

NEW YORK STATE DEPARTMENT OF AGRICULTURE AND MARKETS

New York State Cattle Health Assurance Program

New York State Sheep and Goat Health Assurance Program

Updates

Kathy Hochul Governor Richard A. Ball Commissioner Eireann Collins October 28, 2023

- FDA Therapeutic Transition ~~Over the Counter Medications to Prescription~~
- New York State Sheep and Goat Health Assurance Program (NYSSGHAP)
- Secure Food Supply Planning

New York State Cattle Health Assurance Program Agriculture and Markets

Therapeutic Transition

New York State Cattle Health Assurance Program Agriculture and Markets

3 Classifications of Animal Drugs

1. **Over-the-counter (OTC)**
 - a) Can be sold by any person/establishment **without a prescription**
2. **Prescription (Rx)**
 - a) Can only be sold to a farmer by a veterinarian or pharmacist.
 - b) Only sold **with a prescription** from a veterinarian
3. **Veterinary Feed Directive (VFD)**
 - a) A drug intended for use in or on feed
 - b) Limited by an approved application to use under the professional supervision of a licensed veterinarian. ***Prescription***

New York State Cattle Health Assurance Program Agriculture and Markets


2017 Veterinary Feed Directive Changes

- **No Growth Promotion**
 - The labeled uses of "medically important" antibiotics for *growth promotion and improvements in feed efficiency* were **eliminated**.
Can still be used for disease prevention & treatment.
- **No Extra Label Use**
 - Any extra-label use of medicated feed is not permitted by law. **Neither veterinarians**, nor their clients may use or direct the use of, a medicated feed in an extra-label manner.

New York State Cattle Health Assurance Program Agriculture and Markets



"No Crumbles at the Feed Store"

- Went into effect in 2017
- Drugs like Tetracycline, Tylosin, Neomycin were most effective



New York State Cattle Health Assurance Program Agriculture and Markets

2023 Guidance for Industry 263 *Injectables*






FDA Guidance for Industry (GFI #263)

Livestock owners will need to either purchase these drugs:



Ends over-the-counter (OTC) sales of antibiotics.

- From a veterinarian or
- Prescription (Rx) will be required from a veterinarian

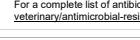

GRI #263

- GFI #263 went into effect **June 11, 2023**
- New labeling for these products will require the following language:
“Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”
- **Once antibiotics have this revised labeling, they will require a prescription**

Commonly used antibiotics affected by GFI 263	
Antibiotic	Product examples
Cephapirin, cephapirin benzathine	Intramuscular tubes: ToDAY® and TOMORROW®
Lincomycin	Injectables: Lincmix® 100, Lincmix® 300, LincMed100, LincMed® 300
Oxytetracycline	Injectables: Lincmix® LA-200®, Noromycin® 300 LA, Bio-Mycin® 200, Agrimycin 200, etc. Boluses: Terramycin® scours tablets, OXY 500 calf boluses
Penicillin G procaine, penicillin G benzathine	Injectables: Penicillin Injectable, Dura-Pen, Pro-Pen-G®, Combi-Pen 48®, etc. Intramuscular tubes: Masti-Clear®, Go-dry™, Albadry Plus®
Sulfadimethoxine, sulfamethazine	Injectables: Di-Methox 40%, SulfMed 40%™ Boluses: Albon®, Sustain III® cattle & calf boluses, Supra Sulf III cattle & calf boluses
Tylosin	Injectables: Tylan 50™, Tylan 200™

For a complete list of antibiotics impacted by this ruling, visit the FDA website: <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/list-approved-new-animal-drug-applications-affected-gfi-263>






Drugs not affected

Drugs that are *not* Antimicrobials

i.e. “Dewormers”




- **Anthelmintics:**
Fenbendazole, Ivermectin
- **Beta agonists:**
Ractopamine, Zilpaterol
- **Coccidiostats:**
Clopidol, Decoquate, Diclazuril

Drugs not affected

Drugs that are **NOT medically important**

- Bacitracin (BMD, bacitracin zinc)
- Bambermycins
- Carbadox
- Ionophores
 - monensin
 - bovatec
 - etc.


***No Antibiotics at the Feed and Grain Store ***

As of June 11, 2023
Local feed and grain stores

MAY NOT sell antibiotics



Unless Licensed Pharmacy

- May purchase these drugs directly through your veterinarian
- Veterinarian can write you a *prescription* to purchase products through *licensed pharmacy*



What if I have a stockpile?



- The FDA intends to allow existing stocks of OTC antibiotics to be depleted, and a
 - Prescription **will not be required** for *labelled* use of existing stock.
 - Be aware of expiration dates!
- **Extra-label Use *****(in a manner that is not in accordance with the approved label directions), Requires Veterinary Prescription.

Prescription Animal Medication

The same rules and regulations apply equally to


- Commercial operations
- Hobby/backyard operations
- Exhibitor/Show Animals
- Livestock species kept as pets

Prescription Animal Medication

Establish a **Veterinarian-Client-Patient Relationship (VCPR)**


- Veterinarian is acquainted with your operation and the keeping and care of your animals
 - Routine Herd Checks &/or
 - Individual Animal Examination



EXTRA-LABEL Drug Use

Actual use or intended use of a drug, in an animal, in a manner, that is NOT in accordance with the approved labeling.

- Use in a species not listed in the labeling
- Use in a different age or classification of animal not listed on the labeling.
- Use for indications (disease and other conditions) not listed in the labeling
- A higher dosage level from the label.
- Increased treatment frequency from the label
- Different route of administration other than those stated in the labeling
- Any deviation from labeled withdrawal time based on these different uses.




EXTRA-LABEL Drug Use

The FDA permits the extra-label use of OTC and Rx drugs

- By **veterinarians** under certain conditions
- and
- When there is a valid VCPR.



In the absence of a valid VCPR, if a drug is used for which it is **not labeled**, the drug is deemed unsafe under the Federal Food, Drug and Cosmetic Act and the **milk and/or meat** is seen as **adulterated**.




Therapeutic Best Management Practices

- Drug use protocols
- Treatment protocols
- Recordkeeping
- Inventory
- Storage
- Personnel training on proper drug use

Per the FDA – if it is not recorded, it did not happen!






NYS Sheep and Goat Herd Assurance Plan





NYSSGHAP Program Objectives

- Integrated disease prevention program that utilizes a team of advisors to develop a farm-specific herd health plan.
- Objectives of this plan are to:
 - Increase the herd's health, productivity and profitability,
 - Assure food safety, public health and consumer confidence in animal agriculture



The NYSSGHAP Farm Team

- NYSCHAP Herd Planner
NYS Field Veterinarian
or
Certified NYSCHAP Veterinarian
- Key Farm Employees
- Producer
- Consultants used on the farm
- Herd Veterinarian




NYSSGHAP

- Sponsored by NYSAGM
- Herd plans are **herd specific** and created within the goals and resources of the farm operation.
- **No enrollment fee** for participation
- Herd Veterinarians are compensated for their time in the planning process by NYSAGM (Voucher)



The steps of herd planning

- Risk Assessments:
 - Objective review of current facilities, management, disease issues and concerns
- Goals
 - Short term vs. long term
- Priority Issues
 - What are the bottlenecks
- Creation of intervention tactics
 - What are do-able steps that are within the farm's resources to address the priority issues



NYSSGHAP

<ul style="list-style-type: none"> • Johne's Disease • Pneumonia • Caseous Lymphadenitis • Clostridial Diseases • Scrapie • Coxiella burnetii (Q Fever) 	<ul style="list-style-type: none"> • Caprine Arthritis Encephalitis • Ovine Progressive Pneumonia • Chlamydial Abortions • Campylobacteriosis • Vibrio
---	---


NYSSGHAP

<ul style="list-style-type: none"> • Soremouth / Contagious Exanthema • Ringworm • Foot Rot * • Copper Toxicity • Urolithiasis • External Parasites 	<ul style="list-style-type: none"> • Haemonchus • Ostertagia • Trichostrongylus • Cooperia • Oesophagostomum • Bunostomum • Coccidiosis
---	--





Secure Food Supply





ANIMAL DISEASES PREVENTION PREPAREDNESS & RESPONSE COURSES PRODUCTS ABOUT




www.securemilksupply.org



www.securesheepwool.org




<https://www.cfsph.iastate.edu/secure-food-supply/>



[Home](#) | [Questions](#)

[HOME PLAN](#) | [PRODUCTS](#) | [VETERINARIANS](#) | [PACKERS/PROCESSORS](#) | [REGULATORY OFFICIALS](#) | [TRAINING MATERIALS](#)



SSWS Plan for Continuity of Business


Foot and mouth disease (FMD) is found in United States livestock. Regulatory Officers will limit the movement of animals and animal products to try and control the spread of this very contagious animal disease.

Foot and mouth disease (FMD) is not a public health or food safety concern. Meat and milk are safe to eat and drink.

The Secure Sheep and Wool Supply (SSWS) Plan for Continuity of Business provides opportunities to voluntarily prepare before an FMD outbreak. This will better position premises with sheep that have no evidence of infection to:

- Limit exposure of their animals through enhanced biosecurity.
- Move animals to processing at another premises and a movement permit issued by Regulatory Officials, and
- Maintain business continuity for the sheep industry, including producers, haulers, packers and wool processors during an FMD outbreak.

<https://securesheepwool.org/>



[Home](#) | [Questions](#)

[HOME PLAN](#) | [MILK PRODUCTS](#) | [VETERINARIANS](#) | [PROCESSORS](#) | [REGULATORY OFFICIALS](#) | [TRAINING MATERIALS](#)



Milk Producers

Steps to Milk

Producer ID Number

Essentiality

Disease Monitoring

Vaccination

Movement Records

Permit Database

Partners and SPSs

Milk Producers

Thanks for providing us to learn more about the Secure Milk Supply (SMS) Plan and how you can voluntarily participate in foot and mouth disease (FMD) in United States livestock. Regulatory Officials will limit movement of animals and animal products to try and control the spread of this very contagious animal disease. FMD is not a public health or food safety concern. Meat and milk are safe to eat and drink.

The SMS Plan for Continuity of Business provides steps to prepare and request a movement permit. Use the resources on the LEFT MENU in our learning.

[Read the SMS Plan \(Secure Milk Supply\) - Secure SMS Plan Overview](#) | [Secure SMS Plan Overview \(2022\)](#)

[Request SMS Plan \(Secure Milk Supply\) - SMS Plan Overview \(2022\)](#) | [Request SMS Plan \(2022\)](#)

[Learn about FMD](#) | [Secure FMD Overview](#) | [FMD Virus in Cattle \(2013-2014\)](#) | [FMD Virus in Swine \(2022\)](#)

<https://securemilksupply.org/milk-producers/>



Thank you and Recognition

- Dr. Melanie Hemenway
- Dr. Jessica Scillieri Smith
- Dr. Patrina Ashley
- Christina Cookingham



Farmer Brown froze in his tracks; the cows stared wide-eyed back at him. Somewhere, off in the distance, a dog barked.

Eireann P. Collins, DVM
New York State Department of
Agriculture and Markets
Division of Animal Industry
 10B Airline Drive
 Albany, NY 12235
<http://www.agriculture.ny.gov>
Eireann.Collins@agriculture.ny.gov

