FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

Update on Indexing

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2022 Aquaculture Drug Approval Coordination Workshop

Agenda

- Overview of the indexing process
- Eligibility for indexing
- Reconsideration of eligibility policy
- How we are moving forward

What is Indexing?

When a Drug is Indexed

- 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 removed

Eligibility for Indexing

"(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"

"(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)."

Reasonable Certainty

Primary eligibility standard

Original interpretation: there cannot be a *reasonable certainty* if a drug is intended for use in a member of a food-producing minor species

Based on longstanding CVM policy used for drug approvals that considers an animal to be food-producing if <u>any</u> member of that species is raised to be food for humans

Non-food Early Life Stages

Exception to the *reasonable certainty* standard to address certain aquaculture species

Human Food Safety must be addressed because these animals will enter the human food supply

The early life stage must be non-food (that stage of the animal is not consumed) and must be contained in a manmade structure

Feedback and Reconsideration

Received feedback from several stakeholder groups (aquaculture, research, drug companies)

Based on this feedback we asked CVM leadership to let us re-examine our interpretation of MUMS Act

Met with CVM regulatory counsel – no statutory change required

Federal Register Notice for Public Comment

- Published: June 24, 2021
- Closed: September 22, 2021

  - *What are the reasons we **should or should not** expand eligibility for indexing to certain discrete subsets of food-producing minor species?*
  - *If you support the expansion of indexing, please describe the **information we should evaluate when determining** which discrete subsets of food-producing minor species should be eligible.*
  - *Are there **any discrete subsets of food-producing minor species** that you believe should be eligible for indexing because they are not intended for consumption by humans or food-producing animals?*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2462]

Eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Request for Comments

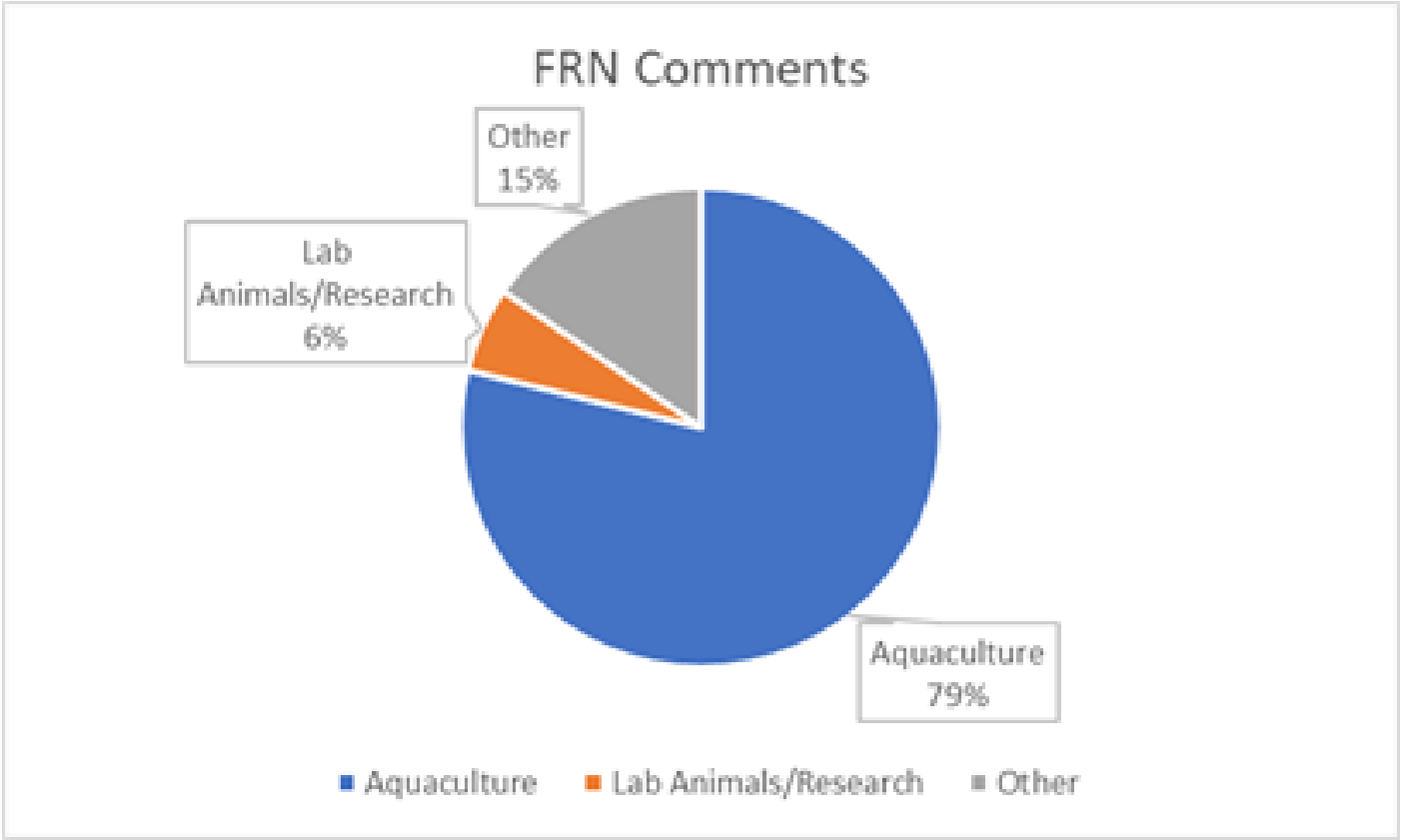
AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is soliciting comments on our current policy on eligibility for indexing. Indexing is the process of adding an unapproved drug for a minor species to our index of legally marketed unapproved new animal drugs for minor species (the Index). Except for in some early non-food life stages, members of a food-producing minor species are not eligible for indexing, even if a subset of animals within a food-producing minor species is not intended to be consumed by humans or food-producing animals. Specifically, we are requesting comment on this policy.

Overview of Comments

- Total of 52 comments
- Three major categories:
  - Laboratory animals
  - Aquaculture
  - "Other" (e.g., veterinary associations, individuals)



What We Learned

- Vast majority of comments *support* expansion of eligibility for indexing
- Many commentors also mentioned:
  - Non-food early life stages
  - Endangered species
  - Definition of ornamental fish
  - Animals used in research

FDA Withdraws Guidance on Indexing of Legally Marketed Unapproved New Animal Drugs for Minor Species

Content current as of:
07/25/2022

July 25, 2022

The U.S. Food and Drug Administration has withdrawn guidance for industry (GFI) #210, "The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species," in order to revise it in accordance with a statutory change to the wording of required label statements and because the guidance no longer represents the agency's current thinking. The FDA plans to issue a revised draft guidance as expeditiously as possible.

The FDA published final GFI #210 in April 2018, which included guidance on a statutory requirement at the time to label products on the Index with the statement "Not Approved by FDA." With the recent statutory change, this statement has been modified for products that are part of the Index.

Additionally, the FDA received feedback regarding guidance #210 in response to a Request for Information in June 2021 asking for stakeholder feedback on expanding eligibility for Indexing for certain groups of animals from food-producing species when there is reasonable certainty that those animals would not enter the food supply.

The vast majority of comments received in response support the contention that there is a "reasonable certainty" that certain subsets of minor species generally considered to be food-producing animals will not be used as food for humans or food-producing animals, including laboratory rabbits and broodstock fish. As we consider these comments, we encourage potential requestors for Indexing to consult GFI #201, "Small Entities Compliance Guide for Index of Legally Marketed Unapproved New Animal Drugs for Minor Species," and consult with the agency's Office of Minor Use & Minor Species (OMUMS). OMUMS will determine the eligibility of a drug for Indexing on a case-by-case basis.

Issued by FDA Center for Veterinary Medicine.
For questions, Contact CVM.

How We Are Responding

- Updating Guidance for Industry #210 – labeling statements and eligibility
- Provide clarity on non-food early life stages and the definition of ornamental fish
- Explore options for endangered species
- Determine if other animals used in research may be eligible for indexing

In the Meantime

We will make case-by-case determinations on eligibility for indexing (reasonable certainty and non-food early life stages)

Please contact us with any questions:

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