‘Violative’ Chemical Residues
Assumptions : Chain of Response & Responsibility : Reality
• What’s driving the flurry of activity about food animal drug use best practices?
• How does USDA-FSIS & FDA fit into the residue avoidance picture?
• How has NYS Department of Agriculture / Division of Animal Industry been involved in food animal residue avoidance?
• What are some of the things we are seeing that have resulted in ‘violative’ tissue residues?
• How can we lessen the chances of causing a violative tissue (or milk) residue?
Along with the obvious technological changes we’ve seen in agriculture over the past 100 years or so, there are subtle ones that we may not think about.
Just like a GPS system used in planting crops, or a robotic milking system, the tools that are available to keep food animals healthy & productive have come a long way along...

So has pressure for sensible and responsible antibiotic use.
Public Health Is The Overriding Argument Driving Chemical Residues & The Use Of Antibiotics In Food Animal

- Residues
  - Bacterial Resistance
  - More Immediate effects (e.g. allergic reaction)

- Consumers, government, companies, processors/distributors, restaurants etc

**McDonalds Plans to Phase Out Chicken Fed Medically Important Antibiotics**

By *Lydia Zuraw* | March 5, 2015

Fast-food giant McDonald’s *announced* Wednesday that, within two years, all of the chicken served at its 14,000 U.S. restaurants will come from farms which raised the birds without medically important antibiotics….
Chain of Response & Responsibility
The veterinarian-client-patient relationship (VCPR) is the basis for interaction among veterinarians, their clients, and their patients and is critical to the health of your animal.

A VCPR means that all of the following are required:

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient and the client has agreed to follow the veterinarians’ instructions.

2. The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the veterinarian, or medically appropriate and timely visits by the veterinarian to the operation where the patient is managed.

3. The veterinarian is readily available for follow-up evaluation or has arranged for the following: veterinary emergency coverage, and continuing care and treatment.

4. The veterinarian provides oversight of treatment, compliance, and outcome.

5. Patient records are maintained.
ANIMAL DRUGS

There are three classes of animal drugs: Over-the-Counter (OTC), Prescription (RX), and Veterinary Feed Directive (VFD). OTC drugs can be sold by any person or establishment without the prescription of a veterinarian. Prescription drugs can only be sold to the farmer by a veterinarian or pharmacist, and only with the prescription of a veterinarian. VFD is a drug intended for use in or on feed, which is limited by an approved application to use under the professional supervision of a licensed veterinarian. Pulmotil® (tilmicosin) is the first VFD product approved for use in cattle. The Food and Drug Administration (FDA) approved the drug as a treatment for groups of cattle in the early stages of bovine respiratory disease outbreak to provide 14 days of sustained in-feed therapy. Pulmotil® is approved for use in beef and non-lactating dairy cattle.

One type of drug is an antibiotic. An antibiotic is a chemical substance or compound that kills or reduces the growth of susceptible bacteria. An antimicrobial is a substance that kills or inhibits the growth of microorganisms such as bacteria, fungi, or protozoans. Therefore, an antibiotic is an antimicrobial drug that attacks bacteria. Any use of a drug not specifically listed on the label is called “extra-label drug use” and is regulated by the FDA under the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994. Using a prescription or over-the-counter drug in an extra-label manner is illegal unless it is specifically recommended under the guidance of a veterinarian working in the context of a Veterinary-Client-Patient Relationship (VCPR). There are no legal extra-label uses of VFD drugs.

Examples of extra-label drug use:

1. Changing the dose, such as giving more penicillin than is listed on the label.
2. Changing the route of administration, such as giving flunixin intramuscularly (IM) or subcutaneously (SQ) instead of intravenously (IV).
3. Changing the frequency of use, such as giving Spectramast™ LC twice a day instead of once a day.
4. Giving a drug to a different production class of animal, such as using Nuflor® in a lactating dairy cow.
5. Giving a drug for an indication (disease) not listed on the label, such as using Excede® for diarrhea.
6. Changing the withholding times, such as not following milk withholding times for fresh cows after dry treatment administration.
7. Changing the amount of drug per injection site.
8. Changing the duration of therapy.

In 2012, USDA-FSIS Introduced New Testing Methods & Testing Strategies

- In July of 2012, USDA announced new chemical residue testing strategies & methods.
- A random & ‘at risk’ testing (determined by USDA plant veterinarian) approach has been changed...more animals are being screened.
- Targeted area testing:
  - Farm level
  - Region level
- New ways of testing:
  - Multi-residue screening methods
  - Testing will be much more precise & will identify more compounds (not just antibiotics)
  - Testing turn-around times will be shortened
FDA’s Action

• In cases of a residue violation identified by USDA-FSIS

  ✓ FDA may issue a violation letter to the [residue-source] business whereby they expect

  • A timely response, which is to include, a management plan on how the business intends to prevent further violations.
Warning Letters are issued to achieve voluntary compliance and to establish prior notice. Warning Letters are issued for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected. AWarning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Warning Letters are posted on FDA's website.
What Happens When [USDA] FSIS Identifies a Violative Residue in Edible Tissue?

A warning letter is issued to the producer (source) of the regulatory significant [violative] residue.

Dear [Name(s)]:

This letter is to inform you that the United States Department of Agriculture (USDA) detected violative levels of residue(s) in the tissue collected from a dairy cow identified as originating from your premises. The test results and sample collection date are listed on the enclosure. The tissue sample(s) were collected as part of the residue testing programs conducted by the Food Safety and Inspection Service (FSIS). FSIS collects tissue samples from livestock and poultry slaughtered at inspected slaughter establishments. FSIS also collects samples of egg products for residue analysis. Samples are then analyzed at Agency laboratories for various drug, pesticide and other chemical residues. Residue levels in meat, poultry or egg products are violative when they exceed allowable levels for one or more chemical substances in the tissue or tissues or product analyzed.

Violative residues constitute adulteration within the meaning of the Federal Food, Drug, and Cosmetic Act and indicate violations of the Federal Meat, Poultry, and Egg Products Inspection Acts and/or State law. Accordingly, USDA FSIS has notified the Food and Drug Administration (FDA) and the appropriate authorities in your state of its findings.

Should another violation be detected in livestock, poultry, or egg products from any premises under your ownership within a twelve (12) month period after having received a FSIS Violation Notification Letter, your name will be posted on the USDA, Food Safety and Inspection Service website (http://www.fsis.usda.gov/Science/Chemistry) as a repeat violator.

It may be helpful to discuss this notification with your veterinarian.

If you have any questions, please contact the Policy Development Staff at: (800) 233-3935 (select option 6) or email residue@fsis.usda.gov.

Sincerely,

Jim Holteman, D.V.M.
Senior Staff Officer- Residue Lead
USDA, FSIS, Policy Development Staff
Enclosure

NYS Department of Agriculture
Division of Animal Industry
Dwight Bruno BSc, DVM
Who should be held accountable for antibiotic residues in meat?

- Beef Industry
- Dairy Industry
- Veal Industry
- All producers

A list no responsible livestock producer wants to be on

The FSIS Residue Violation Information System List identifies all producers that have marketed food animals which have tested positive for antibiotic residues at slaughter. The list is updated weekly, ranges from 110 to 140 pages and includes the names, addresses and phone numbers of producers who have marketed animals with antibiotic residues and businesses that have purchased their cattle during the previous 12 months.

Not only does this list present a negative image for the cattle industry, but it is a target for increased scrutiny from industry critics. The reputation of individual producers and of the entire livestock industry is at stake.

Legislation is being considered that would withdraw seven classes of antibiotics from food production unless the animals are sick or unless the drug companies can prove that their use does not harm human health. The effort has the support of the American Medical Association, the American Public Health Association and 350 other groups.

The opinions of groups outside of agriculture also have a significant impact on government policy and consumer purchasing decisions. A good example is the organic section at the grocery store, where sales have steadily risen. Consumer perceptions concerning antibiotic use and misuse in farm animals have helped fuel that growth.
FDA Has Broad Enforcement Authority
Federal regulators have cited a dairy farmer for selling cows with higher-than-permitted residues of antibiotics.

A US District judge in Buffalo issued an order barring XXX from selling cattle to be slaughtered for human consumption until he complies with federal limits on antibiotic residues.

XXX owns a farm in [NY], which sells its dairy cattle to an auction yard in [NY]. A Food and Drug Administration complaint says “he’s sold cows for at least a decade with residues of penicillin and sulfadimethoxine in the animals’ edible tissue, posing a public health risk.”

The agency also says XXX illegally gave the cows higher-than-allowed dosages. The US Department of Agriculture says it has cited XXX 6 times in the past 10 years and that he violated the law by failing to keep adequate records of which cows were medicated.
A Violative Chemical Residue Identified in a Dairy Cow --Case Example--
A Case Example

- Drug was prescribed by the herd veterinarian & the veterinarian has a valid veterinary-client-patient relationship (the drug was drop shipped to the farm by a drug company).

- Producer administered 20cc of drug, subcutaneously-in one location, to the cow in question.

- Producer followed his veterinarians instructions: ‘administer the drug according to label directions.’

? How could the producer have failed to follow label directions if the drug vial label directions were followed?
Label directions include what is stated on all the literature that comes with the drug, including the insert.

(2.2 mg/kg) BW (2 mL, sterile suspension per 100 lb BW). Administer at 24 h intervals for five consecutive days. Do not inject more than 15 mL per injection site.
What Are Some Of The Causes For The Violative Residues We Are Seeing?
** Apparent Reason(s) Residue Occurred**

- **WITHHOLDING**: 85%
- **DOSAGE**: 7%
- **INDICATION**: 1%
- **FREQUENCY**: 1%
- **ROUTE**: 4%
- **SPECIES**: 2%

**Data Compiled From DAI Residue Investigations**

NYS Department of Agriculture
Division of Animal Industry
Dwight Bruno BSc, DVM
Is Our Industry Making Progress In Reducing Violative Residues?

The Short Answer is, YES.

NYS Department of Agriculture
Division of Animal Industry
Dwight Bruno BSc, DVM
14 States/135 Repeat Violations 2014-2015 US & Canada

CA 27%
PA 24%
NY 7%
OH 7%
IN 13%
MI 2%
NE 3%
SD 2%
VT 1%
WA 1%
WI 3%
CN 2%
FL 3%
GA 3%
IA 2%
MI 2%
WA 1%
WI 3%

NYS Department of Agriculture
Division of Animal Industry
Dwight Bruno BSc, DVM
SULFADIMETHOXINE
PENICILLIN
FLUNIXIN
DESFUROYLCEFTIOFUR
AMPICILLIN

TYLOSIN
TULATHROMYCIN
TILMICOSIN
TETRACYCLINE
SULFAMETHOXAZOLE
SULFAMETHAZINE
SULFADIMETHOXINE
PENICILLIN
OXYTETRACYCLINE
NEOMYCIN
GENTAMICIN
FLUNIXIN
DIHYDROSTREPTOMYCIN
DESFUROYLCEFTIOFUR
NYS 2014-2015 Production Type & Residue—9 Repeat Violators

- SULFAMETHAZINE
  - BOB VEAL
- NEOMYCIN
  - BOB VEAL

NYS Department of Agriculture
Division of Animal Industry
Dwight Bruno BSc, DVM
How Can You Minimize The Chances of A Residue Violation?
Records, Communication and Good Herd Drug Use Practices

I Just Treated Number 56, Be Sure To Mark It Down and ID her.

When?

Some Time Later

56 was sold before her meat withholding date—I told you to record the information and identify her!
Record Keeping; An Indispensable Part Of Any Good Management Routine

Permanent
Read & Follow The Label!

- Species
- Indication for use
- Route of administration
- Dosage
- How often administered
- Other directions

Cattle:
— For bovine respiratory disease and acute bovine interdigital necrobacillosis: administer by intramuscular or subcutaneous administration at the dosage of 0.5 to 1.0 mg ceftiofur equivalents/lb (1.1 to 2.2 mg/kg) BW (1 to 2 mL sterile suspension per 100 lb BW). Administer daily at 24 h intervals for a total of three consecutive days. Additional treatments may be administered on Days 4 and 5 for animals which do not show a satisfactory response (not recovered) after the initial three treatments. In addition, for BRD only, administer intramuscularly or subcutaneously 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW every other day on Days 1 and 3 (48 h interval). Do not inject more than 15 mL per injection site.

Selection of dosage level (0.5 to 1.0 mg/lb) and regimen/duration (daily or every other day for BRD only) should be based on an assessment of the severity of disease, pathogen susceptibility and clinical response.

— For acute post-partum metritis: administer by intramuscular or subcutaneous administration at the dosage of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW (2 mL sterile suspension per 100 lb BW). Administer at 24 h intervals for five consecutive days. Do not inject more than 15 mL per injection site.
Proper Drug Use Practices Includes Discarding Drugs That Are Outdated, Contaminated Or Otherwise Compromised (refrigeration?)
What Else Can Cause A Residue Violation Even If Label Directions Are Followed?

• Animal’s illness may affect the rate at which a drug is metabolized.
• If an animal is down or positioned in such a way that circulation is impeded.
• A drug is not thoroughly mixed (or ‘shaken’) so the concentration per cc is higher than it should be.
• Another drug contaminates the container (vacuum takes out residue from a syringe previously used to administer a different drug).
• Medicated milk replacer storage error (medicated vs non medicated).
Things To Think About **Recording**
When You Administer Medicine
To Your Herd Animals
1. **Keep accurate treatment records**, in some sort of system (notebook, computer program, a binder—whatever, work with your veterinarian—if it happened, record it…a record system could include
   - Animal treated (good ID)
   - Reason for treatment
   - Date of treatment
   - Drug used
   - Dose of drug
   - Route of administration
   - Meat & milk withholding times
   - Person(s) administering the treatment

2. **Identify treated animals.** Examples include chalk, leg bands and segregation to another pen.

3. Make it clear **who is allowed to access** the drug storage area and who is allowed to administer treatments.

4. **Medicate herd animals as directed by your veterinarian or, according to all label instructions**, if it’s a over the counter medication. If exact label instructions are not followed you may affect meat and milk withholding times.

5. **Never use unapproved medication…. No ‘home brew’ drug mixtures.**

6. **You CANNOT administer drugs to your herd animals in a way that is not indicated on the label (extra label drug use)**, whether you obtained it from your herd veterinarian or you purchased it over the counter (feed store, internet---etc).

6. Take time to sit down with your herd veterinarian(s) and **review farm drug treatment protocols and drug use best management practices**—on a regular basis.
Dear Sir(s):

This letter is to inform you that the United States Department of Agriculture (USDA) detected violative levels of residue(s) in the tissues collected from a dairy cow identified as originating from your premises. The test results and sample collection date are listed on the enclosure. The tissue sample(s) were collected as part of the residue testing program conducted by the Food Safety and Inspection Service (FSIS). FSIS collects tissue samples from livestock and poultry slaughtered at inspected slaughter establishments. FSIS also collects samples of egg products from residue analysis. Samples are then analyzed at Agency laboratories for various drug, pesticide and other chemical residues. Residue levels in meat, poultry or egg products are violative when they exceed allowable levels for one or more chemical substances in the tissue or tissues or product analyzed.

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If you have any questions, please contact the Policy Development Division at: (800) 233-3935.

Sincerely,

[Signature]

Scott E. Sechohm, DVM
Deputy Director
Policy Development Division

Enclosure
### FSIS Residue Violation Information System

**Notice:** Biased data to be used for resource planning only.

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<tbody>
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<td>Name</td>
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<tr>
<td>Estab No.</td>
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<td>Case No.</td>
<td></td>
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<tr>
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<td>Coll. Date</td>
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<td>Cows - Dairy</td>
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<tr>
<td>526673</td>
<td>EAR TAGS: 212NH1997</td>
</tr>
<tr>
<td>07/05/2011</td>
<td>BACK TAGS: 4431</td>
</tr>
<tr>
<td>RetainTAG: 45499673</td>
<td>KIDNEY</td>
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Controlling seq: Source(s) = 52448 and Sampled(s) = 526673

RPT19
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<th>TIBS</th>
<th>Results</th>
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<th>Date Completed</th>
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LIMS Number: 5562/29991

Species/Description: Animal-Cattle-Dairy Cow

**** FOR LABORATORY USE ONLY ****

Final Review: [Signature]  Date: 7/28/11
LEARN

Laboratory electronic application for results notification

PSNNet.gov where state and information intersect
lab results for establishment 09172 M ILN 569074901

LEARN results for a specific establishment may only be released to the establishment from which they were collected.

LAB RESULT REPORT--RESIDUE

Date Posted: 9/23/2011
Establishment: 09172 M
Form No. 00028573
Collection Date: 07/05/2011
Sample Type: Surveillance Residue-In-Plant Testing
District/Circuit: 6013
ILN: 569074901
Date Received At Lab: 07/07/2011
Project: KSB - E. coli 0157:V 0157:H7
Slaughter Class or Product: Retail
Producer State: NY
Producer Name: Animal-Cattle-Dairy Cow
Production Date: June 19, 2011
Production Lot No:
Product Held: Yes
Product Held: No
Retail Tag No: 45499673
Residue Violator Case No:
Tags: Ear Tag: 212W11997
Back Tag: 4431
Back Tag: 16997
Back Tag: 4431
Back Tag: 4431
Inspector Name: Garfield Eicher III
Inspector Phone: 814 239-2465
Lab: Midwestern Lab - Chemistry
Contact Name:
Contact Phone:

ANALYSIS RESULT: RESIDUE DETECTED, VIOLATIVE

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<th>Result</th>
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<td>Kidney</td>
<td>Pencillin</td>
<td>0.32 ppm V</td>
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<tr>
<td>Liver</td>
<td>Sulfa</td>
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<tr>
<td>Liver</td>
<td>Furadone</td>
<td>Not Detected</td>
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Click here for product disposition instructions.

Copy of report sent to establishment management? NO

This application is designed to be used with Internet Explorer 4.0 or 5.0.

http://dchqlatca/leam Retorna libres.cfm?tag=Sample1&ILN=569074901&establishmentd... 7/25/2011
Notice of Inspection is hereby given pursuant to Section 764(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)] and Part F of Subchapter J of Title VIII of the Public Health Service Act [42 U.S.C. 262-264].

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, call (888) 714-5067. The website address is www.sba.gov/ombudsman. FDA has an Office of the Inspector General that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-6850 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/industry.

4 Applicable portions of Section 764(a) and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)] are quoted below:

Sec. 764(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (a) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce and (b) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants who manufactures, processes, packs or holds food, drugs, devices, tobacco products, or cosmetics) who manufactures, processes, packs, or holds food, drugs, devices, tobacco products, or cosmetics in interstate commerce and who (c) shall extend to all things therein (including records, trial papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or other for which any provision of this Act, have been, or are being manufactured, processed, packed, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence by paragraph (2) shall extend to financial data sales data other than shipment data, pricing data, personnel data, or other financial data.
REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §89.2000 & §89.2091

FIE#:  

Firm (Legal) Name: ___________________________  Date Current Inspection Ended: ___________________________

Firm (Physical) Address: ___________________________  Lead Investigator: ___________________________

City: ___________________________  Lead Affiliation (check one): ___________________________

State: ___________________________  Federal  ___________________________

ZIP Code: ___________________________  State Agency (check one): ___________________________

Phone #: ___________________________  (name) ___________________________

GPS Coordinates of Inspected Site: ___________________________  FDA District Office: ___________________________

Name and title of person(s) interviewed: ___________________________

Name and title of most responsible person at this site: ___________________________

Operational Status: (Check only one)  Operational  Seasonal  Inactive  Out of Business

(See Instructions)  [If firm is OBS, Stop ALL Inspections]

Information above includes changes to firm’s name and/or address.

Section 1 – Complete for ALL firms:

1. a) Type of firm inspected? (Check ALL that apply)

☐ Processor  Food Mill (PDA Licensed)  On-farm Food Mill

☐ Protein Blender  Food Mill (not PDA Licensed)  Feeder of Ruminants

☐ Transporter (Hauler)  Pet Food Manufacturer  Human Food Processor

☐ Distributor Retailer  Animal Feed/Pet Food Retail  Other

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of ruminant animals?

☐ YES  ☐ NO

c) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of non-ruminant animals?

☐ YES  ☐ NO

d) Is the firm aware of the BSE rule, 21 CFR 89.2000?

☐ YES  ☐ NO

2. If the firm is manufacturing feed, does it use bovine (animal fat from cattle) in animal feed formulations?

☐ YES  ☐ NO

3. Does the firm receive feeds or feed ingredients that contain or may contain prohibited material (PM)? (Check only one)

a) If yes, does the firm use a system to ensure that any feed containing PM does not enter the production process?

☐ YES  ☐ NO

b) If yes, does the firm use a system to ensure that any feed containing PM does not enter the production process?

☐ YES  ☐ NO

3. Does the firm receive feeds or feed ingredients that contain or may contain prohibited material (PM)? (Check only one)

a) If yes, is the system effective in preventing prohibited materials from entering the production process?

☐ YES  ☐ NO
Section 2 – Complete for ALL firms: EXCEPT: Firms that are ONLY Q1a Firm Type = “Other” OR Firms that are ONLY Q1a Firm Type = “Feeder of Ruminants”

7. Are the outgoing feeds or feed ingredients containing prohibited materials labeled with the caution statement, “Do not feed to cattle or other ruminants”? (Check only one)
   - □ NO
   - □ PM is Only for Rendition
   - □ PM is Only in Retail Pet/Lab Feed

8. Describe the firm’s system for tracking prohibited materials throughout their receipt, processing, and distribution:
   a) □ YES
   b) □ NO

9. a) Does the firm manufacture, process, blend, repack, or transport BOTH products containing prohibited materials AND products containing only non-prohibited materials? □ YES □ NO
   b) Does the firm manufacture, process, blend, repack, or transport BOTH products containing prohibited materials AND feeds or feed ingredients that may be used for ruminants? □ YES □ NO

10. a) If the answer to Q9a is “NO,” then SKIP to Question 11.
    If the answer to Q9a is “YES,” does the firm have a system in place to avoid cross-contamination? □ YES □ NO
    b) If the answer to Q9a is “YES,” check ALL of the following that describe the measures the firm has in place to avoid cross-contamination.
       - □ Sequence of feeds
       - □ Flushing the system (please describe)
       - □ Written sequencing and cleaning procedures
       - □ Documentation maintained of sequencing and flushing
       - □ Finished materials discarded or treated with the caution statement
       - □ Physical clean-out (e.g., vacuuming, cleaning)
       - □ Dedicated equipment used for prohibited materials
       - □ Product containing prohibited material is always in packaged form when in the firm’s possession
       - □ Other (please describe)

11. Please describe any additional safeguards the firm has in place to ensure that prohibited feeds or feed ingredients containing prohibited materials are not obtained.
   □ YES □ NO □ Unknown
Section 3 — Complete this section ONLY if the firm is marked as:  
Q1a Firm Type = “Renderers”

12. Describe the firm type: (check one or more if applicable)
- Independent Renderers (rendering facility not associated with a slaughtering facility)
- Livestock Slaughtering Facility with On-Site Rendering
- Transfer Station, Transporter
- "D" Processor (non-cooking facility)
- Other (please describe)

13. Does the firm process cattle and/or cattle offal, with or without other livestock species?  
   □ YES  □ NO
[If Q1a=“NO”, then skip to Section 4]

14. Does the firm collect, receive or process material (including dead stock cattle 30 months of age or older) that contains “cattle material ground in animal feed” (CMPAF)?  
   □ YES  □ NO

15. a) Does the firm produce tilaver for use in animal feed?  
   □ YES  □ NO
b) If NO, does the cattle contain not more than 0.15% insoluble impurities?  
   □ YES  □ NO
c) If (b) is “NO”, is outgoing tilaver containing more than 0.15% insoluble impurities labeled with the caution statement “Do Not Feed To Cattle Or Other Ruminants”?  
   □ YES  □ NO

16. Does the firm differentiate cattle less than 30 months old from those that are 30 months of age or older?  
   □ YES  □ NO

17. Does the firm separate CMPAF from material that may be used in animal feed?  
   □ YES  □ NO

18. a) If YES, check all of the following methods that the firm uses to separate CMPAF from material that may be used in feed:
- Remove strained muscles and offal from the carcass
- Remove the vernal column and head from the rest of the carcass
- Remove only the brain and spinal cord
- Other (please describe)

19. Is the CMPAF labeled “do not feed to animals”?  
   □ YES  □ NO

Section 4 — SKIP this section when the firm is ONLY marked as:  
Q1a Firm Type = “Other”  OR  
Q1a Firm Type = “Transporter (Handler)”

19. a) Are any uncooked feeds or feed ingredients transported in bulk form?  
   □ YES  □ NO
b) Are any incoming feeds or feed ingredients transported in packaged form?  □YES  □NO

c) Does the firm utilize its own transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients?  □YES  □NO

d) Does the firm utilize other firms’ transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients?  □YES  □NO

ea) If 1d(6) is “YES,” do ALL incoming transporters provide written assurance that they utilize dedicated transport equipment or utilize measures that adequately prevent commingling or cross-contamination with prohibited material?  □YES  □NO

20. a) Are any outgoing feeds or feed ingredients transported in bulk form?  □No Outgoing Feeds/Ingredients  □YES  □NO

b) Are any outgoing feeds or feed ingredients transported in bagged/packaged form?  □No Outgoing Feeds/Ingredients  □YES  □NO

c) Does the firm utilize its own transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients?  □No Outgoing Feeds/Ingredients  □YES  □NO

d) Does the firm utilize other firms’ transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients?  □No Outgoing Feeds/Ingredients  □YES  □NO

ea) If 20d(3) is “YES,” do ALL outbound transporters provide written assurance that they utilize dedicated transport equipment or utilize clean-out measures that adequately prevent commingling or cross-contamination with prohibited material?  □YES  □NO

Section 5 – Complete this section ONLY if the firm is marked as: Q1a) Firm Type = “Feeder of Ruminants”

21. Are ruminant feeders doing the following?

a) Observing the cautious application on feeds containing prohibited material (PM)  □YES  □NO  □No PM-feeds on premises

b) Maintaining copies of labeling for feeds containing animal protein (AP)  □YES  □NO  □No AP-feeds on premises

(Not including retail pet food for cats and dogs)

c) Maintaining copies of purchase invoices for feeds containing animal protein  □YES  □NO  □No AP-feeds on premises

(Not including retail pet food for cats and dogs)

d) Feeding non-ruminant species (not including cats and dogs) feeds containing prohibited material  □YES  □NO  □No PM-feeds on premises

f) Feeding cats and/or dogs  □YES  □NO

Section 6 – Complete for ALL Firm Types

12. a) Check all deviations that were noted at the time of inspection  □Commencing  □Labeling  □No Deviations Noted

□Recordkeeping  □Feeding Ruminants Prohibited Material

b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation,

___________________________________________________________

13. Are you attaching any descriptions, exhibits, records, labeling, reports or supplemental information?  □YES  □NO
Complete one attachment C for each sample investigated.

The information on each Attachment C is a source and sample combination. This means that all the information on the Attachment has to be related to the source identified in the section "Name and Address of Owner of Animal" from FDA Warning Letter. If you determine during your inspection that 1) the owner wasn't correctly identified, or 2) the residue can't be properly traced back or 3) the investigated source ownership charged, then terminate the inspection per Question #2. You should complete a new Attachment C for each new source investigated.

When completing Attachment C, Question #2, select only one answer for either an FDA investigation (A) or a state investigation (B). If B is selected, fill in the appropriate 2-letter state code.

Complete questions 9-14 for each residue reported for each sample.

Make sure you properly relate the source to the sample in EVIS.

Send to HRY-235, ATT: Deb Cara

- A complete Attachment C for each source/sample investigated.
- A summary of findings for each investigation.
- If the Attachment C (at least the first two pages) is not printed from the system, please write the source Id on the front page of the Attachment.
EVALUATION FORM FOR ILLEGAL RESIDUES IN MEAT AND POULTRY

Complete this form only when a timely residue violation is investigated by an on-site inspection. Complete a separate form for each violation except when there are multiple violations per source. See Section 3 for further details. Submit the completed form and ALL the following:

1. A completed summary of the investigation (FDA Form 101 parts A to E, or equivalent)
2. A legible copy of USDA-FSIS letter to owner
3. A legible copy of the USDA-FSIS laboratory report
4. Any other relevant documents, e.g., FDA 463

The information gathered via this form is crucial to the Residue Reduction Program. To reduce errors, PLEASE TYPE OR PRINT USING BLACK INK.

Section 1

BACKGROUND INFORMATION

<table>
<thead>
<tr>
<th>FSIS Sample Number</th>
<th>FSIS Sample Collection Date</th>
<th>FSIS Warning Letter Date</th>
<th>FSIS Case Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>528673</td>
<td>07/05/2011</td>
<td>08/30/2011</td>
<td>6-0026-11</td>
</tr>
</tbody>
</table>

CONCENTRATIONS OF RESIDUE(S) IN TISSUE AS REPORTED BY FSIS:

Residue | Tissue | Concentration
--------|--------|----------------
PENICILLIN-Vio | KIDNEY | 0.1200

SPECIES: COWS - DAIRY
SAMPLE COLLECTION DATE: 07/05/2011 FSIS Warning Letter Date: 08/30/2011

DHYDROSTREPTOMYCIN-Vio | KIDNEY | 4.6400

SPECIES: COWS - DAIRY
SAMPLE COLLECTION DATE: 01/24/2006 FSIS Warning Letter Date: 02/09/2006

GENOTICIN-Vio | KIDNEY | 4.5000
GENOTICIN-Vio | LIVER | 3.9400

NAME AND ADDRESS OF FIRM FROM FSIS WARNING LETTER IDENTIFYING AS OWNING ANIMAL:

Firm Name:
Address:

Transmittal No
FORM FDA 3411g (1/94)
Page 1
OTHER INFORMATION ABOUT THIS FIRM:

Farm Type: DAIRY FARM, PRODUCER/INDEPENDENT GROWER

Phone:

Owner:

Farms IDENTIFIED as BEING RELATED to THIS SOURCE:

Name:

Address:

INSPECTIONS ATTRIBUTED TO THIS SOURCE:

Transmittal No
FORM FDA 2410a (1/90 )
1. WERE THE NAME AND ADDRESS OF THE ANIMAL OWNER IDENTIFIED ABOVE BY USDA SPELLED AND LISTED CORRECTLY? ................. YES/NO
   YES (up to #1). NO (see A District Program Monitor to make corrections in PVIS and to notify appropriate PVIS personnel.)

Section 2
THE INVESTIGATION
(Questions 2 - 6)

2. TYPE OF INVESTIGATION CONDUCTED IN RESPONSE TO CURRENT PVIS SUSPECT REPORT (circle one letter):
   A. FDA INVESTIGATION (complete 1 or 2 below)
   B. STATE ______ (enter 2-letter state code)
      (Circle one number for either A or B):

   1. On-site Inspection (Complete Remainder of Report).

   2. Inspection Terminated Due to:
      a. Unable to locate source or traceback
      b. Investigated source's ownership changed
      c. Incorrect source identified by USDA
      d. Other ______

3. DATE INVESTIGATION/INSPECTION STARTED: _/__/__ (mm/dd/yy)

4. DID THE OWNER IDENTIFIED AT SLAUGHTER ADMIT TO TREATING OR AUTOMANIZING THE TREATMENT OF THIS ANIMAL/HERD/FLOCK...........? YES/NO
1. List the following information for all individuals/organizations who handled the animal/ herd/flock...within three months prior to the slaughter date.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Date Animal Acquired</th>
<th>Date Animal Disposed of</th>
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<td>Firm type (i.e. dealer, hauler)</td>
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<td>Reason for Acquisition</td>
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<td>Reason for Disposition</td>
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<td>Reason for Disposition</td>
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</table>
| E. None of these:
Which source is it is responsible for the residue? (Write the letter A, B, C, D, or E)
6. IS THE SLAUGHTER CLASS OF COWS - DAIRY REPRESENTATIVE OF THE PRODUCER'S BUSINESS?

IF YES (go to #7) / NO (circle one below)

The general description of this production unit is (circle one):

A. Dairy Farm
B. Swine Operation
C. Feedlot (Calf)
D. Poultry Flock
E. Beef Ranch (other than Feedlot)
F. Veal Operation
G. Other (Select One):
   1. Sale/Auction Barn
   2. Buyer/Dealer
   3. Multi-species Unit
   4. Slaughter Facility
   5. Other

7. APPROXIMATE SIZE OF BUSINESS (circle one):

Number of Animals (On the premises at the date of inspection/investigation):

A. 1-20
B. 21-210
C. 211-500
D. 501-1000
E. Over 2000

Note: For dairies use total animals on continuous production unit, do not include sales/replacements reared by a contractor at remote locations
E. GENERAL ANIMAL MANAGEMENT PRACTICES OF BUSINESS (Answer each letter):

A. One individual or multiple individuals are authorized to treat animals
   (1)One/ (2)Multiple.................................................. 1 / M

B. Utilizes services of veterinarian.............................................. YES/NO
   (If you please circle one)
   1. On as-needed basis (non-routine)
   2. For herd health programs only, including pregnancy checks
   3. For all veterinary medical needs (feed health and as needed)
   4. As a member of staff

C. Mixes own feed...................................................................... YES/NO
   (If you please circle all that apply)
   1. Grinder/mixer/mill routinely cleaned/flushed after processing
      of medicated feeds
   2. Uses sequencing to control unsafe contamination
   3. Conforms to codes for milk
   4. Mixes non-medicanted feed only

D. Bags commercial feed (a complete feed)................................. YES/NO

E. Uses medicated milk replacer................................................... YES/NO

F. Feeds, or allows the young to suckle milk from treated dams........ YES/NO

G. Observes the directions of products used during the dry cow period.... YES/NO

H. Water for animals comes from a private water source (wells, etc.).... YES/NO

I. Has system for separating treated and non-treated animals.......... YES/NO

J. Keeps medical records.......................................................... YES/NO

   Circle all numbers below that are included in medical recordkeeping:
   1. Animal ID
   2. Treatment date
   3. Drug(s)/medicated feed used
   4. Dosage(s) given
   5. Route of administration
   6. Withdrawal time for meat and milk
   7. Individual who administered drug
   8. if treatment recommended by veterinarian
   9. Dose animal can be slaughtered

K. Keeps records on the sale and purchase of animals..................... YES/NO

L. Keeps records on inventory & accountability of drugs & medicated feeds YES/NO
The following questions are about the drug(s) whose use resulted in the current tissue residue violation. If multiple animals are involved and uses/cause/treatments vary among animals please complete a sec of the following questions (9-14) for each animal. (Also if multiple residues are reported for a single sample complete questions 9-14 for each residue reported.)

9. NAME OF DRUG USED ON THE ANIMAL WHICH CAUSED THE RESIDUE
   (Obtain from the product label if available; if unknown write "UNKNOWN")

   DRUG NAME: ____________________________
   (Trade/Proprietary name preferred)

   NVDA# ____________________________ or BDC# ____________________________

   IS THE PRESCRIPTION LABEL PRESENT? YES/NO
   (i.e. "Caution Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

10. DRUG(S) WERE ADMINISTERED AS FOLLOWS:

    DOSE (i.e. 500mg/#+times) ________ ROUTE ________ FREQUENCY ________

    FOR ROUTE WRITE IN LETTER USING LIST BELOW:

    A. Intravenous     D. Intramuscular
    B. Intranasal       E. Oral Solns.
    C. Intramammary    F. Liquid Tablet
    G. Drinking Water  H. Milk Replacer
    I. Parenteral       J. Topical

    FOR FREQUENCY, WRITE IN LETTER USING LIST BELOW:

    A. Once          D. TID (Three times daily)
    B. QID (Every day) E. QID (Four times daily)
    C. BID (Twice a day) F. EOS (Every other day)     G. PRN (As Needed)
    H. Other

   DATE OF LAST TREATMENT:

   ____________________________

   Transmittal No: ____________________________
   FORM FDA 2410g (1/98)

   COMPLIANCE PROGRAM
11. REASON THE DRUG WAS ADMINISTERED TO THE ANIMAL/HERD/FLOCK.
(circle one letter):

A. If used because of illness, specify illness(es) treated:


B. If used as a preventive measure (circle all numbers that apply):
   1. Prior to transportation
   2. Prior to addition to an established herd/flock
   3. Prior to or during introduction to a farm, ranch, or region with endemic disease
   4. To aid animal or flock's adjustment to changes in weather conditions
   5. Other:

C. If used as a growth promotant/production aid

D. Other:

----------------------------------------
12. Is drug labeled for the use indicated in question 11? Y/N/CAN'T BE DETERMINED:

A. PRODUCT WAS PURCHASED FROM INDICATE NAME, ADDRESS, AND FIRM TYPE:
   NAME: ____________________________
   ADDRESS: ____________________________

(circle one number)
1. Farm/Supply Store
2. Mail Order
3. Feed from a Commercial Feed Mill
4. Mobile Feeder/Salesperson
5. Veterinarian
6. Other

B. Did veterinarians, through a valid veterinarian-client patient relationship (VCPR), prescribe the use of the drug in #5? YES/NO

(if yes, verify and answer 12c and 12d)

Is there a veterinarian's label on the product? YES/NO

Does the veterinarian's label on the product specify the following:

1. Indication for Use? YES/NO
2. Dosage? YES/NO
3. Duration of Therapy? YES/NO
4. Expiration Date? YES/NO
5. Name and address of practitioners? YES/NO
6. Contraindications? YES/NO
7. Route of Administration? YES/NO
8. Withdrawal Period? YES/NO
9. Active Ingredients? YES/NO
COMPLETE C AND D BELOW IF A FOLLOW-UP AT THE VETERINARIAN IS CONDUCTED

(CP 7271.010, Part III, pp. 4-5)

C. Do the veterinarian's records substantiate a valid VICK? ........................................... YES/ NO/ CANNOT BE DETERMINED

D. Was the prescribed use:

1. Consistent with an approved product's label? ........................................... YES/NO

2. Modification of indications, dose, precautions of an approved product? YES/NO

3. compounded from one or more (approved or unapproved) ingredients? ....... YES/NO

(If #1 is yes, circle one answer for each letter):

   a. For a (T)herapeutic or (P)roduction use .......................... T/P

   b. Based on (C)linical needs or (A)nticipation of sale ...... C/A

   c. product (i)s or is (N)ot promoted for sale ....................... I/N

If compounded by a veterinarian, list all the components of the product:

<table>
<thead>
<tr>
<th>Product 1</th>
<th>Product 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Components:</td>
<td>Components:</td>
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<td>A.</td>
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<td>E.</td>
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<td>F.</td>
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</table>

Prescribed withdrawal time ____ days  Prescribed withdrawal time ____ days
13. What was the PRIMARY factor causing this violation?

(circle one letter):

A. Production Management Causes
   (If production management is the cause, circle one number):
   1. Animal(s) fed colostrum or milk containing drug residue
   2. Animal(s) fed medicated feed by mistake
   3. Drug administered to animal(s) by mistake
   4. Failure to keep proper animal identity and treatment records
   5. Inadequate segregation of treated animal(s)
   6. Failure to follow labeled/prescribed withdrawal time
   7. Feed manufacturing CMC deviations

B. Extra-Label Use
   (If extra label use is the cause, circle one number):
   1. Veterinarian’s prescribed withdrawal period not observed
   2. Withdrawal period verbally recommended by veterinarian not observed
   3. Animal treated with higher than the recommended dosage or drug
   4. Labelled route of administration not observed
   5. No withdrawal period prescribed
   6. Drug not approved for species
   7. Frequency of treatment different than on label
   8. Duration of treatment longer than on label

C. Unable to Determine.

D. Interviewer stated drug used was not the same as residue reported by FSIS.

E. Interviewee told purchaser/hauler animal was medicated - animal later diverted for human food.

F. All label/prescription directions followed and documented, residue still occurred.

G. Other
14. What are ADDITIONAL factors contributing to this violation? (circle one letter):

A. Production Management Causes
   (If production management is the cause, circle one number):
   1. Animal(s) fed colostrum or milk containing drug residue
   2. Animal(s) fed medicated food by mistake
   3. Drug administered to animal(s) by mistake
   4. Failure to keep proper animal identity and treatment records
   5. Inadequate segregation of treated animal(s)
   6. Failure to follow labeled/prescribed withdrawal time
   7. Feed manufacturing cGMP deviations

B. Extra-Label Use
   (If extra label use is the cause, circle one number):
   1. Veterinarian's prescribed withdrawal period not observed
   2. Withdrawal period verbally recommended by veterinarian not observed
   3. Animal treated with higher than the recommended dosage of drug
   4. Labelled route of administration not observed
   5. No withdrawal period prescribed
   6. Drug not approved for species
   7. Frequency of treatment different than on label
   8. Duration of treatment longer than on label
   9. Unable to determine

C. Interviewer stated drug used was not the same as residue reported by FSIS.

D. Interviewer told purchaser/hauler animal was medicated - animal later diverted for human food.

F. All label/prescription directions followed and documented, residue still occurred

G. Other ________________________________
35. ACTIONS TAKEN TO EDUCATE INDIVIDUAL/ORGANIZATION(S) RESPONSIBLE PARTY FOR CURRENT VIOLATION ON HOW TO PREVENT THE OCCURRENCE OF TISSUE RESIDUE VIOLATIONS IN THE FUTURE (circle all that apply):

A. Discussed the need to adhere to drug-label instructions with special emphasis on dosage, withdrawal time, routes of administration, and approved species

B. Discussed the need to properly identify animals

C. Discussed the need to keep good medical and sales/purchase records on treated animals

D. Discussed the need to maintain a well-pen for treated/sick animals, especially the need to separate treated dams (or their products) from sucklings

E. Discussed availability of husbandry information and consultation services provided by Federal/State/Country Extension Service

F. Discussed inventory and accountability of all drugs and medicated feeds

G. Other:

i.e. Consult tests, QA program, (lists people involved w/drugs, control access to drugs, etc.)
Order Form for Producer Ear Tags

Traditional colored ear tags (one ear a batch) _______ boxes

Small plain hanger tags 1/2" wide by 1½" tall
with 4 ear numbers ½" tall (bags of 25) _______ bags

Large plain hanger tags ½" wide by 3" tall
with 4 ear numbers ¾" tall (bags of 10) _______ bags

Application for plain ear tags (same as approved for Speakey tags for sheep and goats) _______ (limit 1 per premises)

Agreement:
- These ear tags are for use only in the premises listed below and may not be resold, divided or resold to other producers.
- Only one order of ear tags may be submitted per request to the Department of Agriculture.
- A record of entry on the tag must be made for 5 years after the ear tags are applied.

Owners Name: ____________________________________________

Farm Name: ______________________________________________

Shipping Address (No P.O. Boxes):
________________________________________________________________________

City, State, Zip: _____________________________________________

Physical Address of Farm:
________________________________________________________________________

(Different than shipping address)

Telephone: _________________________________________________ Date: __________________

E-mail: ____________________________________________________

Producer signature (required): ________________________________

Your signature (required) indicates that you accept the terms of use and distribution of these tags (see above).

A producer signed order form is required for each tag order from one farm, including members. To receive your free tags, please complete this form and send it by one of the ways listed below:

- Phone: (518) 457-3103; many, you must call in an order
- Email: forms.dairy@agriculture.ny.gov
- Mail: forms.dairy@agriculture.ny.gov

Division of Animal Industry
108 Airline Dr. Albany, NY 12233-4001
# Individual Animal Treatment Record

All records should be maintained for at least 3 years.

<table>
<thead>
<tr>
<th>Date</th>
<th>AnimalID</th>
<th>Problem/Diagnosis</th>
<th>Product</th>
<th>Dosage</th>
<th>Route Given*</th>
<th>Site</th>
<th>Meat Withdrawal</th>
<th>Notes</th>
<th>Initials</th>
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*Route Given: manner of delivery (oral, intramuscular, subcutaneous, intravenous, etc.)

[Diagram of animal and medication]
Tissue Residue Inspections

Drug inventory to be completed by all federal and state investigators conducting tissue residue inspections.

PSIS Sample Number: __________________________

Fiscal Year: __________________________

State: __________________________

FDA District: __________________________

Type of Animal: __________________________

Please circle the drug tradename of all drugs found at the firm (drugs are listed alphabetically by active ingredient and under each active ingredient by dosage form and trade name.) If you don’t know the brand name of the drug then circle the generic name in bold. The information collected via this inventory will be used to develop future sampling strategies. While completing this document please look for and document the use of any illegally compounded products, Animal Medicinal Drug Use Clarification Act (AMDUCA)-prohibited drugs, or unapproved drugs (a further description of these products can be found at the end of this inventory). Space has been allotted at the end of the list for additional drugs you may find on the premises. Return this drug inventory survey to your local FDA district Tissue Residue Coordinator. If you have any questions on this inventory please contact Deborah Cara at (240) 276-9209 or Fran Reil at (240) 276-9211.

- Acepromazine Maleate (tranquilizer)
  - Injection
    - PromAce® Injectable
    - Acepromazine Maleate Injection
  - Oral
    - PromAce® Tablets
    - Acepromazine Maleate Tablets

- Albendazole: (antiparasitic, benzimidazole family)
  - Oral: Valbazen®
The following drugs (both animal and human), families of drugs, and substances are prohibited for extralabel uses in all food-producing animals:

- Chloramphenicol
- Clobenpropit
- Diethylstilbestrol (DES)
- Dimenidazole
- Ipronidazole
- Other nitroimidazoles (i.e., metronidazole)
- Furazolidone, Nitrofurazone, other nitrofurans
- Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfaibomethazine, and sulfaethoxydiazine)
- Fluoroquinolones (enrofloxacin, danofloxacin, orbifloxacin)
- Sytoxpeptides (vancomycin, teicoplanin, oritavancin)
- Phenylbutazone (in female dairy cattle 20 months of age or older)

Compounded Drugs:

- FDA defines compounding as the manipulation of drugs to obtain products that differ from the starting materials in an approved dosage form of drug. Under ANDUCA, compounding is considered to be extralabel drug use and must be done from approved finished dosage form approved drug only.
- It is illegal for veterinarians or pharmacists to compound unapproved finished new animal drug products from bulk drugs.
- Non-commercial labels may serve as a cue for identifying compounded products.
<table>
<thead>
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<th>FIELD</th>
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<tr>
<td>INSPECTION OFFICER</td>
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**Observations:**

- [Observation 1]
- [Observation 2]
- [Observation 3]

**Signature:**

- [Signature]

**Employee Information:**

- [Name]
- [Title]
- [Date]
FDA/NYS DAM List of Common Tissue Residue Citations (9/1/09)

1. Causing a residue of an approved human or animal drug above an established safe level, safe concentration, or tolerance, through use of the drug contrary to its labeling.

Specifically, USDA reported under case number 07-0563-NY that a dairy cow (calf), bearing farm tag 127, offered for beef (slaughter for human food) by you contained an illegal drug residue for sulfadimethoxine. You owned and treated the suspect cow with Albon (sulfadimethoxine) contrary to its labeling.

2. A prohibited drug was administered in an extralabel manner (species and class, dosage, duration, frequency, route, or withdrawal time) to a food-producing animal(s).

Specifically, you treated the suspect dairy cow, identified with farm tag 127, with Pfizer's Albon (sulfadimethoxine 17g bolus) in an extra-label manner. You administered three boluses on the first day, two boluses on the second day and one bolus on the third and final day for ulcer/indigestion prior to shipping to Empire Livestock Marketing, LLC, Dryden, NY on 2/25/03. You said that your cows weigh approximately 1,000 to 1,400lbs or 1,500lbs on average. Albon’s label states the approved dosage rate for animals that weigh 1,000 - 1,200lbs is 2 boluses on the first day and 1 bolus on the subsequent three to four days.

3. An approved human or animal drug was administered in an extralabel manner (species and class, dosage, duration, frequency, route, or withdrawal time) to a food-producing animal without benefit of a valid veterinarian-client-patient relationship.

Specifically, you treated the suspect dairy cow, identified with farm tag 4410, with penicillin G procaine at a rate of 25ml intramuscular injection per day for 3 days. You said that your cows weigh approximately 1,000 to 1,400lbs or 1,200lbs on average. Vet One’s Pen One Pro (penicillin G procaine), the drug you used to treat the suspect cow, label states the approved dosage rate is 1 ml per 100 lbs bodyweight or 10ml to 14ml and 12ml on average for cows on your farm.

4. Failure to follow your veterinarian’s prescription for (species and class, dosage, duration, frequency, route, or withdrawal time).
5. Expired drug(s) were observed in the drug storage area.

Specifically, I observed one 250ml vial of Di-Methox (sulfadimethoxine) injection-40%, Agri Labs, St. Joseph, MO, Lot 4906817, Exp. 5/03 on the non-lactating shelf of your drug storage room.

6. Treatment records were not (complete, maintained)

Specifically, you treated the suspect dairy cow, farm tag 127, with Albion (sulfadimethoxine) and your cattle treatment record fails to include the dosage administered, the route of administration, the identity of who administered the drug and an indication that review of the cattle treatment record was performed prior to offering milk or the animal for sale for human food.

Specifically, you treated the suspect dairy cow, farm tag 4410, with penicillin G procaine and your cattle treatment record fails to include the dosage administered, the route of administration, the identity of who administered the drug and an indication that review of the cattle treatment record was performed prior to offering milk or the animal for sale for human food.

7. Failure to (identify, segregate, and quarantine) treated animals

Specifically, you do not segregate and quarantine treated animals

8. You lack an adequate inventory system for determining the quantities of drugs used to medicate your livestock.

Specifically, you do not have a system to determine the quantities of drugs used.
On 07/05/11, a mature dairy cow, identified with ear tag 21/ENH1997 and back tag 4431, was slaughtered at Tr County Packing Inc (East 95% 72%). As FSIS case 3-0416-11 (From 21/ENH1997), cow 21/ENH1997 was sampled and positive for EA. On 07/05/11, the dairy cow was reported to USDA and FSIS. The animal was not returned to the farm, and the owner was instructed to dispose of the meat.

On 07/06/11, the animal was inspected by a FSIS inspector and returned to the farm. A FSIS inspector from the New York District Office conducted a review of the farm's records and found that the animal had been treated with an OTC medication, but the medication was not recorded in the farm's records. The inspector also noted that the farm had not been proactive in seeking assistance from the regulatory agency.

The farm was given a 10-day period to comply with FSIS regulations. If the farm does not comply, the facility will be cited for non-compliance.

FSIS compliance data were collected and reported to the appropriate authorities.

An inspection for Compliance with 210FR 359.1000 was performed and a report prepared.

A FDA tissue residue drug inventory was prepared.
DB
1234 Any Street
Town, NY 12345

FEI: 300939284
Case No: 11-0658-NY
Form No: 528673

Date: 11/16/11

Summary of Findings

A limited inspection of this dairy farm was conducted in accordance with FDA State contract HHSF 222006740145P under CP 7371.006 - Illegal Tissue Residues in Meat and Poultry. As case number 8-0658-11, FSIS reported that this producer sold a dairy cow identified with ear tag 21ZNH1997 and back tag 4431 for food. This cow was sold on 7/11 at Maplehurst Livestock Market Hinsdale, NY. Cow 21ZNH1997 was slaughtered at Tri-County Packing Inc [Est. 052731], Claysburg, PA on 07/05/11. FSIS sampled this animal and found penicillin in kidney @0.32 ppm [FSIS Form No. 528673].

Upon arrival at the DB farm, I introduced myself to Mr. B, farm owner and manager. Mr. B provided information regarding farm operations and accompanied me on my inspection. Mr. B stated he makes all decisions regarding the sale and treatment of his animals. D B administers all animal medications. Upon conclusion of this inspection, I gave Mr. B one copy of the Milk and Dairy Beef Residue Prevention Protocol [2009] and, a FDA-493.

D B owns this farm of 250 acres and does business as a sole proprietor, under the name, D B. An additional 250 acres are leased. The farm supports 150 cows in milk. 350 animals in total. Adult animals are housed at this location. Young stock are at several other facilities. Daily milk production of 8000 lb. per day is sold through the Dairy Cooperative, Syracuse, NY.

Several different livestock haulers transport cattle animals. Currently B U of Anytown, NY is the principal hauler. At the time of the residue JF and J5 trucked the farm's cattle animals. J S of Thistown, NY was the trucker who transported the cattle cow with the residue on 7/11. Cattle animals are marketed primarily through Maplehurst Livestock Market in Hinsdale, NY. D B sold all his cattle in the 2007 dairy buyout. He then purchased heifers and milk cows from various sources. Various forms of identification are the result. Mr. B does apply a visible herd bangle tag to the milking cows (numbers 1-200). This is the identification he uses. Other ID is not recorded in any cow records. Heifer calves are given a herd bangle tag at birth. These may be replaced and changed when they enter the milking herd. Bull calves are not identified. If a bull calf has lost her bangle tag, there may be no ID on her when she is taken for sale. Truckers do not apply any ID upon pickup at the farm, nor do they leave receipts. ID is only recorded at the livestock market. D B does receive a cow ear tag number as ID with the check receipt from Maplehurst Livestock Market. I discussed, with Mr. B, the importance of unique identification being applied to and recorded for all animals leaving the farm. Mr. B stated that he would consider applying metal NY's "41" tags in all animals prior to sale.

All calves are fed colostrum. When bull calves must hold over, prior to sale, they are fed the same nonmedicated milk replacer as heifer calves. Treated milk is also mixed with the milk replacer.
Adult animals are fed a mixed ration prepared by blending farm forages with mineral and protein supplements purchased, in bulk from Carrell in Poland Center, NY. I. F. D.B, although he had no written documentation, felt assured that prohibited nutrients are not used in the manufacture of his dairy feeds.

Medications are stored in a utility room and refrigerator in the main barn and several shelves off the parlor. A medication inventory was prepared using the FDA Tissue Residue Drug Inventory Form. A drug inventory is not maintained.

Most animal medications are purchased from Carlson & Co, a veterinary drug supply route truck, which is associated with Attica Veterinary Associates, Attica, NY. Veterinary services are provided through I.R. DVM, Attica, NY. Veterinary services are utilized for emergency or non-routine visits only. Prescription drugs are purchased through Dr. R. If Dr. R. treats a cow or a foal of various medications are prescribed, verbal instructions are given; written instructions are not recorded. According to D.B., a veterinarian is not routinely consulted if a drug is given in an extralabel manner. Medicated animals are identified with one leg band and housed in a separate treated pen. This pen is milked separately.

Permanent medication records are not maintained. Temporary medication records are maintained on a sheet in the barn by K.B. Only the month, date, and cow ID number are recorded. Records are kept until the cow is sold or is back in the milking routine. These records generally are recorded for mastitis treatments, which are given only by D.B and only during the AM milking.

I showed D.B. his FSIS warning letter and he acknowledged receipt of his copy. I defined and explained the terms first time and repeat violator.

D.B. reluctantly acknowledged ownership of cow 21ZRH1997 and confirmed he sent her to sale for feed. The receipt from Mapleslant Livestock Market for 7/4/11 documented ear tag 21ZRH1997 was associated with backtag 4431. No farm bangle tag was recorded. Since no farm treatment records are kept and since all identification from a cow is not recorded, Mr. B admitted it was probably his cow. The NYS-21” tag had to have been on the cow when she was purchased after 2007. He was not sure if a bangle tag was present when she was sold.

D.B. stated that in early summer, the farm had a mastitis problem. A veterinarian was not consulted. He has a standard mastitis treatment, which was given to him by his previous veterinarian (now retired), many years ago. The protocol includes 60 cc of procaine penicillin given IM in one spot, one time daily along with an intramammary infusion of 10,000 units of a daily mastitis tube. This treatment is given once daily in the AM. It is continued until the mastitis is resolved. The cow is held out of the milking according to the label milk and meat withdrawal instructions. As no treatment records are kept, it is not known how many times or what dates this cow may have been treated. The treatment protocol is any 1 extralabel use of penicillin. According to the label, the dose, amount given, amount given in one site, and meat and milk withdrawal times for the amount of drug administered are all extralabel.
During discussions with D B, I explained the distinction between approved and unapproved drug usage. I emphasized the requirement that livestock producers follow all label directions, explicitly, including dosage and meat withholding time. I explained the requirement that all extra-label drug usage be initiated and supervised by a licensed veterinarian.

I recommended D and K B establish a permanent medication record system using a modification of the medication record form found on page 42 of the Residue Prevention Protocol. I recommended they use these records to document: date of each treatment, animal identification, product administered, treatments day, dosage, route of administration, reason for treatment, and withholding times for milk and meat. I recommended he review his medication records, prior to consigning animals to sale, and document performance of these “pre-sale” reviews in the far right column provided for this purpose. D and K B agreed to institute these recommendations. I also stressed the importance of the application and recording of unique identification (specifically NYS “21” metal ear tags) prior to sale or animals leaving the farm.

An inspection for compliance with 21 CFR 189.2000 was conducted and report prepared.

I advised D B that he had violated the FD&C Act and additional violations could result in prosecution.

ATTACHMENTS:
FDA Assignment
FDA-483
Attachment C
FDA Tissue Residue Drug Inventory Form

Crocket Johnson-Seward DVM Vet2
NYS Department of Agriculture & Markets
Summary Comments

There is no such antibiotic as ‘Panaceamycin’

Think Before You Treat-Consult With Your Veterinarian

- Animal History, Production Potential, Value As **Quality** Beef Vs Milk Production

- Treatment Success, Pre Treatment Condition(s)...long term prognosis

- Costs/risks associated with medication, product withhold, inventory and management of inventory

*Work with your herd veterinarian, develop a plan, follow it and review it from time to time.... best management practices are a moving target!*
Thank You For Listening