PRODUCING MILK AND MEAT RESPONSIBLY
It's simple. When you use five select ceftriaxone injectable and mastitis treatments from Zoetis on label, we guarantee that you won't have a violative ceftriaxone milk or meat residue. To get the Residue Free Guarantee™, just purchase a product from an approved supplier.* Then, make sure your records show the identification of the animal, the dose and rate of administration (including location), the date(s) treated and withdrawal times observed. That's it.

To learn more, just talk with your veterinarian or Zoetis representative, or call 888-ZOETIS1 (888-963-8471). And to see if your operation is at risk, take the risk assessment at AvoidResides.com.

*Residue Free Guarantee: If you use a Zoetis-branded ceftriaxone product according to label indications and experience a violative ceftriaxone milk or meat residue, Zoetis will compensate you for the beef market value of the animal or purchase the tanker of milk at fair market value. You must purchase the product from a Zoetis-approved supplier, use the product according to label indications, have documentation of the product purchase and treatment records, and have conducted training on appropriate use to ensure proper dose and route of administration of the product. Extra-label use as prescribed by a veterinarian is excluded from the guarantee. If you experience a violative residue violation after following label indications and the above steps, contact Zoetis VMIPS (Veterinary Medical Information and Product Support) at 888-ZOETIS1 (888-963-8471) to report the situation.

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The Food and Drug Administration and the National Conference on Interstate Milk Shipment (NCIMS) have developed a cooperative state-federal program to ensure the sanitary quality of Grade A milk and milk products shipped interstate. Mandatory reporting to a National Milk Drug Residue Data Base is required under that program. Each year, there are residue tests on nearly 4 million samples of milk from farms, bulk milk pickup tanks, plants, and stores. In the past, most testing was being done for beta-lactams (penicillin, cephalosporins) with some testing done for sulfonamides (sulfa drugs), aminoglycosides (gentamicin, streptomycin, neomycin), macrolides (tylosin, tilmicosin, erythromycin), tetracyclines (oxy- and chlorotetracycline) and fluoroquinolones (such as enrofloxacin or Baytril).

**Milk: good and improving**

Figure 1 shows that our track record on preventing milk drug residues is good and has gotten better over the past nine years. Nearly 37 million samples have been tested during that period. Note that there has been a steady decrease in the incidence of positive milk samples. During the 2011 fiscal year, there were only 1,076 positives (0.0028 percent or 300 positives per million milk samples tested). By contrast, we see more positives for beef and pork because they are tested more frequently. For beef and pork, the incidence of residues was 0.070 percent or 1,400 positives per million samples tested.

There are two types of sampling. One type is simple random sampling, also called scheduled sampling. That involves carcasses that appear to have come from healthy cows and have been passed for human consumption. There also is inspector-generated sampling. Inspectors can call for sampling of carcasses from slaughtered animals that appeared abnormal for some reason or whose carcasses showed some tissue damage. For example, a carcass may show some injection-site lesions. Each year, carcasses are sampled from between 3 and 4 percent of the 2- to 3 million head of dairy cows slaughtered. There have been three in-plant tests used in the past. Of them, the so-called KIS test is the most sensitive and now is most heavily used by far.

**Meat: potential for gain**

Figure 2 shows that the incidence of positive carcass samples essentially did not improve between 2003 and 2009. The last year for which data is available. In 2010, there were 73 positive tissue samples for each 10,000 dairy cows tested. That incidence rate is down from recent years, but not much better than where we were seven and eight years ago. According to the USDA/FDA Residue Violation Information Database, here are the top 10 dairy cow tissue residues between 2007 and 2011:

1. Penicillin
2. Flucloxacin
3. Sulfadimethoxine
4. Cefitexofur
5. Gentamicin
6. Sulfamethazine
7. Oxytetracycline
8. Neomycin
9. Tilmicosin
10. Ampicillin

Some of these drugs have no place in the farm medicine chest. Gentamicin is not approved for use in dairy cattle, and neither gentamicin nor tilmicosin can be used in an extra-label manner for dairy cattle. Sulfamethazine and Tilmicosin are not approved for use in milk. That sampling reveals we see fewer than 300 positives per million milk samples tested. By contrast, we see more than 70 positives per 10,000 dairy cow tissue samples tested.

We need a more concerted effort to improve the situation with cows sent to slaughter.
ENHANCED SCRUTINY MEANS NEW PRACTICES

With more pressure from taxpayers and the medical field, FDA continues to beef up drug residue testing.

by Geof Smith, D.V.M.

FEDERAL regulations have been stepped up for drug residue sampling in the dairy industry, and researchers are finding that dairy farms that have had drug residue violations in the past are at higher risk of having new problems.

The author is at the College of Veterinary Medicine, North Carolina State University, Raleigh.

EVERY TANKER OF MILK must be screened for beta-lactam antibiotics before being unloaded at milk processing plants.

900 “targeted” milk samples would be compared with 900 “random” samples. The FDA generated a list of dairy farms that have had drug residues in milk, and determined what laboratories their milk samples were sent to.

Over the course of 2012, FDA investigators visited those labs and randomly collected milk samples that originated from farms with previous residue problems (these are the “targeted” samples). At the same time, investigators were collecting milk samples from other dairy farms without a previous history of drug residues (these are the “random” samples).

All milk samples were sent to an independent laboratory (not a federal government lab and not a milk industry lab) for testing. Collected samples will be tested for approximately 30 different antibiotics, including some not used in cattle and others that would be illegal to use in cattle.

In addition, they are screening milk samples for flunixin (Banamine) and several other nonantibiotic compounds. Any milk samples that contain drug residues will not be traced back to the farm of origin — this is simply a study to see whether some farms are at higher risk of having milk residues than others.

Sampling is scheduled to continue through the end of 2012. If the study shows multiple milk samples containing antibiotic residues outside of the beta-lactam family, this could ultimately lead to more milk samples being screened for other drugs.

It is currently too expensive to test every tanker of milk for every possible drug. However, we may see the testing change somewhat. For example, one idea that has been proposed would be to eliminate the regulation requiring every tanker of milk to be tested for beta-lactam antibiotics and randomly test each tanker of milk for a different class of antibiotics.

There are about six main classes of beta-lactam antibiotics: penicillin, ampicillin, amoxicillin, cephalin and ceftriaxone. In addition to beta-lactam antibiotics, milk may be screened for other drugs by employing a random sampling program.

For beta-lactam antibiotics prior to unloading at the milk processing plant (this includes drugs such as penicillin, ampicillin, amoxicillin, cephalin and ceftriaxone). In addition to beta-lactam antibiotics, milk may be screened for other drugs by employing a random sampling program.

The FDA Center for Veterinary Medicine (FDA-CVM) has mentioned on several occasions the need to advance testing for other classes of antibiotics. In part, this had led to the milk sampling survey study currently being done by the federal government.

Stopped-up sampling is here

In November of 2010, the FDA announced a milk sampling study to investigate whether dairy farms with histories of residue violations in cow milk might have higher milk residue potential due to poor on-farm drug use practices.

Ultimately, it was decided that for beta-lactam antibiotics prior to unloading at the milk processing plant (this includes drugs such as penicillin, ampicillin, amoxicillin, cephalin and ceftriaxone). In addition to beta-lactam antibiotics, milk may be screened for other drugs by employing a random sampling program.

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The number of drug tests run on dairy cattle has skyrocketed. It is a steroid approved for use in pregnant swine or swine intended for breeding. It is a steroid approved for use in pregnant swine or swine intended for breeding. It is a steroid approved for use in pregnant swine or swine intended for breeding. The first is that there are a few older drugs that don’t have established tolerance limits. Therefore, any concentration found will result in a residue violation. The drug dexamethasone is one of these. It is a steroid approved for use in dairy cattle at a maximum dose of 10 milliliters with zero slaughter or milk withdrawal. Therefore, whether you have a residue or not is based on what the assay can detect. A new testing method for dexamethasone was recently adopted by the FDA that can detect much lower levels than the old test could find. Based on this, there have been dexamethasone residue violations in both beef and dairy cows reported in the last year, and new withdrawal intervals were developed. Talk with your veterinarian and make sure you have proper withdrawal information. The good news is that meat and milk in the United States is incredibly safe. Both should be considered healthy, wholesome products. But, scrutiny of the dairy industry is higher than it has ever been, and the analytical techniques used by the FDA are quite sophisticated. If there are problems with proper drug use on your dairy, you are going to get caught sooner or later. •

MILK SAMPLES ARE BEING TESTED for about 30 different drugs in the current FDA study. This includes nonantibiotic compounds such as flunixin. It also includes some drugs not used in cattle and others illegal to use in cattle. 3. It can clearly distinguish between different drugs—even when multiple drugs are present in the same sample. 4. The time and personnel needed to obtain the results is dramatically reduced. This new assay can detect over 50 drugs at once, meaning the number of drug tests run on dairy cows has skyrocketed. It is important to realize that, between cull dairy cows and veal calves, the dairy industry represents the vast majority of residue violations found in animal agriculture. So, if you feel like you’re being watched more closely as a dairy producer compared to your friends down the road who raise chickens or pigs, that’s why. Historically, the dairy industry has had a much bigger problem with drug residues, and testing methods are becoming more sophisticated.

Finding lower doses In addition to new testing methods being able to detect multiple drugs at one time, modern analytical tests are able to detect drugs at much lower levels than in previous years. A tolerance is the maximum concentration of a particular drug that is allowable in meat or milk. There are two important things that dairy producers need to realize pertaining to tolerance. The first is that tolerance levels only apply when you are using a drug approved for dairy cattle. If you are using a drug not specifically approved for dairy cows in an extra-label manner (such as Nuflox or Micotil), then any concentration of the drug that the FDA detects is considered a residue violation. These drugs have established tolerance levels for beef cattle, but they don’t apply to dairy cows since they are not specifically approved for use in adult dairy cattle. In these cases, the recommended withdrawal interval is based on the detection limit of the drug screening assay.

Therefore, your veterinarian may tell you not to sell the cow for “45 days” after using a drug that says “28 days” on the bottle. The longer withdrawal recommendation is at least partially based on the fact that the dairy cow has to have tissue concentrations at a lower level than, say, a beef cow.

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A valid veterinarian-client-patient relationship (VCPR) is more than a phone call or email. Your vet should take a herd-level view of your herd’s health.

by Laura Moser

The first step listed in most drug residue prevention protocols, including the National Dairy FARM Program (Farmers Assuring Responsible Management), is establishment of a veterinarian-client-patient relationship (VCPR). A VCPR is also required by law in most states in order for a veterinarian to diagnose or treat an animal, prescribe or dispense medications. But determining the validity of your VCPR is not always clearly defined. The American Veterinary Medical Association says a VCPR exists when the veterinarian knows your herd well enough to be able to diagnose and treat any medical conditions your animal develops. The AVMA is clear that a valid VCPR cannot be established online, via email or over the phone.

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TREATMENT of mastitis remains the most common reason for antibiotic use in lactating dairy cows; consequently, the judicious use of antibiotics and implementation of management practices that prevent milk residues is essential for maintaining human food safety. Similar to the marked drop in bulk tank antibiotic residues (see pages 4 and 5 of this supplement), bulk tank somatic cell counts have also tapered over the last seven years as reported by the USDA in conjunction with the National Mastitis Council (NMC), indicating a reduction in mastitis in U.S. herds. Quality is more than SCC

This supports the goal for the production of high-quality milk and residue avoidance, but the focus on reducing mastitis and preventing residues must remain a top priority for producers. NMC is an excellent source of science-based information on mastitis control, milk quality and prevention of milk residues. Likewise, the National Milk Producers Federation’s National Dairy Farm Program includes a handbook on milk and dairy drug residue prevention. These organizations have been instrumental in preventing mastitis and drug residues in milk. Their recommended management practices can be summarized in five basic steps:

Step 1: Develop and implement an effective mastitis control program that is farm-specific.
Step 2: Use only approved drugs for lactating dairy cattle, and follow label directions for treatment and milk discard times.
Step 3: Identify treated cows at the time of treatment. If possible, treated cows should be segregated and milked last.
Step 4: Accurate and complete treatment records should include identification of the treated cow, drugs used, milk discard times and treatment outcomes.
Step 5: Test milk for residues using a screening test that is specific for the drug used with milk being sampled when the screening test is negative.

It takes a team

Drug residue avoidance and mastitis control take a group effort. The herd veterinarian is a valuable partner in the development of mastitis control programs, drug use protocols, effective drug choices and monitoring animal health progress. Learn more about this relationship on page 10 of this supplement.

Farm personnel play a vital role in preventing drug residues in bulk tank milk. Owners and/or managers set priorities that include residue prevention, developing and implementing effective mastitis control strategies and comprehensive training of employees. The milking crew is responsible for following milking hygiene and procedure protocols. They also serve as sentinels who identify mastitis, may treat cows and are responsible for diverting treated-cow milk from the bulk tank.

Housing, feeding and crops personnel help by providing a clean, dry environment for the herd and a proper ration to promote energy balance and immune function. The treated cow plays a role in residue prevention, as well. If she has an effective immune system, then she will be less susceptible to infection and reduce the need for antibiotic therapy. With acute cases of mastitis, feed intake and milk production may be reduced resulting in lower drug clearance rates and higher milk discard times. Also, purchased cows and cows with a shorter than anticipated dry period can be at risk for drug residues in milk.

The associated personnel who handle dairy industry also play a role in residue prevention. Suppliers of milking equipment, products to support the dairy farmer and nutritional consulting all support the farm efforts to maintain animal health. They can help reduce the need for drug therapy, thereby reducing the risk for drug residues in bulk tank milk. Preventing drug residues in milk depends on a collaboration with every individual involved in the farm operation in support of an effective mastitis control program, judicious use of drugs, identifying treated cows, maintaining accurate records and testing milk following the milk discard time.

WHEN TO SCREEN

A. Purchased cattle
B. Both extra-label drug use and approved drug use
C. If dry period was shorter than originally anticipated
D. Treated cows with low milk production
E. Any time there is a question about residue status

A highly functioning cow immune system prevents residues by keeping withdrawal times on-target. Many of the same steps used to prevent mastitis can help prevent residues in milk.

SPECTRAMAST LC
brand of cefotiofur hydrochloride sterile suspension

For IntraMammary Infections in Lactating Cows Only

FOR USE IN ANIMALS OR THERAPEUTIC USE IN ANIMALS
DO NOT FOR HUMAN USE

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS FOR USE
SPECTRAMAST LC® (ceftiofur hydrochloride) Sterile Suspension, is indicated for the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, Escherichia coli, and B. sepsis

PRECAUTIONS:
- SPECTRAMAST LC® Sterile Suspension is contraindicated in animals previously found to be allergic to the drug.
- Prevention of violative residues

CONTRAINDICATIONS:
- Administration of SPECTRAMAST LC® Sterile Suspension is contraindicated in animals previously found to be allergic to the drug.

DOSEAGE:
- One syringe (1 mL) into each affected quarter. Repeat this treatment in 24 hours. For extended duration therapy, once daily treatment may be repeated for a maximum of 3 days, at 24-hour intervals.

SIDE EFFECTS:
- Drug residues in milk

Learn what other products help you avoid residues at AvoidResidues.com. Or, just flip the page.*
MEAT and milk residues in dairy cattle are ever growing concerns that continue to generate attention for the industry. For this reason, producers must understand drug labeling, use antibiotics properly, ensure their veterinarians before administering treatments and involve them in developing written protocols.

Three things to watch

Dale Moore, clinical professor and director, Veterinary Medicine Extension, with Washington State University, cites three main issues facing dairy producers when using antibiotics in their herd.

“First, dairyman must know if the antibiotic they are using to cure the disease they are treating,“ she says. “Next, milk and meat residues must be avoided by using antibiotics according to on-label specifications or extra-label prescriptions from their veterinarian. Lastly, is minimizing antibiotic resistance transmission in cattle and humans.”

Understanding and interpreting the information on a Food and Drug Administration (FDA) label is the best place to start when beginning antibiotic treatment. The product information on the label includes: product name, name of the manufacturer, drug identification number (D.I.N.), active ingredient in the product and the concentration of the active ingredient. It also details information for proper usage, namely the intended species of use (cattle, horses and swine), class of livestock like lactating cows or calves and the disease which the drug is intended to treat.

Some of the most important information found on the label is the specified dosage (based on weight), how often it is administered, length of time for treatment and the administration method as intramuscular, subcutaneous, oral, intramammary or intrauterine. Finally, storage requirements and the expiration date appear on each label.

When antibiotics are used according to the aforementioned FDA label specifications, it is considered on-label use of an antibiotic. John Lee, a veterinarian with Zoetis, emphasizes the importance of following the labeled instructions. “Varying from the labeled route of administration can greatly affect the length of meat or milk withdrawal time and lead to violative residues,” Lee says.

“A good example is flunixin (a leading non-steroidal anti-inflammatory drug) in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.”

Zoetis also states that any drug used in an extra-label manner is a prescription drug that requires a licensed veterinarian in a VCPR.

Varying from a provided or prescribed label can greatly affect the length of meat and milk withdrawal time.

Prescriptions require a vet

More prescribed categories of drugs available for use to the industry as prescription drugs since they can be used only on order of a licensed veterinarian. While these antibiotics are intended to be used according to on-label specifications, a veterinarian prescription is required for lawful use.

The veterinarian who prescribes these drugs must hold a valid veterinarian-client-patient relationship (VCPR) with the dairy. See page 10 for more on VCPRs.

Moore and Lee both agree that the area that needs closer monitoring is extra-label drug use in dairy cattle. “Penicillin alone accounts for more than one-third of all residue violations in bulk dairy cattle, and many of those violations are due to the use of that product in an extra-label manner,” Lee states.

In the Animal Medicinal Drug Use Clarification Act (AMDUGCA) of 1994, the FDA recognizes the professional judgment of veterinarians and allows the extra-label use of drugs by them under certain conditions. More specifically, it defines extra-label use as: “Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.”

Extra-label use of drugs can only be prescribed by a veterinarian. Not following the label exactly is extra-label use.
A CALL FOR BACKUP

A tag mix-up at a slaughter plant got Victory Farms in hot water with the FDA. But after a workshop put on by its veterinary clinic, the farm created new protocols that eliminate gray areas, save money and lessen the chance of a future FDA debacle.

by Hoard’s Dairyman staff

SEVERAL years ago, Kevin Souza got a call he didn’t deserve. An FDA (Food and Drug Administration) employee told him a tissue sample from a Victory Farms’ cow tested positive for drug residue. As someone who takes pride in following protocols, Kevin was understandably perplexed.

Kevin checked the records at Victory Farms, the 2,900-cow operation his family owns with two other families near Milbank, S.D. They milk their herd of nearly all Jerseys and Jersey crosses three times per day in early lactation and two times the rest of the year. As the experience would be on most busy farms, he wasn’t planning on doing tag research on a dead animal that day between all the other tasks he had planned.

The tag number FDA personnel didn’t match up with any cow recently shipped on his dairy. This is a farm that can be pretty confident in its tags because every calf gets four forms of identification before it goes into the hutch.

Kevin said his employees didn’t say anything, but their skeletal faces showed that they didn’t like the idea of changing the protocols they had used for nearly their entire careers. In his search for backup, Kevin called Neubauer and Dr. Sousa to teach his employees to know the shots they were using, how withdrawal times were figured and all the new things they were doing to prevent drug residues today and in the future.

He gathered the team for an all-day seminar with Gary and Dr. Sousa. After that meeting, “It really opened everybody’s eyes, and changed us right off from there,” explained Kevin.

Seminar shake-up

When the Dakota Valley Veterinary Clinic of Milbank held a clinic-wide seminar on drug residue prevention last year, Kevin attended on behalf of Victory Farms. Joe Soussa, D.V.M. (no relation to the Souza family), a partner in the clinic and the veterinarian for Victory Farms, tries to organize one big meeting each year on a timely topic. This workshop centered on what today’s residue tests can pick up.

“Dr. Sousa ran 10 blind bulk tank tests from his clients. Some came from hospital pens, and others were saleable milk tests to show all the detectable drugs. In the past day, in the day, they talk about beef quality assurance and the record keeping required to ensure quality meat. “When mistakes happen,” Dr. Sousa explained, “the better record system you have, the easier it is to get it straightened out so you don’t end up with a residue black eye.”

One of the biggest things Dr. Sousa’s clients took away from the meeting was revamping their treatment protocols. “If we use drugs that don’t need extra-labeling, we are still capable of maintaining a healthier herd,” Dr. Sousa suggested, “and it’s a lot easier to avoid residues when drugs stay on-label.”

Dr. Sousa thinks many farms have more drugs than they actually need. Another big practice is only noting that a cow was treated for mastitis, rather than labeling which products were used.

Returning from the seminar, Kevin, who describes himself as “old school,” realized that some of the protocols on the farm were “old school,” too. “Although we had set protocols, we didn’t really know if we were doing things right,” Kevin explained. The scientific data presented at that seminar by Dr. Sousa and Gary Neubauer, D.V.M., senior veterinarian dairy veterinary operations with Zoetis, got him nervous about some of the protocols at Victory Farms.

The first thing Kevin did when he arrived home from the seminar was call a team meeting for the five employees involved in the drug administration process. This included his call and dry cow manager, herd manager, two stall women and a utility employee who gives shots from time to time.

“I told them that I learned that our infusions might not be doing any good for the cows.” Then he told them, “We need to change our protocols.”

“Kevin said his employees didn’t say anything, but their skeletal faces showed that they didn’t like the idea of changing the protocols they had used for nearly their entire careers.

In his search for backup, Kevin called Neubauer and Dr. Sousa to teach his employees what he learned at the session.

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Most expensive drug

Gary took time to explain to Kevin’s team that we need to look at the cost of cure with every treatment.

“If you find the cost of cure, first you have to look at efficacy,” Gary said. “It doesn’t really work!”

In the case of penicillin, our number one drug on the violator list, the answer is yes. It was one of our first antibiotics, and it still works pretty well. Today, there are probably better drugs out there for some infections, but penicillin is still there.

“Next, I look at the cost of drug per day,” Gary suggested. Penicillin, which you can find some places for as low as $6 per bottle, also has a cost in milk withholding.

“A typical penicillin dosage for a 1,500-pound cow is 45 to 75 cc’s at 3 to 5 cc’s per pound. But what is the milk withdrawal time?” Neubauer asks.

“The label for penicillin does say 48 hours for milk withholding. But that’s at 1 per 100 pounds. Above that is extra-label and requires a prescription.”

“45 cc’s, you would need to send a request in to PARAD (Food Animal Residue Avoidance Databank) to ask what they would recommend,” said Neubauer.

“If their recommendation is seven to 10 days,” pushed Neubauer, “calculate your milk loss. Then add in your chances for residue because of the volume.”

Gary said Kevin got this right away. He hadn’t been using a lot of penicillin but had been using some. When we look at the rest of the story, we realize we’re using penicillin extra-label in those high dosages. This makes the withdrawal time and missed revenue soar.

In general, Victory Farms now uses as little extra-label protocols as possible. Kevin estimates that they cut farm drug costs by 10 percent.

“Now, our go-to drugs have no milk withholding,” Kevin explained. It keeps everything simple, and there is less worry about whether they actually did a treated cow.

Instead of treating everything that has a problem, as they did in the past, they look at the economics — paired with the risk of putting a cow with a residue into the food supply — and ship many cows earlier.

“With the excess replacement animals we’ve got, we can afford to do more voluntary culls,” Kevin explained.

Thinking back to the incident a few years prior, Gary and Dr. Sousa helped Victory Farms develop an on-farm backtrack program for cows heading to slaughter. Victory Farms delivers some animals directly to the sale barn, while others are picked up by a local buyer.

Working with the sale barn, Kevin orders a stack of “back tags” — pieces of paper that work like contact paper. At Victory Farms, every time an animal heads to slaughter, a back tag is applied using the self-adhesive paper, and the tag number is recorded in the “remarks” section of DairyComp.

That way, unlike the situation years earlier, the farm is reading the same numbers as the FDA and sale barn if there were a problem.

According to Dr. Sousa, most sale barns only use the small paper back tag for identification.

With the changes made at Victory Farms, Kevin is much more comfortable with the data presented. “Now we’ve cut out gray areas on our farm. It’s just not worth the risk of doing some of the things we’ve been doing before. The risk is just scary.”

But Dr. Sousa reminds us that each farm is different. Work with your veterinarian to find the protocol that works for your farm.

Talk with your veterinarian about your current protocols. You may be able to save money on drug costs.

Penicillin is one of the most costly drugs used on farms today when we consider the cost of cure equation.

Consider working with area slaughter plants to get free back tags for animals leaving the farm.

Produce Milk and Meat Responsibly
Check the drug label when she enters the parlor. Organize your dry cow drugs with those for calves, heifers and steers.

by Steven D. Vaughn, D.V.M.

The FDA’s Center for Veterinary Medicine, Rockville, Md.

Evaluation, Center for Veterinary Medicine, U.S. Food and Drug Administration, Rockville, Md.

by Steven D. Vaughn, D.V.M.

Tomarket a new animal drug must obtain an approved New Animal Drug Application (NADA) for their product. An approved NADA means that the drug product has been evaluated by CVM and found to be safe and effective for its intended uses. As part of the evaluation, CVM looks at safety of the drug relative to the animal, humans who are administering the product, humans who eat food derived from treated animals and to the environment.

A sponsor of an NADA must demonstrate safety for each species and class of animal in which the drug will be labeled for use. Each species or class of animal presents different safety questions that must be addressed in order for the drug to be approved. Data is required for drugs labeled for use in dry dairy cows to ensure that unsafe animal drug residues in meat and milk do not occur. Additional residue data for drugs approved in dry dairy animals is necessary to determine if and for how long drug residues may persist after the dairy cow resumes lactation. CVM sets an appropriate milk withholding time for the drug when the cow begins lactating again to prevent unsafe residues in milk.

CVM is working with drug sponsors to make labels easier to understand. One of the areas that can be confusing is the definition of lactating versus nonlactating cattle.

For dry cows

CVM is aware that users may mistakenly interpret a drug label to mean that drugs approved for use in "nonlactating dairy cattle" are safe when used at dry-off, that is, in cows between two lactations. But the term "nonlactating dairy cattle" includes dairy heifers, dairy calves and steers according to current industry standards and a long-standing FDA practice. These classes of dairy cattle have not yet or will never produce milk for human consumption. On a drug label, the term "nonlactating dairy cattle" does not include dry dairy cows. Dry dairy cows previously produced milk for human consumption and will again in the future after completion of the "dry period" between lactations.

The FDA is currently working with product sponsors to clarify that dry dairy cows are a unique class of dairy cattle. Therefore, dry cows should be treated with drugs specifically labeled for use in dry cows.

Storage is different

The purpose of the drug labeling and storage requirements of Item 15r of the Grade A Pasteurized Milk Ordinance (PMO) is to ensure that dairy producers are aware of the labeling directions on the drugs that they are using to treat dairy animals. Dairy producers are reminded to read labels and understand how to properly use and administer animal drugs. The use of drugs in a class of dairy animals, for which they are not approved, outside of an appropriate extra-label use under the supervision of a veterinarian, may lead to residues in meat and/or milk.

For the purpose of Item 15r of the PMO, drugs indicated for use at dry-off should be stored with the "nonlactating drugs," not with the "lactating" cow drugs. Therefore, drugs intended for use in dairy calves, dairy heifers and dry dairy cows should be segregated from drugs for cows that are currently being milked. This required storage system should also be followed for drugs intended for use in goats, sheep and other dairy animals.

The only drugs that should be stored with the "lactating drugs" are drugs that are specifically indicated on the drug label or on a veterinarian's label for extra-label drug use to be used specifically in lactating dairy animals. For the purposes of complying with Item 15r of the PMO, "lactating dairy animals" means those dairy animals that are currently producing milk.

Labels are changing to reflect that drugs used at dry-off will be approved for lactating dairy cattle.

The PMO requires that drugs used at dry-off should be stored with drugs for nonlactating dairy cattle, like heifers.

Drugs approved for dairy cattle are found to be safe and effective by the FDA’s Center for Veterinary Medicine.
The day FDA called

An on-farm FDA inspection means your farm is already not in compliance. Here’s one farm’s experience.

by Daniel E. Little, D.V.M.

ROBERT and Zeke recently received a call from an FDA employee to inform them of a 3 a.m. inspection at their premises several days later. This was in response to a cow sold for slaughter that had a violative drug residue in her kidney at the time of slaughter.

I initially became involved with Robert and Zeke’s dairy a few months earlier to assist them with an FDA warning letter concerning an antibiotic residue in a slaughter animal. Unfortunately, this was the farm’s second FDA notice. My initial walk-through confirmed FDA concerns that the dairy’s owners did not administer the drugs consistent with the dosage level, withdrawal period, species limitations or other use requirements set forth on the drug’s labeling. This was further complicated by the lack of written treatment protocols and records. The source of the drug residue was quickly traced to the hoof trimmer’s use of long-acting sulfas.

Meat and milk sales ceased

Imagine my surprise when I was informed that another violation had occurred after we had spent weeks designing and implementing a new treatment and monitoring system. However, I soon learned that the most recent violation was not due to any approved treatment but rather the use of an over-the-counter (OTC) drug to induce uteruses in postpartum cows. Since the farm had received previous warning letters, the FDA responded with a consent decree for permanent injunction which enjoined or prohibited the dairy from selling meat or milk.

Inspectors are trained to understand protocols and procedures. They may have training in chemistry or biological sciences, or they may not. While it is a crime to understand since it requires that the documentation on your farm describes how procedures are conducted on your dairy and how you record data that creates a history of what has been done. The reason for an FDA inspection in this case was based on a failure of the on-farm processes to provide a product free of violative residue.

Therefore, the primary thrust of the investigation was to determine where and how the quality system (if it existed) broke down and what is necessary to ensure that the problem does not recur.

In simple terms, written protocols should spell out what needs to be done, how farm personnel are to perform the tasks and how they are to record what has been completed. The inspector may lack the knowledge to know if the correct treatment was administered. However, they are experts at determining whether or not a written protocol was followed and accurately documented. In this case, all existing protocols were followed correctly. However, one employee had determined that the only way to cure metritis was to also infuse the uterus with an oral medication that was not on the dairy’s list of treatment drugs. Since this was an OTC drug, I had no control over the purchase or use of the product.

Drugs must be used for the diagnosis stated on the label and at label dosages whether or not they are purchased from your veterinarian. The inspector will evidence by the lack of written treatment of any actions taken by your veterinary personnel.

In the event of incomplete records, it is assumed that the drugs are not being used correctly and are resulting in meat or milk residues. All cows must also be visibly marked so that anyone walking by can tell that they are a potential drug residue. The cows that were treated “off protocol” were not recorded or physically marked.

A tour with FDA

At one point, the inspector asked Zeke to walk him through the entire diagnostic and treatment process. Next, he asked an employee to explain the process to him. Therefore, it is critical that you stay with your employees at all times and during all aspects of any investigation of your dairy. Any actions by the inspector to harass or pressure an employee should result in a diplomatically stated request for the inspector to harass or pressure his or her behavior. You have the right to protect your employees.

On Robert and Zeke’s farm, he started asking employees questions without notice. At one point, Zeke had to intervene between two employees and the inspector. Zeke’s challenges with reading comprehension, and his speech disability, made it difficult for him to communicate with the inspector. Suddenly, the inspector asked the employee in Lees’ face to ask questions (although Lees does not have a hearing disability) and further frustrated Les with his own inability to speak. The intercommunication was quite unfortunate since Lees had received understanding of the treatments on the dairy and is an extremely loyal employee. Imagine how difficult this situation could be in the event that employees do not speak fluent English.

At some point, farms under inspection could be asked if other individuals on the dairy administer treatments to your animals. This includes veterinarians, hoof trimmers, calf raisers, breeding technicians, milking technicians or feeder raisers. Anyone who has the authority to treat animals is expected to have been trained to your protocols and maintain accurate treatment records. These individuals are also expected to be able to explain how the treatments are administered.

Zeke had a bad habit of leaving drugs sitting in window sills around the dairy, another practice we had already discontinued prior to the FDA visit. Inappropriate storage temperature and conditions (exposure to sunlight) are the possible basis for a claim of adulteration of a drug. If stored improperly, it is difficult to determine if the use of the drug will result in normal residue clearance times from the animal.

Drug storage examination

Ideally, all drugs would be placed into a controlled (locked) storage area. Additionally, records would be maintained that document the date and amount of product received and the date and amount of product taken out of the storage area. This provides the basis for an accurate inventory of drug usage for any time period.

Since the use of an OTC drug had already been determined by the inspector the most recent drug residue, inventory reconciliation was a primary area of interest for the inspector. The treatment records were also entered into the herd computer, but we were not comparing the computer records so the inspector wrote down all of the history and observations and asked Robert to sign the affidavit. When they refused to sign, the inspector taunted them with “is there something in the report that is untrue? If so, what is it?”

Robert and Zeke signed the form fearing that they would be in more trouble if they resisted. Since this is ultimately a legal question, please consult your attorney before signing any affidavit. Hopefully, the experiences of Robert and Zeke and my comments will help you to discover areas of your dairy that might benefit from improved processes or procedures. Together, we can continue to ensure that we are producing safe and wholesome products into the computerized herd records so that we can calculate the quantity of drugs used in treatments and compare it with inventory discrepancies.

Minnie also began examining the record of every animal that was selected to be culled from the dairy. Les selects the cows to be sold, looks for a treatment leg band and adds a “Do to the list. Minnie then looks up each animal and verifies that each cow does not have a meat or milk withdrawal in effect due to a recent treatment. Robert or Zeke then initial and date the completed form before the animals can be released from the farm.

Don’t just sign the affidavit

At the end of the inspection, the inspector wrote down all of the history and observations and asked Robert and Zeke to sign the affidavit. When they refused to sign, the inspector taunted them with “is there something in the report that is untrue? If so, what is it?”

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Farms without drug residues will not be producing food that is less safe or wholesome than the food we are consuming. If you see an FDA inspector, you’re being asked to do your best and to report your experience to the inspector to get your market back.

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For decades, the importance of “good” health records has been stressed. Yet, most dairies still lack the accurate and consistent records needed to avoid drug residues and evaluate the effectiveness of their health protocols. Incomplete records of extra-label drug use is the most commonly cited reason for a violation at slaughter. Though improvements have been made, dairy cattle are still too often times more likely to be flagged for a carcass residue than their feedlot counterparts. The main problem is health and treatment records not good enough.

Consider repo records

Think about your reproduction records. Every time a cow is bred the date, sire and, in most cases, technician and breeding code are recorded in a standard way either through DHIA or on-farm computer software. These quality records allow you to effectively manage and monitor the effectiveness of the reproductive program through conception and pregnancy rates.

Now, think about your health records. Although the Pasteurized Milk Ordinance (PMO) clearly states what constitutes complete treatment records (see ‘What should good health records look like?’), each dairy can record whatever information it wants in any way it likes. As a result, health records are often inconsistent and incomplete for proper drug residue avoidance and lack the accuracy and consistency needed to evaluate the outcomes of health management decisions. This isn’t good enough.

Good health records need to be functional in order to aid in residue avoidance and herd management. They must be quick and easy to keep and support individual cow management decisions. They must also be accurate and consistent to allow efficient summaries and evaluation needed to make outcome-based herd health decisions. The third function, residue avoidance, is a result of the others.

A collaborative study this summer highlighted health record opportunities that we can capitalize on to get it right and use to influence treatment decisions while enhancing residue prevention.

Dairy health management

As part of a USDA-funded project to improve dairy health records and foster valid veterinary-client-patient relationships, Washington State University created a health records assessment tool. Three veterinary students supported by Zoetis used the tool while they observed the diagnosis, treatment and recording of mastitis, metritis, pneumonia and lameness on 105 dairies totaling 80,000 cows. They also interviewed owners and managers and evaluated drug cabinets to complete their assessment of health management on the dairy. Here is what they found.

Is there a written treatment protocol?

Of the four diseases evaluated, fewer than 50 percent of all operations had a written treatment protocol, and only half of those were actually following the written protocol. Protocol drift occurs in the absence of active, immediate feedback. Workers, making what they think are inconsequential changes, could put the dairy at risk of having a drug residue violation, especially now that more extensive testing is required by law.

Veterinarians are always cited as playing an important role in residue avoidance. The veterinarian should be a key member of the management team when it comes to developing, implementing and evaluating health protocols, including those for keeping health records. Creating written treatment protocols and reviewing them at least every six months ensures farm management and the veterinarian remain aware of what is being done on the dairy. Taking written protocols a step further and develop a protocol for record keeping, too!

Are protocols used in an extra-label manner properly labeled by a veterinarian?

The answer was no. All dairies used at least one drug in an extra-label fashion, yet fewer than 25 percent had a proper label from their veterinarian.

Most dairies could improve health record keeping. Written protocols eliminate “drift” from the original procedure.

COULD YOUR RECORDS process be improved?

A collaborative study this summer found that all dairies could make some aspect of their operation better.

WHAT SHOULD GOOD HEALTH RECORDS LOOK LIKE?

During a drug residue violation investigation, the inspector will ask whether you keep medical records and list nine items described in the PMO for complete treatment records. In the study, not one dairy had all the information available in its treatment records. Complete health records should include:

1. Animal’s identification.
2. Treatment date.
3. Drug(s)/medicated feed used.
4. Dosage given.
5. Route of administration used.
6. Withdrawal time for meat and milk.
7. Name of the individual who administered the treatment. (Individual administering treatment is no longer asked; however, it is kept on record for accountability.)
8. Whether treatment was recommended by a veterinarian.
9. Date the animal can be slaughtered and/or milk can be used.

All this information should be readily available for two years. It can be kept in a combination of computerized health records, written treatment protocols and daily treatment sheets. Make sure anyone entering information uses the same abbreviations and codes for the computer database and treatment records.
Dairy Wellness is a core value that drives everything we do. When we do what’s right for our industry, we do more for our industry. We produce healthier animals. And better food. When we’re committed to working together to avoid a damaging drug residue violation on our dairies, we’re committed to Dairy Wellness. It’s the difference we make. For our animals. For our dairies. For our food supply.

See how Dairy Wellness makes a difference for you.

Please join us at facebook.com/dairywellness.