 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.