

Update from the Office of Minor Use and Minor Species

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Aquaculture Drug Approval Coordination Workshop
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U.S. Food and Drug Administration

CENTER FOR VETERINARY MEDICINE



Today's Topics

- * **OMUMS Updates**
 - * **Status of OMUMS Programs**
 - * **Specific Update on MUMS Grants**
 - * **Current events**



NRSP-7



- * National Research Support Project # 7 (www.nrsp7.org)
- * USDA program to facilitate approvals for minor species/minor uses of agricultural importance (*all fish are minor species*)
- * Dr. Amy Omer – FDA Liaison to the program
amy.omer@fda.hhs.gov (240) 402-0564

NRSP-7 Process in a Nutshell

- * **Partnership with 4 University researchers**
- * **Generally work on 4 technical sections:**
 - * Target Animal Safety
 - * Effectiveness
 - * Human Food Safety
 - * Environmental Impact
- * **Data placed in Public Master File (PMF)**
- * **Pharmaceutical company files New Animal Drug Application (NADA) using NRSP-7 PMF by reference**

Current NRSP-7 Stats

- * 29 Approvals to date
- * 7 Active projects

Active projects for pheasants (2), quail, goats, salmon (2), cattle (minor use)



NRSP-7 Fish Project

Erythromycin

Type A medicated article

For the control of mortality due to bacterial kidney disease associated with *Renibacterium salmoninarum* in freshwater-reared Chinook salmon

Project Status

Erythromycin Type A medicated article

Technical Section	Status
Target Animal Safety	COMPLETE
Human Food Safety	COMPLETE
Effectiveness	COMPLETE
Environmental Impact	Final version to be submitted this summer

NRSP-7 Fish Project

Strontium Chloride Immersion

For the skeletal marking of Pacific salmon fry in freshwater



Project Status

Strontium Chloride Immersion

Technical Section	Status
Target Animal Safety	Report to be submitted this fall
Human Food Safety	White paper planned
Effectiveness	Alaska data to be compiled
Environmental Impact	To be submitted this year

NRSP-7 Funding Crisis



- * **Project not renewed by USDA for fiscal year 2017 - Funding ends 9/30/2016**
- * **Planning committee being formed to re-establish the program**
- * **Stakeholders lobbying USDA and Congress**
- * **Meanwhile, will write up studies and apply for other funding, e.g., MUMS grants**

Indexing



The Index of Legally-marketed Unapproved New Animal Drugs for Minor Species

- * An alternative to the approval process
- * Non-food minor species only
- * Dr. Dorothy Bailey manages this program.
dorothy.bailey@fda.hhs.gov (240) 402-0565

Indexing Status



- * **A relatively new program (first listing 2009)**
- * **A total of 11 products on the Index**
- * **2 for ornamental fish:**
 - * **sGnRHa + domperidone (Ovaprim) injection for spawning ornamental fish broodstock**
 - * **Metomidate (Aquacalm) immersion for sedation and anesthesia of ornamental fish**
- * **Moving to electronic submissions**

Designation

- * The “orphan drug” program for veterinary drugs
- * Incentives to industry:
 - * Eligibility to apply for grants
 - * 7 years exclusive marketing rights
- * Dr. Stuart Jeffrey manages this program
stuart.jeffrey@fda.hhs.gov (240) 402-0568



Designation Stats for Aquaculture Projects

- * 91 of 137 projects (claims) on the list
- * 14 of the 20 approved
- * 1 of the 4 conditional approvals
- * 25 of the 34 terminated
- * 52 of the 80 currently active projects
- * 16 different drugs and 13 sponsors



MUMS Grants

To be eligible:

**The product must be “designated”
through CVM/OMUMS**

AND

**The study protocol must have been
reviewed and accepted by CVM/ONADE
prior to application**



MUMS Grants

- * The sponsor must get the designation
- * Research partners must be identified in the sponsor's investigational file (INAD)
- * Identified research partners can apply for MUMS grants *directly*



Grants Statistics

- * **OMUMS has been awarding grant money since FY2009**
- * **A total of 51 grants/interagency agreements have been awarded**
- * **Of these, 43 have been for aquaculture studies**
- * **These 43 studies represent \$2,207,952 dollars**
- * **We anticipate having at least \$500,000 to award in FY2017**

Update on MUMS Grants

In addition to studies intended to *directly* establish target animal safety or effectiveness, some manufacturing studies are eligible for funding, provided a protocol has been accepted by CVM/ONADE

These may include studies to demonstrate stability, homogeneity, segregation, and validation of analytic methods

MUMS Grants

Upcoming open application periods:

6/17/2016 to 8/12/2016 (FY17 part 1)

11/18/2016 to 1/13/2017 (FY17 part 2)

6/16/2017 to 8/11/2017 (FY 18 part 1)

11/17/2017 to 1/12/2018 (FY 18 part 2)

For more info on MUMS Grants:

Request for Applications (RFA)
announcements: Go to
<http://www.grants.gov> and search for the
keyword “MUMS” in the “Grant
Opportunities” search box at the top
(Call Stuart Jeffrey for help)

Guidance for Industry 61

61



Guidance for Industry FDA Approval of New Animal Drugs for Minor Uses and for Minor Species

(This version of the guidance replaces the version that was made available on April 15, 1999. This document has been revised to update the contact information, Part 1- Section XI (Other Guides), and minor formatting changes).

This Guidance Document supersedes GUIDELINE 26, "Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Minor Use of Animal Drugs."

For questions regarding this document, contact Meg Oeller, Center for Veterinary Medicine, Food and Drug Administration, Office of Minor Use and Minor Species Animal Drug Development, HFV-50, 7500 Standish Place, Rockville, MD 20855, 240-276-9005, email: margaret.oeller@fda.hhs.gov.

Additional or updated copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, 7519 Standish Place, Rockville, MD 20855 and may be viewed on the internet at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine

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Revised Guidance 61

- * **Delayed again - Sorry**
- * **Completely revamped to describe programs and incentives established by the MUMS Act of 2004**
- * **Describes special considerations and programs that aim to support the approval of drugs for minor uses and minor species**

Revised Guidance 61 Covers:

- * **User Fee Waivers**
- * **Minor Use Determinations**
- * **Designation**
- * **Special considerations for Aquaculture product development**
- * **Conditional approval**
- * **Indexing – stand-alone guidance – to be published any minute**

Any questions?



Thank You!

Contact:

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