



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2008

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U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Temperature classification system for species grouping

Dear Dr. Erdahl:

We provide the following discussion regarding definitions of "coldwater", "coolwater", and "warmwater" as used to categorize species of freshwater-reared finfish and the temperature grouping scheme which you proposed in correspondence dated October 24, 2007.

Please note that while the 2005 Public Aquaculture Production Database (PAPD) contains information for fish reared in marine or brackish waters, for this submission we considered temperature grouping for freshwater-reared finfish only. In communications with Dr. Jennifer Matysczak, Dr. Tom Bell found this agreeable. More information would be needed to develop a scheme for saltwater species.

The temperature grouping scheme that you proposed assigned specific temperature ranges to the categories "coldwater", "coolwater", and "warmwater." As indicated in your submission by the need for a fourth "cross-over" group, tying these groups to specific temperatures can be problematic. Without specific rearing temperatures for species from the facilities represented in the database, it is difficult to say whether the temperature ranges used for the PAPD are the most appropriate. Altering the temperature ranges by one or two degrees could potentially impact which category some of the cross-over species fall into. When developing a temperature grouping scheme such as this, temperatures at which fish are most susceptible to important diseases should be considered.

Traditionally, we have considered coldwater, coolwater, and warmwater groups to include the following:

Coldwater: Family Salmonidae (e.g., salmon, trout, char, grayling, mountain whitefish, and Dolly Varden)

Coolwater: Walleye, sauger, saugeye, yellow perch, northern pike, muskellunge, tiger muskellunge, June and razorback suckers, and shovelnose, pallid, and white sturgeon

Warmwater: Ictalurid catfish, tilapia, hybrid striped bass, tropical ornamental finfish, and species commonly reared above 26 °C that have not been identified as coolwater species

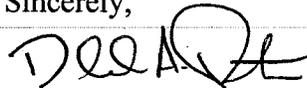
Additional species may be added to the coolwater list as more species are encountered in the drug approval process and post-market surveillance. Note that this classification is akin to species grouping based on family but is loosely tied to temperature by the use of the words coldwater, coolwater, and warmwater. Water temperatures in pivotal studies should be representative of expected conditions of use for the drug.

A potentially viable alternative is grouping freshwater fish in two categories- 1) coldwater and 2) coolwater and warmwater (combined).

As always, we will consider any alternate science-based proposal brought forward. Finally, we note that an approved indication for all freshwater-reared finfish includes both publicly cultured and commercial species; and therefore, privately cultured finfish must also be considered when developing a species grouping scheme.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at 240-276-8343 or Dr. Edward Chen, Acting, Leader of the Aquaculture Drugs Team, at 240-276-8327.

Sincerely,



Donald A. Prater, D.V.M.

Acting Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine