U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE
OFFICE OF MINOR USE AND MINOR SPECIES

2020 Aquaculture Drug Approval Coordination Workshop

UPDATES ON THE INDEXING PROGRAM

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Topics to Cover

- Overview of the Indexing process
- Current status of the program
- Explanation of eligibility for Indexing
- The future of the program
- Discussion of the broodstock survey

What is Indexing?

- Alternative to the approval process
- Provides legal marketing status, not an approval
- Three-step process
  - Determination of Eligibility
  - Outside Expert Panel
  - Addition to the Index

Once a Drug is Added the Index

- Post-Market Requirements
  - Report Adverse Drug Events
  - Annual Drug Experience Report
- Can promote and advertise in accordance with the Index listing
- If the same drug, in the same dosage form, for the same intended use is approved, the Index listing must be terminated

Current Status

- There are currently 14 drugs on the Index
  - 11 drugs indicated for terrestrial/avian species
  - 2 drugs indicated for ornamental fish
  - 1 drug indicated for terrestrial, avian, and aquatic species
- More drugs in the pipeline, but there is room for growth
- Majority of drugs currently on the Index or in process are for terrestrial animals (laboratory and zoo animals)

Eligibility for Indexing

- The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) states that the Index is limited to:

"(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and (B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) (including, for an anti-microbial new animal drug, with respect to antimicrobial resistance)."

Eligibility for Indexing (cont'd)

- When first implementing the Indexing process, a conservative approach was taken when interpreting the MUMS Act:
  - There cannot be a "reasonable certainty" if a drug is intended for use in any member of a food-producing minor species
  - This interpretation is based on longstanding CVM policy that considers an animal to be food-producing if *any* member of that species is raised to be food for humans

The Future of Indexing

- Reconsidering eligibility requirements based on interpretation of a “reasonable certainty” that an animal will not be consumed by humans
- CVM/OMUMS wants to be flexible and increase drug availability to underserved populations of animals
- OMUMS recently hired two new members


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