



Center for Veterinary Medicine (CVM)

**NGFA-PFI FEED AND PET FOOD JOINT CONFERENCE
September 18, 2018**

**Steven M. Solomon, D.V.M., M.P.H.
Director**

CVM Vision and Mission



Vision

“Excellence, Innovation, Leadership”

Mission

“Protecting Human and Animal Health”



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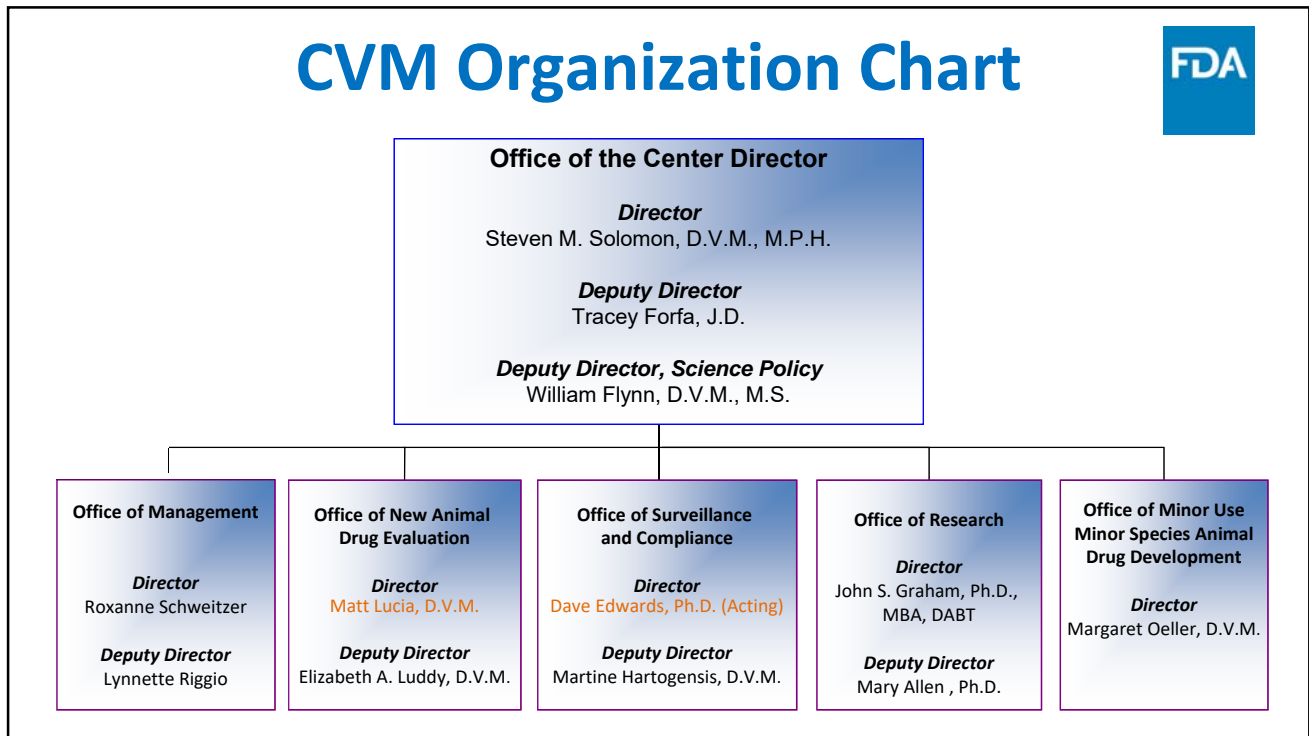
Thank you, Randy, for that introduction. I want to thank both NGFA and PFI, Randy and Dana, for the invitation and also Dave Fairfield and Pat Tovey for continuing to include FDA on the agenda.

While we approach animal food from different perspectives, we have an equal share in ensuring that we continue to have one of the safest food supplies in the world, and that any safety concerns are addressed swiftly.

Last year, I spoke to you all about my overall vision for CVM, my guiding principles, and priorities.

Now, in my second full year as CVM's director – my guiding principles and priorities haven't changed. The work under those general areas changes slightly as we continue to make progress, but the overall focus on food safety, pre-market review, encouraging innovation for both new drugs and food ingredients, and finding ways to combat antimicrobial resistance remains the same.

CVM Organization Chart



Dr. Steve Vaughn – ONADE – Dr. Matthew Lucia

Dr. Dan McChesney – OS&C – retired beginning of May

Three acting directors of OS&C

- Jenny Murphy
- Dr. Pat McDermott
- Dr. Dave Edwards

We posted the announcement for the position of Director, Office of Surveillance and Compliance, earlier this summer.

The other major change is the Commissioner's Office reorganization. While not final yet, Commissioner Gottlieb feels strongly that he wants direct interaction with the agency centers, where he feel most of the day-to-day work takes place. For some time now, I report directly to the Commissioner.

The reorganization proposal does away with most of the prior Directorate structure. The proposal keeps in place portions of the Office of Foods and Veterinary Medicine under Dr. Ostroff with a new title of Office of Food Policy and Response. What is important is that the central coordination on cross-cutting foods issues remains, particularly as relates to FSMA.

Guiding Principles



- Protecting public health
- Regulating based on the best evidence and science
- Leveraging and collaborating with domestic and international health and regulatory partners
- Operating transparently
- Encouraging continuous quality improvement
- Engaging stakeholders



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I want to re-share my guiding principles with you all, as I hope you have seen these principles reflected in your interactions with CVM over the last year and that you will see them reflected in the remarks I make today. These principles help us stay focused on our public health mission.

As many of you know, I have been a strong advocate for an Integrated Food Safety System for a long time now. The only way to fully achieve our mission of protecting human and animal health is by leveraging and collaborating with our fellow public health and regulatory partners. We also need to actively engage with our industry and consumer stakeholders so we understand their issues and concerns as we address a number of ongoing and emerging challenges.

Key Initiatives



Pre-market Animal Drug Review

- Animal Drug User Fee Act (ADUFA)
- Animal Generic Drug User Fee Act (AGDUFA)
- Minor Use/Minor Species (MUMS)

Food Safety Modernization Act (FSMA) Implementation

Antimicrobial Resistance Strategy

- National Antimicrobial Resistance Monitoring System (NARMS)
- Supporting Antimicrobial Stewardship in Veterinary Settings (5-Year Plan)

Emerging Technologies and Innovation

- Genome Editing and Genetic Engineering
- Whole Genome Sequencing and Stem Cell Research

Unapproved and Compounded Animal Drugs

Post-market Drug Safety, Effectiveness, and Quality

- Adverse Drug Experiences (ADE)
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

Outreach to Consumers and Stakeholders



Agenda



- Food Safety Concerns
- Challenges with Pet Food
- Ingredient Safety
- Antimicrobial Resistance
- Hot Topics
- Opportunities for Cooperation

Today I am not going to go through all the work ongoing in CVM, but rather I will highlight a few topics: Food Safety, Ingredient Safety, Combatting Antimicrobial Resistance, and a few hot topics.

Jenny Murphy will be covering FSMA implementation for you all in her presentation, so I won't be discussing specifics of implementation but more global concerns related to food safety.

Food Safety Concerns



- Success stories
 - Animal food industry has responded well to numerous challenges
- Opportunities for improvement
 - We continue to observe serious and repeated hazards in animal food

For food safety: We have successfully faced many challenges together, such as the emergence of BSE and other prion diseases, economic adulteration of the supply chain with melamine and cyanuric acid, and the challenge of ensuring safe animal food after natural disasters, which we are facing again this hurricane season.

Unfortunately, we continue to observe serious and repeated hazards in animal food, such as monensin in horse feed, vitamin and mineral toxicities or deficiencies, medicated feed carryover, as well as the emergence of new pathogens.

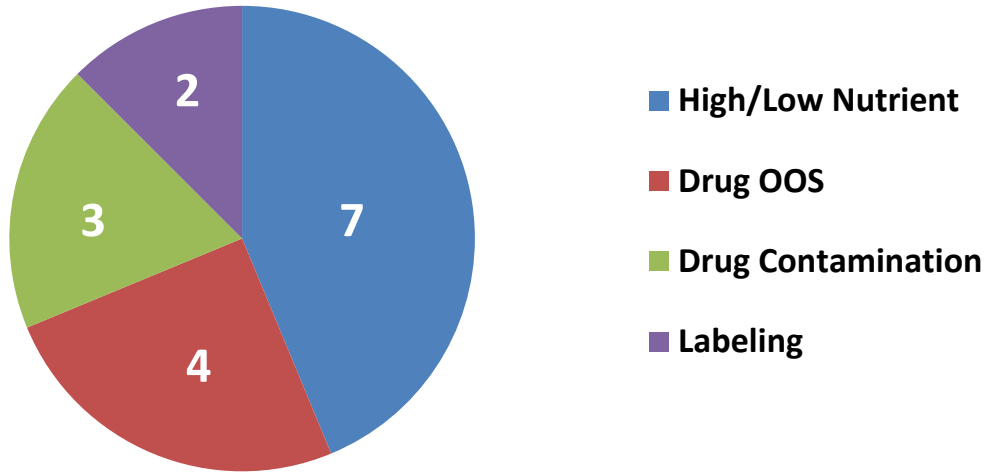
Every year we get reports of dead horses from a single farm, and every year, we track most of those cases back to the horse feed being contaminated with monensin. It is a well-established fact that monensin is toxic to horses, and monensin poisoning is completely preventable. Firms handling monensin and making horse feed need to think about how they can control this hazard and prevent this from continuing to happen.

There are other hazards in animal food that are preventable, too, and implementation of the PCAF regulation should be helping guide you to the principles of preventing these food safety issues as opposed to reacting to them.



Food Safety Concerns

Livestock and Poultry Food Recalls



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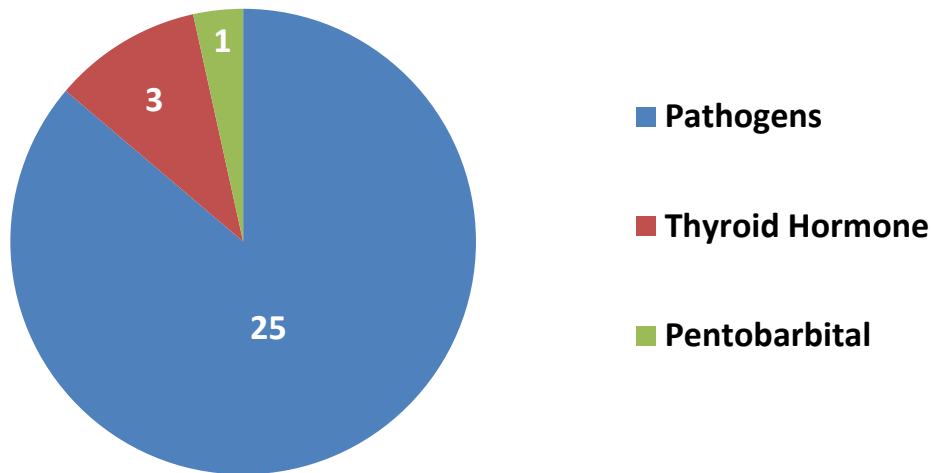
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Over the last 12 months, we have had 16 recalls of livestock food for hazards such as drug contamination, medicated feeds with drugs out of specification, excess salt or selenium and vitamin deficiencies, and labeling concerns.

Food Safety Concerns



Pet Food Recalls



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For pet food over the last 12 months, we've had 29 recalls for hazards such as pathogens, thyroid hormone, and pentobarbital.

These are patterns that we've seen repeat over the years. The majority of the pathogen recalls have been in raw pet foods containing *Salmonella* or *Listeria monocytogenes*, but there were also 6 pathogen recalls for products other than raw pet food (which were primarily treat products).

In addition to *Salmonella* or *Listeria monocytogenes*, products were recalled for *Clostridium botulinum* (1 treat) and pathogenic *E. coli* (O121) (Raw product that also had *L. mono*).

Food Safety Concerns



- Too many recalls – too many sick animals
- There will always be emerging hazards, but the industry needs to work to correct patterns for established hazards



There continue to be too many recalls and too many animals getting sick or dying.

No farmer should have to worry about the health of their animals and their livelihood because of the animal food they feed. No pet should get ill from eating pet food, and no person should get ill from feeding their pet.

The animal food industry is dynamic, and we will continue to face new hazards as production practices change and new animal food ingredients, new product trends, and supply chains emerge. The next couple of slides are representative of hazards that continue to be real challenges for our industry.

Challenges with Pet Food



- Contaminants
 - Pathogens
 - Pentobarbital
 - Thyroid Hormone
- DCM and “Grain-free” Diets



Pathogens in pet food continue to be a public health concern.

Pentobarbital contaminated meat and gullet with associated thyroid tissue resulting in the presence of thyroid hormone in pet food products both led to adverse events in consumers’ pets. Consumer complaints associated with these adverse events led to the resultant recalls.

Food safety needs to be controlled, and one of the ways it can be controlled is through your supply chains, which highlights the importance of working with trusted suppliers to help ensure safe pet food.

Dilated cardiomyopathy (DCM) and its potential association with diet has also garnered a lot of attention this year. We're actively working with our partners in Vet-LIRN (Veterinary Laboratory Investigation and Response Network), the veterinary community at large, and the pet food industry to understand this problem.

Challenges with Pet Food Pathogens



- All pet food facilities' hazard analysis and food safety plans should prepare pet food facilities for producing pathogen-free pet food
- Manufacturers should ensure scientific validity of pathogen control methods

I know I spoke last year about pathogens in pet food. Last year, I wanted you all to know of my concern and to stress the importance of prevention. I think that message was heard, based on some feedback we received.

What I likely did not do last year was acknowledge the work that much of the pet food industry, especially the kibble and treat industry, has done to implement systems that have been effective in controlling pathogens.

As we enter into FSMA implementation, we want to continue to work on effective controls and how to control pathogens in new matrices, such as raw pet food.

Any new pathogen control methods that the industry is considering must be validated in the matrix.

We also encourage you all to share food safety information with one another. Validation studies in animal food matrices are sparse, and we want to encourage you all to share that information and, when appropriate, make it publicly available. That helps keep the industry, academia, and regulators up to speed on the most current information.

Challenges with Pet Food Pathogens



- Pathogens in pet food continue to be a public health concern
- Consumers should have confidence that the food they bring into their homes is safe for them to handle and their pets to eat



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Even though a lot of work has been done, pathogens in pet food still remain a **public health** concern and something we have to continue to focus on, especially as consumer trends change and emerge, such as with the expansion of the raw pet food market.

This year – we had the terrible misfortune of connecting a contamination issue in a pet food with serious illness in children. We also had animal illnesses that were associated with contaminated pet food. In both instances these were raw products.

Luckily for us, technology is improving for detecting food safety hazards. Technology, such as whole genome sequencing, can help us tie together contamination events to better understand what went wrong, **and we are increasing our use of such tools.**

Challenges with Pet Food

Pentobarbital



- Pentobarbital should NOT be found in animal food
- Recognize that pentobarbital can come from multiple sources



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Earlier in my career at FDA, I remember that pentobarbital emerged as an issue, and when I returned to CVM last year, pentobarbital came back as an issue and it came back in full force.

We have had **6 recalls** involving pentobarbital since **FY15**.

Pentobarbital simply should not be found in animal food.

The American public, especially pet owners, demand this of us as regulators and you as the industry – and they deserve to know and take comfort in the fact that their animal food doesn't contain a substance that is intentionally used to euthanize animals.

There was about a 14 to 15 year timespan between the last pentobarbital recalls and the start of the most recent recalls.

This goes to prove that if we are not diligent, hazards can re-occur – and they can come from unexpected sources.

Most of us probably think that pentobarbital comes from a couple of bad actors that use a euthanized animal when they know they aren't really supposed to.

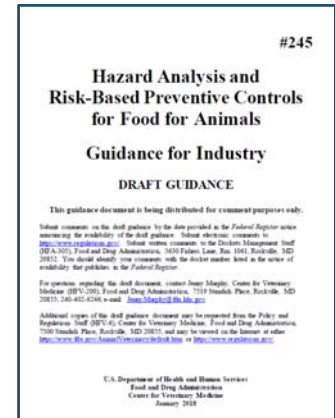
New evidence is showing that it may be a much more pervasive problem throughout the animal food supply than originally thought, and we have reason to believe rendered products can be a source for pentobarbital, if not controlled.

Challenges with Pet Food

Pentobarbital



- FDA current thinking/activities
 - Draft GFI #245 – **pages 53-54**
 - Updating old policies to reflect new FSMA hazard analysis and preventive controls framework
 - Working with industry to implement FSMA to ensure control of pentobarbital hazard



Here is our current thinking and some of the activities FDA is doing around pentobarbital:

- In our draft guidance #245 for hazard analysis and risk-based preventive controls, we have identified pentobarbital residues as a potential chemical hazard in animal food. You can find that information on **pages 53 to 54** of the guidance.
- We have several old policies, such as our compliance policy guides, that need to be revisited, since we have this new food safety regulation designed to control hazards.

- Rendered ingredients are a valuable animal food ingredient and we don't want you to think we do not recognize that and the valuable services the rendering industry provides to both the animal food industry and the environment.
- Under the PCAF regulation, you have the opportunity to review your hazards and select the appropriate preventive controls.
- We are putting pentobarbital on your radar as something you need to consider as a hazard.
- You really need to put some effort into thinking about pentobarbital during your hazard analysis – based on your incoming ingredients and processes, is this a hazard for your facility? If it is – what are you going to do to ensure that the hazard is controlled?
- We are willing to work with you all as you implement the PCAF regulation (such as through education, guidance, meetings, and discussion) to help ensure the control of this hazard.

- We know that some of you are already taking steps to address this hazard and are aware of the recent communication that the National Renderers Association provided to caution members from picking up euthanized animals.
 - That is a step forward for food safety.
 - However, we want to encourage you to continue your work and outreach across the pet food industry and to the veterinary community, as this is going to be an issue that impacts all of you and it is necessary to work together to find the ultimate solutions.
- As you work on difficult issues from both the industry and regulatory perspective – you have to find the commonalities.
 - The good thing is – we have a shared goal of safe animal food.
 - We have had some pretty frank conversations around this topic with NRA **and PFI** staff – we appreciate the willingness to continue the dialogue, as it’s important for all of us.
 - As you work to address this as an **animal food industry (in partnership with the veterinary community)**, we want to keep the dialogue going and to be able to continue to work together to promote our shared interest in food safety.

Challenges with Pet Food Thyroid Hormone



- Adverse events and recalls continue
- Contamination highlights the importance of ingredient sourcing



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Gullet with associated thyroid tissue resulting in the presence of thyroid hormone in pet food products, causing thyrotoxicosis in animals, continues to occasionally occur.

This highlights the importance of establishing a relationship between supplier and manufacturer to ensure that safe ingredients are being used.

We have discussed our concerns with this contamination event with industry, but continue to see recall events.

Challenges with Pet Food DCM and “Grain-free” Diets



- Fully understanding the potential association between diet and DCM will require cooperation between FDA, the veterinary community, academia, and the pet food industry
- A July 12, 2018 **FDA CVM Update** warning about the potential connection between DCM and diet has stimulated reporting

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As we have seen with raw pet food, consumer demands drive trends in the pet food industry. And sometimes those trends may lead to some unexpected findings. One of those trends is the push for “grain free” diets, and one of the unexpected findings this year has been reports of dilated cardiomyopathy.

Six months ago I was going through life thinking a pulse was arterial blood moving through a blood vessel and having one was a good thing.

The potential association between diet and DCM is a complicated issue that deserves our attention, and consumers should have confidence in the food that they're feeding to their pets. However, it's a complicated issue that will require cooperation to fully understand.

CVM has received more than 140 reports of Dilated Cardiomyopathy (DCM) so far this year, with most of those reports following our July 12 CVM Update. For comparison, we've had 3 or fewer reports in prior years.

Challenges with Pet Food DCM and “Grain-free” Diets



- 90% of reported cases were eating “grain-free” diets
- Peas and lentils (pulses), and/or potatoes are commonly included in both “grain-free” and grain-containing foods associated with DCM cases

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Approximately 90% of reported cases were eating grain-free diets (or products labeled zero-grain). Approximately 10% ate grain-containing diets (rice). 92% of all cases were exposed to diets that list peas in the top 6 ingredients. Some of the grain-containing diets listed peas high in the ingredient list. Protein source has been variable, including kangaroo, salmon, bison, lamb, turkey, and even beef and chicken.

CVM is continuing to investigate this issue and is working closely with our partners in the veterinary cardiology and nutrition communities and the pet food industry. This is an example of the principles I outlined before in action. This is focused on a public health issue, we are being transparent, we are collaborating and leveraging with relevant partners to help address the issue, and we are engaging stakeholders (who knew there was an association with pulse ingredients).

Pre-market Review

Food



- CVM review of new food ingredients
 - Food Additive Petitions
 - GRAS Notices
 - AAFCO Ingredient Definitions



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In keeping with the theme of prevention, one of the roles FDA has in protecting public health and keeping our food supply safe is our responsibility to ensure that new food ingredients and new drugs are safe and effective.

CVM has two pre-market review programs that are both essential to the safety and security of animal health.

The first is our pre-market review program for new animal food ingredients via food additive petitions, GRAS notices, or in cooperation with AAFCO. As I discussed last year, while review by CVM is not necessary if adequate information exists for a firm to self-conclude that a new ingredient is GRAS, we strongly encourage firms to work with us for new ingredients. While GRAS self-conclusion is acceptable under the Food, Drug, and Cosmetic Act and may seem more expedient than waiting for a CVM review, it is not without challenges.

Pre-market Review



Food

- Animal Food Ingredients and ADUFA/AGDUFA
 - New guidance
 - Increased transparency
 - Deletion of Ingredient Standards and Definitions Provision in FDAAA

You might not expect to find animal food provisions in the reauthorization for the animal drug user fee program, but these provisions provide us the opportunity to work on some key pieces for our pre-market review program.

The first is the development of a new guidance document to help firms better understand how to work with us prior to submitting a food additive petition.

Talking to us early in development can help conserve time and money and ensure the data you generate is useful for regulatory purposes. This will help you understand the data requirements that will be needed for our review, and will help increase efficiencies in the development process.

Most of the ingredients being developed today are much more complex than the ingredients that have historically been used in animal food, which can raise questions about safety that need to be addressed with feeding trials and data about the manufacturing process.

When this new guidance document is published, you will have more information about how to interact with us during the development process, and when it is useful to submit preliminary data or protocols before submitting a petition or other submission.

The second provision is about increased transparency regarding submissions that we're reviewing. We're very aware of the concerns in the industry regarding review times, and we're actively working on improving our efficiency and ensuring that we're asking the right questions.

We'll be reporting the number of petitions that are pending, and how long they've been pending. This will allow everyone to see how increased submission volume has resulted in slowed review times with current staff. While we are taking steps to increase efficiency of our internal processes, we recognize that this is essentially a resource challenge, and we want to work to engage with you to better understand what would meet the needs of the animal food industry.

Congress also reminded us of the importance of considering all available data, including foreign data, and ensuring that we're explaining why additional data are necessary if we determine that a petition is inadequate. We appreciate these concerns and will continue to ensure that all data and information are considered in petitions and that firms understand the scientific rationale for any additional data requests.

Finally, the ingredient standards and definitions provision of the 2007 FDA Amendments Act (FDAAA) was deleted.

Enactment of this provision has long challenged the Agency, and its deletion provides an opportunity for us to reaffirm our relationship with AAFCO as a means of developing definitions for ingredients used in animal food.

The AAFCO feed ingredient definition process has a long history as the most comprehensive list and description of acceptable ingredients for animal food. Continuing to work with AAFCO on defining ingredients ensures consistency for the regulated industry and serves our public health mission by having our scientists conduct the review of new ingredients.



Pre-market Review

Drugs

- CVM review of New Animal Drug Applications
 - Safety (human food, user, target animal)
 - Effectiveness
 - Quality Manufacturing
 - Proper Labeling
 - Environmental Impact

The second of our pre-market review programs is for the review of new animal drugs. While most of you are not drug manufacturers, some of you make medicated feed and medicated feed is one of the primary delivery mechanisms for animal drugs in livestock.

We review new animal drug applications to make sure they are:

- Safe (for the target animal species, the user of the drug, and for drugs fed to livestock – any human food safety concerns that may result following consumption of edible animal products).
- We make sure the drugs are effective and are manufactured in a manner to ensure a quality and consistent product.
- We also spend time, similar to animal food, making sure that the labeling is appropriate for the product.
- And we have to consider the potential impact of any new drug on the environment as part of our approval process.

Pre-market Review



Drugs

- To facilitate the approval of animal drugs, including those in medicated feed, the Animal Drug User Fee Act and Animal Generic Drug User Fee Act were passed into law in 2003 and 2008, respectively
 - Provide resources that support timeliness and predictability of application reviews
- ADUFA IV/AGDUFA III reauthorized in August 2018
- One of the new provisions of the reauthorized ADUFA is a shortened review time for certain medicated feed combinations, once all of the drugs have been individually approved

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CVM's resources for reviewing new animal drugs was greatly enhanced with passage of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

Both ADUFA and AGDUFA provide necessary resources that support the timeliness and predictability of CVM's review of new animal drug applications.

A major success for CVM this year was the renewal of both ADUFA and AGDUFA in August.

With ADUFA, there were some changes that impact our review time frames for certain medicated feed combinations – which is of benefit to both the animal drug producer and the medicated feed producer.

The importance of this change to the review and approval of qualifying medicated feed combinations within 60 days, in the reauthorized ADUFA is that it:

- 1) Reduces time to approval of a feed use combination after the single drug alone is approved, and
- 2) Prevents the delayed use of newly approved single drugs that provide novel or improved health benefits or animal production characteristics, as many drugs are only used when in approved combinations with other new animal drugs

Prior to this change, a sponsor would have to wait up to 180 days for the approval of the medicated feed combination after the last individual drug is approved.

Because most medicated articles are not used alone, this would delay the use of the newly approved single medicated article until the combination was approved 6 months later. Sponsors wanted to be able to be able to more closely tie these two approvals.

AMR Updates



- Significant progress has been made in our antimicrobial stewardship and Veterinary Feed Directive efforts
 - All drug sponsors voluntarily met the January 2017 milestone
 - Substantial outreach to, and by, the veterinary community, animal producers, and other key stakeholders has occurred
 - Continued engagement of VFD Rule stakeholders is critical to continued success
 - Increasing inspectional oversight

While we have a role in making sure that new animal drugs are safe, effective, and available on the market, we also have a role in ensuring antimicrobial stewardship.

One major piece of ensuring antimicrobial stewardship is increased oversight through our Veterinary Feed Directive program.

While VFD has been around for some time, the revised regulation in 2015 increased awareness.

I – along with the CVM staff – were very impressed by the reaction from the animal drug community when 100% of sponsors complied with 100% of the applications affected by our Guidance for Industry #213 by January 2017.

CVM has been working to conduct high levels of outreach to help animal food producers, the veterinary community, and animal food manufacturers to understand the VFD program and their roles and responsibilities.

For example, CVM representatives have participated in over 180 in-person or webinar presentations, have answered nearly 400 individual questions on various VFD topics, and continue to provide additional information on our website when needed.

We are committed to continuing outreach and your feedback and questions are what helps us know what communication and outreach is needed.

Similar to FSMA inspections, we have tried to take a practical approach to building and developing our VFD inspection program. We started out small and made adjustments based on the initial inspections.

This year, the majority of VFD inspections will continue to reach all 3 major parties involved with a VFD order: the authorizing veterinarian, the animal feed distributor, and the producer. All 3 serve important roles in the Veterinary Feed Directive program, which is one of our key programs for monitoring antimicrobial drug use.

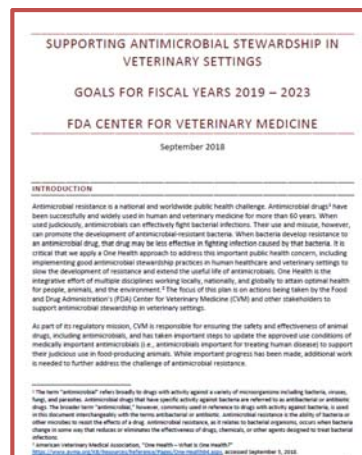
VFD inspections are going to be conducted by both FDA investigators and state officials. While states will be conducting inspections, we have been hearing from states about some potential challenges, particularly with the portion of the VFD inspection involving the authorizing veterinarian.

We are working through some of these concerns with our state partners, which does include making some updates to our VFD tool as a part of our commitments to collaboration and continuous improvement.



AMR Updates

- On September 14, 2018, CVM published a 5-year plan for **Supporting Antimicrobial Stewardship in Veterinary Settings** that outlines the key goals and objectives that will be our focus during fiscal years 2019 – 2023
- We have divided our approach into two phases:
 - Phase 1 actions initiated between fiscal years 2019–2021
 - Phase 2 actions initiated between fiscal years 2022–2023
- Phases are the target for initiating work and do not necessarily represent when the actions will be completed



Last week, we rolled out our 5-year antimicrobial resistance strategy.

Continued implementation and oversight of the veterinary feed directive program is a key piece of the 5-year plan.

AMR Updates



- Goals of 5-Year Plan
 - Align antimicrobial drug product use with the principles of antimicrobial stewardship
 - Foster stewardship of antimicrobials in veterinary settings
 - Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

Global Food Supply



- Concerns about global outbreaks and role of animal food as a vector
- These events highlight the importance of actively maintaining biosecurity practices, reviewing suppliers, and other food safety practices
- Proactive engagement with FDA is necessary to facilitate review of any novel mitigation products



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To truly protect our food supply, we have to be aware of what is happening outside of the U.S. that may have an impact domestically as we import and export food.

I bring this up today as there is an emerging issue that animal food manufacturers, particularly those making swine food, need to be mindful of.

As some of you may have heard, there has been an outbreak of African Swine Fever in China. African Swine Fever is a virus that impacts pigs (it is not zoonotic) that has a high mortality rate and for which there are currently no vaccines or treatments available.

The U.S. pork industry is concerned about the possibility of an introduction of African Swine Fever in the U.S., which could have catastrophic impacts to that industry if that happens. Based on some research the pork industry has conducted, they believe that animal food could serve as a potential vector for the introduction of foreign animal diseases, such as African Swine Fever.

On September 4, the pork industry sent out some communication to help the industry have conversations with their feed suppliers about these concerns. The communication discusses questions that producers should be asking, such as questions about a facility's biosecurity practices, supplier programs, and other factors that the industry felt could be impactful to the safety of animal food.

I know that representatives of the animal food industry, including NGFA, have been meeting with the pork industry to keep an eye on this emerging situation.

FDA is also in conversation with USDA, the pork industry, and the animal food industry as we evaluate this situation.

There are still a lot of unknowns and gaps in the data, and we want to continue to think through those gaps in a science- and risk-based manner. In the interim, it is always a good idea to evaluate your practices, biosecurity, and supplier review from time to time as an overall effort to continuously improve food safety practices.

FDA's commitment to the industry is that we are willing to facilitate expedited regulatory review with any sponsor submitting a possible mitigation product added to animal food that may help address animal health concerns associated with foreign animal disease transmission.

We want to encourage sponsors to come to us early in the process when data becomes available – come in early and often so that we can think proactively as opposed to reactively.

Thanks to NGFA and others in the feed industry you for your work to date on this matter, and we all know we will need to continue to work together in the future, whether it be for this particular disease or other animal health safety challenges.

Response to Natural Disasters



- We have updated our guidance and our Q&As on the use of crops and other commodities exposed to flood waters
- The updated version is posted on our website
<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm620507.htm>

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FDA is taking a more proactive approach to emergency response, sadly because the Agency has had to respond to many disasters and has learned a lot of lessons in the past few years.

This includes reaching out to our regulatory as well as industry partners to anticipate what type of impact a storm or other disaster will have, and trying to mitigate it or provide guidance on recovery as soon as possible.

Last week staff reached out to NGFA and PFI to see if there was anything we could do in anticipation of Hurricane Florence and to let you know who to contact if necessary.

In addition to the normal emergency response team, a group of senior food leaders at the agency has been organized and is prepared to address questions quickly during the recovery phase.

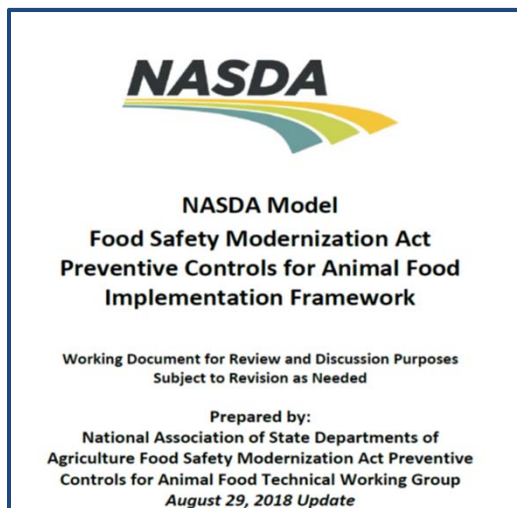
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We are continuing to work on our IT infrastructure to build an inventory and potentially do some modeling of impacts, which I know that you all are doing as well.

As always, we are grateful for your ongoing collaboration and cooperation as we address the myriad of issues before us.

Breaking News

NASDA PCAF Framework



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In my opening slides, I touched on FSMA implementation, and before I close I wanted to circle back to FSMA and the PCAF regulation to share some new information with you all.

FDA has always enjoyed strong partnerships with our state and local partners as part of an Integrated Food Safety System (IFSS).

Within the IFSS, we have an especially strong connection with our state animal food regulators, particularly those in both the Association of American Feed Control Officials (AAFCO) and the National Association of State Departments of Agriculture (NASDA).

One prime example of this partnership is in a document made public for the first time at the NASDA Annual Meeting in Hartford, Connecticut last week – the NASDA Model FSMA Preventive Controls for Animal Food Implementation Framework.

We expect the Framework to be provided electronically today to the broader AAFCO and NASDA memberships and to our industry partners, including NGFA and PFI.

Members of CVM staff and staff in ORA have been working closely with members of NASDA and AAFCO over the past two years to put together this framework that outlines the shared responsibility of animal food safety and provides state agencies with a framework to develop prevention-focused systems based on the FSMA PCAF regulation.

A similar model framework exists for state agencies to implement the FSMA produce safety regulation.

The NASDA Model FSMA Preventive Controls for Animal Food Implementation Framework contains 8 chapters that focus on areas such as the foundation of law, infrastructure, training, outreach, inspection and compliance, and laboratory support – the elements necessary to help state programs modify and update their existing programs to incorporate the principles of prevention that exist in the FSMA animal food regulations.

States historically have conducted approximately 80% of the animal food inspections for FDA, and this framework document builds on that work and other work already done to promote uniformity and consistency, such as work done by AAFCO, the Partnership for Food Protection, and the Animal Feed Regulatory Program Standards (AFRPS).

We will continue to work with our state partners to help them build animal food safety programs, which is of benefit to all of us as we continue to promote and advance public health.



Recognizing the Work of NGFA & PFI

- Commitment to educating the animal food industry
- Working across industry sectors to help promote FSMA implementation
- Promoting a collaborative atmosphere and being true food safety partners

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- I would like to take a moment to thank both of my hosts today – NGFA and PFI – and to recognize some of the great work they are doing on behalf of the animal food industry.
- Both organizations have put a lot of effort into thinking about food safety and preventive practices to support FSMA implementation.
- We recognize that there is still work to be done, but we think that the work done by these two groups to help promote FSMA understanding and preparedness has provided essential ground work to identify your hazards and the appropriate preventive controls.

- Both NGFA and PFI have invested a lot of time and energy into training.
 - My staff has told me that members of both organizations (*including Dave Fairfield, Pat Tovey, and Matt Frederking to name of few*) were instrumental in helping develop the Food Safety Preventive Controls Alliance (FSPCA) course.
- The dialogue that happened throughout the FSPCA was a learning opportunity for everyone and helped to direct that curriculum to something that was useful for and representative of the industry.
- NGFA and PFI, along with AFIA, were also some of the first groups to host an FSPCA course and they continue to help provide courses or trainers to the industry.
- There is always a need for education and training – whether it is because of changes in staff, new regulations, or new technology – and providing a source of training to the industry (from the industry) is always going to be beneficial.

- Back to my core principles:
 - We truly appreciate the collaboration we have had with both NGFA and PFI in recent years.
 - These collaborations have helped give us a greater sense of appreciation for the work that each other does, and I hope I can say that they have been beneficial to both sides.
 - While we may not always agree, we have a relationship that is based in mutual respect and we are willing to listen to each other's concerns.
 - There are a lot of moving parts to implementing new regulations – and we know we have to continue to work together if we both want to be successful and achieve that shared goal of safe animal food.



How NGFA & PFI Can Help FDA-CVM

- Continuing collaboration
- Sharing data on emerging hazards
- Providing input to guidance documents
- Engaging legislators and appropriators

- In the spirit of collaboration, we can use your help with a few things.
- The first three are somewhat self-explanatory and I have touched on those throughout this presentation.
- One area that you are in a unique position to assist us with is talking to legislators and appropriators at all levels.

- FSMA implementation presents a resource concern for both FDA and the state agencies. For us to be able to support FSMA implementation, including developing additional guidance and tools to help industry, there is a need for additional resources.
- The NASDA PCAF Framework I mentioned – for that to be able to be successful and to help states build these prevention-oriented systems, they are going to need sustained resources.
- While FDA has made significant investments in the states over the years with appropriated funds, additional investments will have to be made to shift programs from the current regulatory approach to a more holistic, prevention-oriented system.



Summary

- Food safety should be everyone's priority
- A safe food supply requires cooperation
 - Ingredient Suppliers
 - Animal Food Manufacturers
 - Animal Food Regulators
 - Consumers

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Reference the CVM Website for the most current information

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Thank you!

