

## Session VII: Part I

### Feral Cats: New Regulatory Pathway, New Approaches

By Dr. Kathy Fagerstone

## FERAL CATS: NEW REGULATORY PATHWAY, NEW APPROACHES



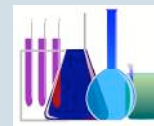
Kathleen Fagerstone, John Eisemann  
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United States Department of Agriculture  
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## What Federal Agency Regulates Contraceptive Products?

FEDERAL AGENCY	PRODUCTS REGULATED
Department of Agriculture	<i>Disease vaccines</i>
Environmental Protection Agency	<i>Contraceptives for wildlife and feral animals</i>
Food and Drug Administration	<i>Contraceptives for domestic livestock, companion animals and zoos</i>



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## Federal Insecticide, Fungicide and Rodenticide Act

- Pesticide products must obtain an EPA registration before manufacture, transport, and sale
- Registration based on a risk/benefit standard
- Grants EPA authority to require data
  - Product Chemistry
  - Hazards: Wildlife and Aquatic Organisms
  - Hazards: Humans and Domestic Animals
  - Environmental Fate
  - Residue Chemistry
  - Product Performance

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## EPA Regulatory Review

### Bait Delivered Oral Contraceptives Minimum Data Requirements

#### Standard Conventional Pesticide Review

Product Chemistry	Standard
Toxicology	6 studies
Nontarget Hazard	3 studies
Environmental Fate	1-3 studies
Product Performance	Lab and Field
Worker Protection	Standard
Residue Chemistry	For food or feed uses

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EPA Regulatory Review	
Injectable Contraceptives	
Abbreviated Data Requirements	
Product Chemistry	Standard with waiver requests
Toxicology	Waiver + acute toxicity data from literature
Nontarget Hazard	Probable waiver
Environmental Fate	None – waiver requests
Product Performance	Laboratory and Field Efficacy
Worker Protection	Precautionary label language
Residue Chemistry	Submit FDA HFS review

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### Federal and/or State Regulatory Authority

- Products are registered nationally with the EPA (FIFRA Sec. 3)
  - Gonacon™
- Then each state decides whether they will register the product
- States may register an additional use for a product under a Special Local Need (FIFRA Sec. 24c)
  - For different species
  - For different use patterns

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**DRAFT LABEL-NOT FOR USE**

<p><b>PRECAUTIONARY STATEMENTS</b></p> <p><b>HAZARDS TO HUMANS AND DOMESTIC ANIMALS</b></p> <p>Keep away from humans, domestic animals and pets. Wear protective gloves when handling. If pregnant, do not handle or administer product. With detergent and hot water, wash all implements used for handling or applying product. Do not use these implements for mixing, holding, or transferring food or feed.</p> <p><b>ENVIRONMENTAL HAZARDS</b></p> <p>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.</p>	<p><b>RESTRICTED USE PESTICIDE</b></p> <p><b>DUE TO NON-TARGET INJECTION HAZARD</b></p> <p>For use by state or federal wildlife or natural resource management personnel or persons working under their authority.</p> <p style="text-align: center;"><b>GONACON™</b></p> <p style="text-align: center;"><b>IMMUNOCONTRACEPTIVE VACCINE</b></p> <p style="text-align: center;"><i>Immunocontraceptive vaccine for use in cervid species</i></p> <p><b>ACTIVE INGREDIENT</b></p> <p>Mammalian Gonadotropin Releasing Hormone.....0.03%</p> <p><b>OTHER INGREDIENTS</b>.....99.97%</p> <p><b>TOTAL</b>.....100.000%</p>	<p><b>USE RESTRICTIONS (continued)</b></p> <p>This product is for use in cervids.</p> <p>Caution is required to prevent accidental self-injection when administering GonaCon™ Immunocontraceptive Vaccine.</p> <p>Pregnant women should not be involved in the handling or injection of GonaCon™. Do not ingest. Avoid contact with eyes.</p> <p>Do not apply this product to food or feed.</p>				
<p><b>PERSONAL PROTECTIVE EQUIPMENT (PPE)</b></p> <p>Applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>-long sleeved shirt and long pants</li> <li>-gloves</li> <li>-shoes plus socks</li> </ul>	<p style="text-align: center;"><b>KEEP OUT OF REACH OF CHILDREN</b></p> <p style="text-align: center; color: red;"><b>CAUTION</b></p> <p style="text-align: center;"><b>First Aid</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 2px;">If swallowed</td> <td style="padding: 2px;">-Call a doctor, poison control center or 1-800-228-2635 ext. 136 immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not give anything by mouth to an unconscious person.</td> </tr> <tr> <td style="padding: 2px;">If in eyes</td> <td style="padding: 2px;">-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.</td> </tr> </table> <p style="font-size: small; text-align: center;">Have this product container or label with you when calling a poison control center or doctor, or when going for treatment.</p> <p style="text-align: center; font-size: x-small;">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 Weight</p>	If swallowed	-Call a doctor, poison control center or 1-800-228-2635 ext. 136 immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not give anything by mouth to an unconscious person.	If in eyes	-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.	<p><b>DIRECTIONS FOR USE</b></p> <p>GonaCon™ Immunocontraceptive Vaccine is for use in female cervids 1 year of age or older. GonaCon™ will render a treated female infertile for multiple years with only one vaccination. However, vaccinating more than once will increase the efficacy and duration of infertility with no known adverse health effects to the vaccinated animals. GonaCon™ may not be effective if given during pregnancy.</p> <p>A single vaccination (1 ml) of GonaCon™ should be administered at least two to three months prior to the 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. Over a period of a few years, as the effect of the vaccine wears off, treated females may once again become fertile and be capable of breeding. Re-immunization with GonaCon™ will again render the females infertile.</p>
If swallowed	-Call a doctor, poison control center or 1-800-228-2635 ext. 136 immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not give anything by mouth to an unconscious person.					
If in eyes	-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.					
<p><b>USE RESTRICTIONS</b></p> <p>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.</p> <p><b>READ THIS LABEL:</b> Read this entire label and follow all use directions and precautions.</p> <p><b>IMPORTANT:</b> Do not expose children, pets, or other non-target animals to this product. To help prevent accidents:</p> <ol style="list-style-type: none"> <li>1) Keep children out of areas where this product is used.</li> <li>2) Store product not in use in a location out of reach of children and pets.</li> <li>3) Apply product only according to the directions authorized.</li> <li>4) Dispose of product container and unused, spoiled or unused product as specified in the <b>STORAGE AND DISPOSAL</b> section on this label.</li> </ol> <p style="font-size: x-small; text-align: center;">(SEE RIGHT PANEL FOR ADDITIONAL DIRECTIONS FOR USE AND RESTRICTIONS)</p>	<p style="font-size: x-small;">Page 1 of 2: GonaCon™ Immunocontraceptive Vaccine              EPA Registration No. 56228-xx</p>					

**Proposed GonaCon™ Label (Restricted Use Pesticide)**

**Directions for Use**

- Immunocontraceptive vaccine for use in cervid species
- For use by state or federal wildlife or natural resource management personnel or persons working under their authority.
- GonaCon™ will render a treated female infertile for multiple years with only one vaccination. However, vaccinating more than once will increase the duration of infertility with no known adverse health effects.
- A single vaccination (1 ml) of GonaCon™ should be administered at least two to three months prior to the rut for full contraceptive effect.
- For longer contraceptive effect, a second vaccination may be given 30 to 60 days after the first injection or the following year.
- Over a period of a few years, treated females may once again become fertile and require re-immunization with GonaCon™.
- GonaCon™ can be administered by either hand or remote injection.

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#### DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

##### REGISTERED PRODUCT AND USE FOR MULTIPLE SPECIES

- **FDA—New Animal Drug Approval (NADA)**
  - *NADA* (allows for use on one species: Ex, GonaCon for Cervids)
  - Use for other species:
    - “*Extra-label*” provision allows for use on other species without FDA notification.
- **EPA—Registration**
  - *Active Ingredient or Technical Registration* (100% capsaicin—red pepper)
  - *End Use Product*—Label lists species and use patterns (ex., 5% capsaicin in a spray for repelling bears). Cannot use for other species.
  - *Special Local Need* (FIFRA Sec. 24c)
    - State registration for different species or for different use patterns
  - 2ee—if same rate and use pattern, can use for another species without EPA notification

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#### DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

##### HOW ARE USES RESTRICTED?

- **FDA—NADA**
  - RX (Veterinarian prescription)
  - Over-the-Counter
- **EPA—Registration**
  - Restricted Use (Use by certified applicator)
  - General Use (Can be sold directly to the public)
  - Further restrictions allowed
    - Ex., for use only by persons trained in bird control
    - Ex., for use only by USDA/APHIS/WS personnel

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### MANUFACTURING PRACTICES

- **FDA—NADA**
  - Good Manufacturing Practices required, as well as characterization of the product and product stability
  
- **EPA—Registration**
  - Not GMP
  - EPA requires characterization of the product, including storage stability

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**DIFFERENCES BETWEEN EPA AND FDA REGULATIONS**

### TESTING

- **FDA—NADA**
  - Investigational New Animal Drug (INAD)
- **EPA—Registration**
  - Less than 10 acres (no regulatory requirement)
  - Experimental Use Permit
    - Requires a basic data package

### STATE AUTHORIZATIONS

- **FDA—NADA**
  - *None?*
- **EPA—Registration**
  - Individual States have authority over use in their state

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