Challenges – A Year in the Making

FDA/CVM
ONADE & OMUMS
2020

U.S. FOOD & DRUG ADMINISTRATION

Center for Veterinary Medicine

Protecting Human and Animal Health

Who are we?

Matt Lucia

Director,

Office of New Animal Drug Evaluation (ONADE)

Meg Oeller

Director,

Office of Minor Use & Minor Species Animal Drug Development (OMUMS)

A little background

Just to refresh your memory about what our Offices do

FDA CVM Responsibilities

ONADE

- Investigational New Animal Drugs (INADs)
- Conditional Approval
- Drug Approval

OMUMS

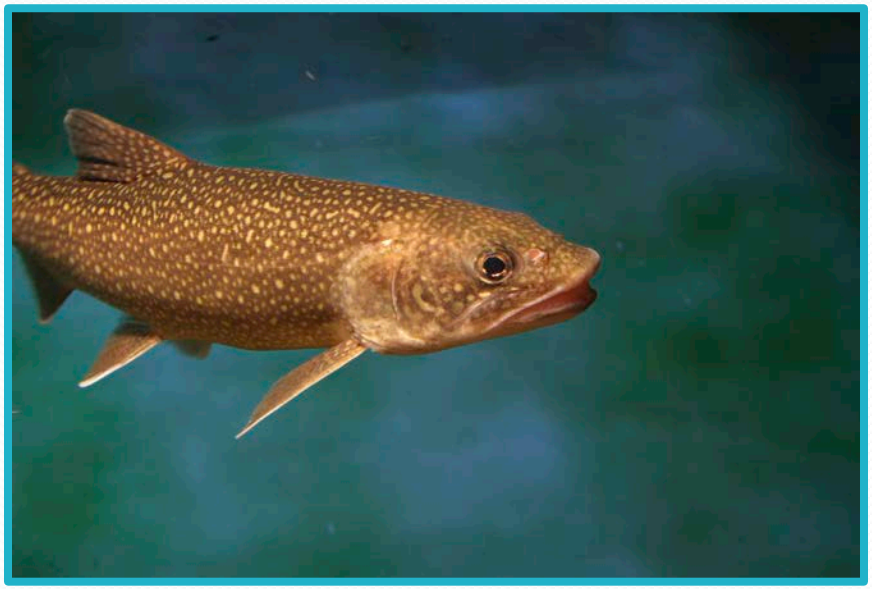
- Incentives
  - User Fee Waivers
  - Designation
- Indexing
- Minor Use Animal Drug Program (USDA)

What we heard from you last year

- **There are problems with drug approval:**
  - **It is expensive**
  - **It takes too long**
  - **Once the drug *is* approved, companies raise the price**
- **Species grouping needs to be better defined**
- **More things (brood stock, baitfish) should qualify for indexing**

Since then…?

ONADE



- Division Director Selections
- Processes related to Approval
- Other Noteworthy GFI Publications
- Aquaculture Strategic Plan
- “Quarterly” Communication

Division Director Selections

- **Dr. Crystal Groesbeck selected as the Director, Division of Therapeutic Drugs for Food Animals**

- **Ms. Laura Stets selected as the Director, Division of Scientific Support**

Processes Related to Approval

- Four draft GFIs published on July 15th that incorporate alternative approaches in clinical investigations for new animal drugs
  - Public meeting held in July 2019
- CMC (manufacturing)
  - FDA vs. EPA requirements

Processes Related to Approval continued

- Discussions related to INAD Database
  - Supporting approval of AQ drugs
- ONADE working with OMUMS on Indexing

Other Noteworthy GFI Publications

- **Draft GFI #262 – Pre-submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices**
- **Revised Draft GFI #256 – Compounding Animal Drugs from Bulk Drug Substances**

Aquaculture Strategic Plan

- Developing an AQ Strategic Plan to highlight and prioritize CVM's AQ activities
- Still in early development
- Cross-Center involvement (ONADE, OSC, OR)

Aquaculture Strategic Plan continued

- Topics being discussed for possible inclusion:
  - Priority AQ drugs
  - Collaboration with external partners for gathering of data to further AQ drug approvals
  - Additional discussions on topics like model species and species grouping

“Quarterly” Communication

- Started at last year’s AADAP conference with meeting between CVM and Stakeholders
  - Discussed challenges to approval process and stakeholder priorities
- Virtual stakeholder meeting in December 2019 between CVM and ADAC

"Quarterly" Communication continued

- 2nd Meeting yesterday on July 27 at ADAC meeting
- Would like to continue to discuss how to build these meetings so that they work for all involved.
  - Frequency of occurrence
  - Agenda driven and solution based

OMUMS

- Designation of MUMS drugs
- Administer grants for Designated projects
- Indexing
- Conditional Approval (eligibility)
- Minor Use determinations (User fee waivers)
- Liaison to other government programs (USDA MUADP)
- Stakeholder outreach

Designated Drugs for Aquaculture

- Of 154 designated drugs – 99 are for aquaculture
- Over 3 million dollars in grants for studies

- Conditional approval for Aquaflor (2007) for columnaris in catfish - led to full approval (2012)
- 14 designated aquaculture drug claims approved

MUADP Status

Projects:

- **Erythromycin for Bacterial Kidney Disease in freshwater reared salmonids has had some delays, but the MUADP is still actively completing requirements**
- **SrCl for skeletal marking of Pacific salmon fry still in progress**

- **Working with research partners and USDA to completely redesign program and secure stable funding**

Status of Guidance For Industry #61

NOT!

Rejoice!

Draft GFI #61 Published

- Published on July 15
- Comment period closes November 12

- **PLEASE SEND US YOUR THOUGHTS**

- What is different?
- How is it organized?

What's in it?

- This draft replaces GFI #61 that was published in 1999
- Contains information about MUMS incentive programs – mainly from the Minor Use & Minor Species Animal Health Act of 2004 (MUMS Act)
- Includes information about the FDA approval process in general, and how it applies to MUMS products - including any special considerations (especially for aquaculture)

Organization of GFI #61

The 1999 version –

FDA Approval of New Animal Drugs for Minor Uses and for Minor Species –

5 main sections –

- **Minor use in a major species**
- **avian**
- **ruminants**
- **rabbits**
- **aquatic species**

A lot of redundant information

The 2020 Draft –

Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species

- **Now unified**
- **Chronological**
- **Describes all MUMS incentives *and* the drug approval process**

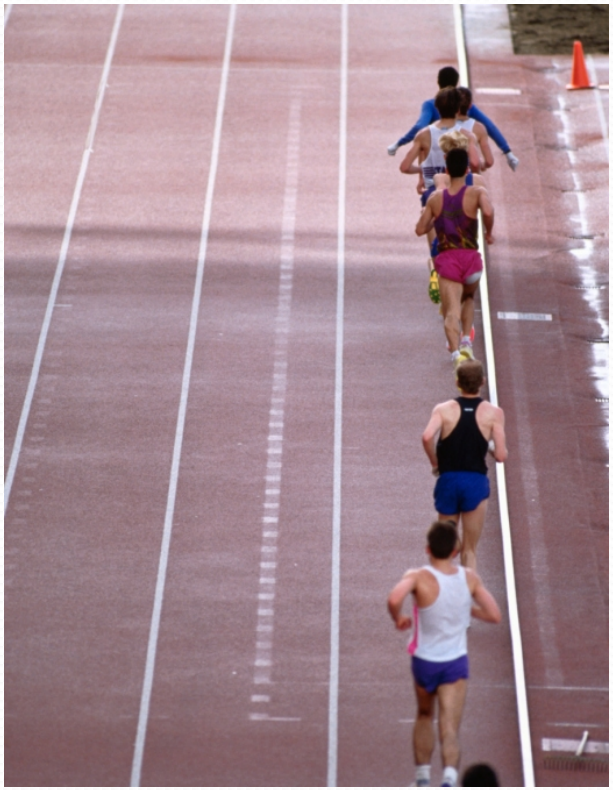
Sections about MUMS Incentives

- **III – The MUMS Act**
- **IV – Early considerations**
- **V – User Fees & Minor Use Determinations**
- **IX – MUMS Designation**
- **XXI – Other Incentives – Short descriptions of: Conditional Approval, the Index of Legally-marketed Unapproved New Animal Drugs for Minor Species, and the Office of MUMS**

Plea

- **Links to the document and to our descriptive presentations can be found at: https://www.fda.gov/animal-veterinary/cvm-updates/fda-issues-revised-draft-guidance-assist-sponsors-animal-drugs-minor-uses-and-minor-species**
- **Please send comments and questions to help us make this the best and most helpful guidance possible**
- **Directions for electronic and for written comments are in the announcement**

Where do we stand now?



We can do it!

What do we need from you?

Tell us your needs for new drugs

- Need to work with manufacturers
- Possibly can coordinate with other countries

Educate us about your industries –

- Lectures about the economics of the industry
- Survey re: broodstock
- Contacts with baitfish industry

What else should we know?

ONADE Info/contacts…

Aquaculture Project Manager:

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ONADE Director: matthew.lucia@fda.hhs.gov

Division of Therapeutic Drugs for food Animals:

Director: crystal.groesbeck@fda.hhs.gov

AQ Team Leader: jennifer.matysczak@fda.hhs.gov

OMUMS Info/contacts…

https://www.fda.gov/animal-veterinary/development-approval-process/minor-useminor-species

OMUMS Director: margaret.oeller@fda.hhs.gov

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Designation/grants: stuart.jeffrey@fda.hhs.gov

MUADP: amy.omer@fda.hhs.gov

Questions?