

Aquaculture Drug Workshop  
June 9, 2016

# CVM Update

***Did You Know?***

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# Leadership changes

- New FDA Commissioner:  
Robert M. Califf, MD



- New Deputy Commissioner for Foods and Veterinary Medicine: Stephen Ostroff, MD
- Search for next CVM Center Director
  - Bernadette Dunham, DVM, PhD, now at Milken Institute School of Public Health at George Washington University involved in a One Health Initiative

# ONADE organizational changes

- Existing review support teams in the **new** Division of Business Information Science and Management (HFV-180):
  - Business Informatics Team (HFV-182)
  - Quality Assurance Team (HFV-184)
  - Project Management Team (HFV-186)
  - Records and Information Management Team (HFV-188)
- Existing pharmacology reviewers into the **new** Clinical Pharmacology Team (HFV-166) in the Division of Scientific Support

***Did You Know?***

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# Animal Drug User Fee Act (ADUFA)

# Animal Generic Drug User Fee Act (AGDUFA)

- Timely review of applications so more new animal drugs are available to the public.
- CVM met or exceeded almost all of performance goals in 11 years of ADUFA and 5 years of AGDUFA.
- Preparing for the next re-authorization of the user fee programs in 2018.

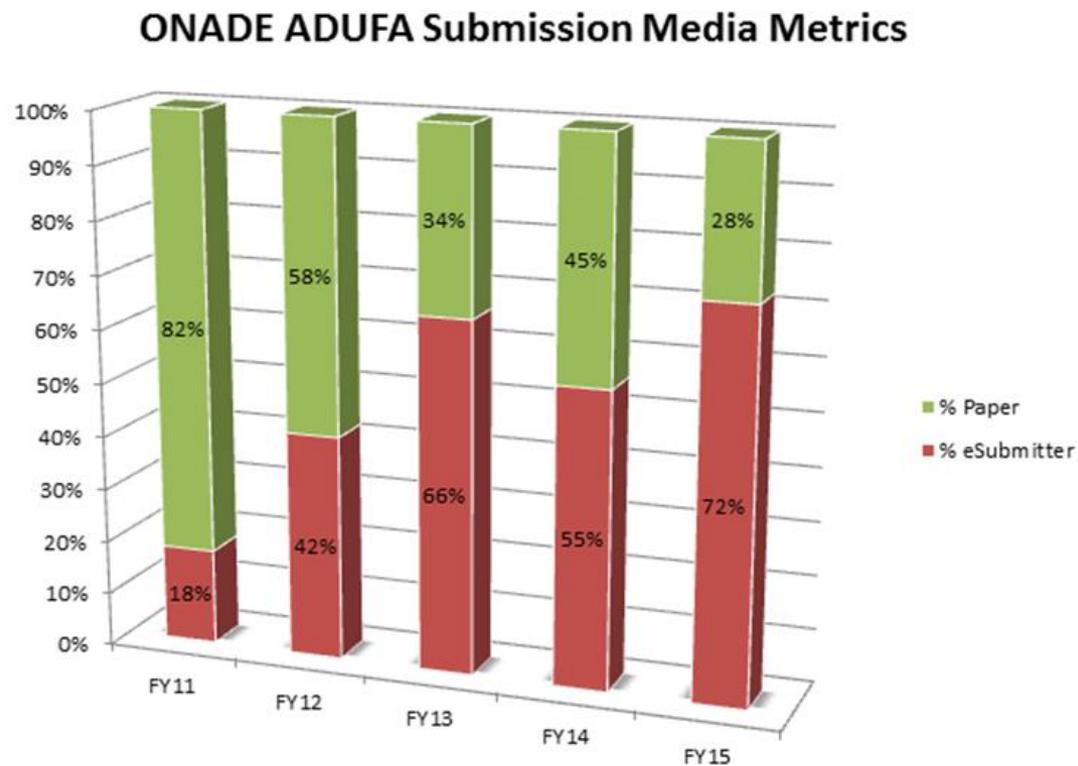


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# Electronic submissions

- Since the release of the CVM eSubmitter tool in FY 2011, ONADE now receives 72% of its ADUFA submissions electronically.
- While there is some up-front time investment to get set up, it makes the applicant eligible for shorter review time for certain resubmissions.



*Do you remember the  
CVM presentations from  
last year?*

# Submission and data quality review

- For CVM to agree that an animal drug is safe and effective, the submissions, study reports, and data provided must be credible. Credibility relies on the submissions, study reports, and data being of high quality.
- While CVM has always evaluated submission and data quality, ONADE has implemented new processes to evaluate these in the submissions we receive.
- Primary Goals
  - Identify and resolve deficient submissions early
  - Develop consistency across ONADE on both submission and data quality assessments
  - More high quality submissions mean fewer amendments and shorter time to approval.

# INAD projects

- Letter sent to aquaculture drug INAD holders in January 2015, followed by calls with INAD holders
- ~100 INADs, ~ 75 projects (each indication for a drug seen as a separate project), same research partners and companies involved in a number of projects
- Aim: facilitate coordination of efforts
  - Improve communication
  - Identify gaps, especially for projects that are close to completion, and how they will be addressed
  - Understand prioritization of projects

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# Significant approval

- FDA approved, for the first time, a genetically engineered animal intended for food, AquAdvantage Salmon
  - Information on approval available on CVM website
  - The Fiscal Year (FY) 2016 Omnibus Appropriations Act prohibits the distribution of genetically engineered salmon into commerce until FDA publishes final labeling guidelines

# Import tolerance granted

- Import tolerance granted for azamethiphos for salmonids
- Import tolerance also previously granted for teflubenzuron for Atlantic salmon

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# Drug shortages

- CVM has been working with the drug companies to alleviate recent aquaculture drug shortages.

# Medically Necessary Veterinary Product (MNVP)

- Used to treat or prevent a serious animal disease or condition, or
- Is needed to assure the availability of safe food products of animal origin, and
- No other available source of that product or adequate alternative drug substitute exists.
- Owner inconvenience and non-therapeutic uses are not reasons for classifying a product as an MNVP.

# CVM's role during animal drug shortage

- Review all animal drug shortage reports to determine if a shortage truly exists.
- Determine if the shortage involves a Medically Necessary Veterinary Product (MNVP).
- Create an action plan to prevent or alleviate an animal drug shortage. The action plan may include:
  - Holding discussions with drug manufacturers and others in the animal health industry,
  - Exercising enforcement discretion (certain situations when the FDA decides not to strictly enforce approval requirements found in the Federal Food, Drug, and Cosmetic Act).

# Example causes of drug shortages

- Unavailable raw materials
- Unavailable packaging materials
- Marketing decisions by manufacturers
- FDA enforcement issues

*Do You Know  
What's Happening  
January 1, 2017??*

# Products transitioning to Rx or VFD

## Rx (prescription)

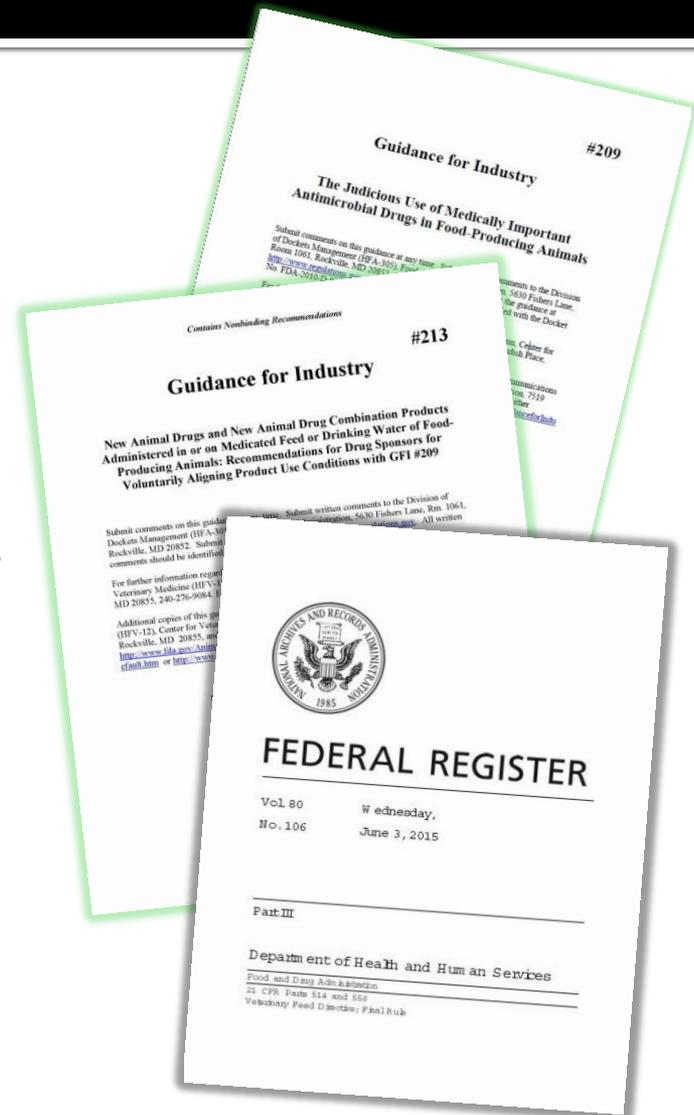
- Immersion oxytetracycline hydrochloride
  - OXYMARINE
  - OXYTETRACYCLINE HCl SOLUBLE POWDER-343
  - PENNOX-343
  - TERRAMYCIN 343
  - TETROXY AQUATIC

## VFD (Veterinary Feed Directive)

- Sulfadimethoxine/ormetoprim (ROMET 30/ROMET TC)
- Oxytetracycline dihydrate (TERRAMYCIN 200 for Fish)
- Sulfamerazine (SULFAMERAZINE In FISH GRADE)

# Background

- Guidance for Industry 209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals
- Guidance for Industry 213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209
- Veterinary Feed Directive regulations revised in final rule published June 3, 2015



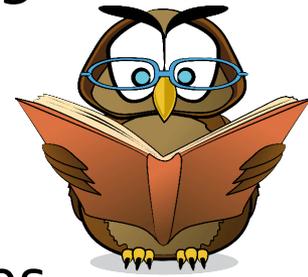
# Outreach

- Aquaculture 2016 presentation
- Western Fish Disease Workshop
- Panel discussion tomorrow
- Professional associations and pharmaceutical companies are also doing outreach



# Action Items for You

- Familiarize yourself with what's changing & devise a plan before January 1, 2017
  - Take advantage of information on CVM webpage or presentations at conferences or via webinar
  - Talk with your veterinarian (establish a relationship with one if you have not already!), the drug company or distributor representatives, and feed mill
- Stay tuned for additional information from CVM, drug companies, professional associations



***Did You Know?***

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# CVM attendees at workshop

## Office of New Animal Drug Evaluation

- Jennifer King, Project Manager
- Jennifer Matysczak, Aquaculture Drugs Team
- Eric Landis, Aquaculture Drugs Team
- Sarah Bembe, Aquaculture Drugs Team
- James Nitao, Division of Manufacturing Technologies
- Kimon Kanelakis, Toxicology Team
- Clint Mitchell, Residue Chemistry Team
- Kristen Beckhorn, Environmental Safety Team

## Office of Minor Use and Minor Species

- Meg Oeller, Director

## Office of Research

- Cindy Stine, Aquaculture Drugs Team

# Thank you!

Questions?

