

NATIONAL
Aquaculture
ASSOCIATION

December 18, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

FAX 301-827-6870

RE: Docket No. 2006N-0067; RIN number 0910-AF67

Dear FDA-CVM:

The following comments on the proposed regulations to implement section 572 (Index of legally marketed unapproved new animal drugs for minor species) of the Minor Use and Minor Species Animal Health Act of 2004 are submitted by the National Aquaculture Association (NAA). The NAA is a national aquaculture trade association whose membership includes a diversity of farm raised aquatic animal species interests, state aquaculture associations and the US Aquaculture Suppliers Association. We want to thank FDA-CVM for their continued assistance as we search for ways to increase the domestic availability of safe and efficacious aquatic animal therapeutic agents.

The proposed regulations appear consistent with the intent and language of the MUMS Act. The proposed regulations provide sufficient guide to index requesters seeking to determine whether a drug or use is eligible for the drug index and what criteria the qualified expert panel should be selected on. The proposed rule also establishes what the qualified expert panel should do.

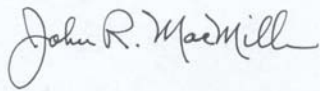
The NAA supports the rules as written. Species of fish raised and their production practices are diverse. It is consequently imperative that FDA-CVM maintain considerable flexibility relative to drug index eligibility requirements. We encourage the FDA to maintain the flexibility as currently proposed to allow requestors opportunity to support their petition for drug index listing. This is particularly important for non-food early life stages of aquatic food animals. We believe it is incumbent on the requestor to provide sufficient "reasonable certainty" that such an animal life stage would not be used for human or animal consumption. It is our view that requests must be considered case-by-case. We support additional efforts to provide both the requestor and FDA flexibility in meeting index eligibility requirements.

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The make-up of the expert panel must also be flexible. We do not know what types of expertise will be needed to successfully answer germane questions of target animal safety and drug efficacy. Citation of credible literature may be all that is required. We believe expert panel fee schedules should be determined between the requestor and consultant. Potential conflict-of-interest issues are legitimately addressed in the proposed rule. We request opportunity to appeal rejection of a qualified expert be maintained. While the expert panel is specifically charged with providing a report on target animal safety and drug efficacy, we suggest the expert panel report might also contain recommendations relative to environmental safety and other germane items. Such additional findings, if provided, should not be automatically discounted by FDA-CVM but may provide supplemental information of value.

The NAA appreciates opportunity to provide comment and hopes these rules will encourage development of safe and effective therapeutic agents for farm raised aquatic animals.

Sincerely,

A handwritten signature in cursive script that reads "John R. MacMillan". The signature is written in black ink on a light blue rectangular background.

John R. MacMillan, Ph.D.
President