United States Department of the Interior

FISH AND WILDLIFE SERVICE
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August 29, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

9030 '97 SEP -8 P1:36

Dear Sirs,

The following are my comments on the "Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses" as was requested in the Federal Register on June 23, 1997 (Volume 62, Number 120). I am a veterinarian with the U. S. Fish and Wildlife Service and a large part of my job involves the Natural Resource Enhancement, Protection, and Restoration of Pacific salmon. We have been trying to work through the INAD process for a few drugs, but, progress toward New Animal Drug Approvals has been very slow and the current regulations have made it even more difficult to effectively treat some of the disease processes we encounter in our fish. Any changes that can be made to streamline the Drug Approval process and decrease the time required to obtain a label will be very beneficial to our fish production objectives.

Comments on **Section B. Creating Additional Statutory Authority**

A conditional approval with post-market surveillance will be beneficial to accelerate the approval process from the perspective of the end users. Currently the fish producers are involved in drug efficacy trials early in the INAD process and that information is used to proceed with the target animal safety, residue depletion, and withdrawal times studies that are done in research facilities. Therefore, the producers do not realize any benefit from participating in these studies until the entire NADA package is submitted and approved by FDA, often several years. If a conditional label could be obtained that had an extended withdrawal time and a limited time for completion of the NADA package, the producers would realize a benefit much more rapidly and be more willing to participate in the process to provide high quality data.

The review of foreign data should be considered by FDA, and, if the information and procedures used are adequate to provide good scientific information, accepted by FDA as a part of the NADA package.

Comments on **Section C. Administrative and Regulatory Changes**

Clear guidelines of the information needed for an approval and the standards by which that information needs to be generated are essential for a smooth and rapid approval process. Rapid comment on packages submitted to FDA-CVM, i.e. 30-60 days, will also help the sponsors collect and organize the necessary data more efficiently.

The development of new residue detection methods should not be required for the extension of a new animal drug label to include a minor species or a minor use. This method development takes time and money that the sponsors are generally not willing to invest for a small market.

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Comments on **Section E. Extending Existing Legal Authority**

Legislation to extend the AMDUCA to permit extralabel use of both "off the shelf" and top coated medicated feed will improve the veterinarian's ability to respond effectively to bacterial infections in minor food animal species. The small number of antimicrobial agents currently available in many minor species promote the use of a single drug for the same disease multiple times which can lead to drug resistance in the bacterial agent. An arbitrarily extended withdrawal time, such as 6-12 months, should protect the human food supply, allow treatment of diseases in early life stages of animal production, and encourage sponsors and end users to pursue a label approval with a shorter withdrawal time based on scientific evidence.

Thank you for your consideration of my comments.

Sincerely,

Joy Evered, DVM

Joy Evered, DVM
Veterinary Medical Officer

UNITED STATES
DEPARTMENT OF THE INTERIOR
FISH AND WILDLIFE SERVICE

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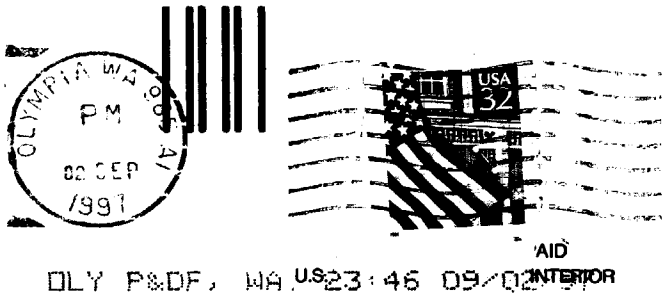
OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

115 ADAA Comments



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