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Comments by the California Aquaculture Association (CAA) on the Draft "Proposals to increase the availability of approved animal drugs for minor species and minor uses"

The California Aquaculture Association (CAA) wishes to thank CVM and FDA for the opportunity to comment on the abovereferenced draft proposals.

The California aquaculture industry comprises over 200 registered growers of finfish, shellfish and plants with a farm gate value in excess of \$70 million. The issue in point is of significant interest and importance to many of the growers, and we offer a number of general comments on the proposals as well as specific responses to the questions posed in the proposals.

First, CAA applauds FDA for taking this first step to address what has become a major impediment to the expansion of aquaculture in California and the US -- the excessive, costly and inequitable regulation of animal drug approval for aquaculture species. We commit to work with CVM and FDA to create new effective and efficient regulations that safeguard both public health and the environment while providing growers with the tools they need to combat the diseases that can cripple their operations.

Second, we urge the FDA to always be mindful of the relative risks under discussion with these minor drug applications compared with many of the other applications in horticulture or other major agriculture species.

Third, the relationship of these proposals to other federal and State regulatory programs needs to be kept in mind.

Four, we do not need to create one large bureaucracy in order to "streamline" another. Given the

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opportunity and responsibility to do so, our industry will respond to the call for safe and responsible use of animal drugs. There is no need to overregulate this program.

Specifically, we have the following responses to your questions by section.

A. Extra label use should be more strictly limited - not absolutely sunsetted - with these proposed modifications. Under certain circumstances there may be a well-founded need for some application of extra label use. Reproductive hormones and implants should also be afforded the same regulatory relief.

B. We have some concern over the possible creation of a monopolistic marketplace if enforcement is too pervasive. Focus of energies and resources needs to be placed on assisting the industry accomplish our mutual goals -- growing a marketable product at the lowest possible cost with no, or the least possible impact on public health and the environment.

C. Industry is likely to politically support a program that works for them. A key to receiving adequate federal funding is communication with the industry. CVM/FDA needs to continue with the outreach to all minor animal groups to solicit support for additional research dollars. We are supportive of the work being done by NRSP7 and would support a database that would assist both industry and the regulators.

D. Exclusivity assurances may be counterproductive if they result in monopolies that force prices too high and in turn, may force growers to seek alternatives to the permitted drug.

E. Sharing of data is likely to facilitate the gathering of needed data -- and thus facilitate and expedite approvals. Liabilities can be limited through indemnifications.

F. A statutory designation for minor use drugs may be useful provided current process is not replaced with a different, but equally cumbersome one.

G. These proposed restrictions may still be overly restrictive. Our industry would need to consider the need for sunseting the non-food drug approval after 5 years, for example. Our general approach would be to grant approval with a proviso that the regulating agency could review the approval for cause.

H. This is a creative solution, but need not exclude the possibility of genetics. Industry expertise is available, but funding is limited. The very need for this new approach is driven by the fact that these growers need assistance. The proposed process does certainly appear to be sufficiently restrictive.

I. International harmonization is essential, especially in the export/import commodities. NGO consultants could perform the calibration needed if data is shared. FDA needs to be especially careful not to jeopardize US producers by asserting its standards at home while other governments tolerate more lax standards for their producers -- and exporters into the US!

Differentiating between minor and major species will help to keep public health and

environmental health risks in perspective and should provide a rationale for a lower level of regulation for the minor uses and species.

Thank you for considering these comments. Please feel free to email Justin Malan, Executive Director CAA at jgmalan@aol.com or call him at (916) 944-7315 if you have any questions regarding these comments. The California Aquaculture Association address for this matter is 3700 Chaney Court, Carmichael, CA 95608.