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FDA Approves Label Extensions for 35% PEROX-AID

FDA Approves Additional Uses for Syndel 35% PEROX-AID® to improve fish health in freshwater finfish.

Existing Treatments	Extension (additional treatments)
Control of mortality due to Saprolegniasis in	Control of mortality due to Saprolegniasis in
freshwater finfish eggs.	freshwater finfish eggs, and all coldwater finfish
	(including all salmonids) and all fingerling and
	adult coolwater and warmwater finfish.
Control of the mortality due to external	Control of the mortality due to external columnaris
columnaris disease associated with	disease associated with Flavobacterium columnare
Flavobacterium columnare in freshwater reared	in freshwater reared coolwater finfish, channel
coolwater finfish and channel catfish	catfish and warm-water finfish, including hybrid
	catfish and blue catfish.
Control of the mortality due to Bacterial Gill	Control of the mortality due to Bacterial Gill Disease
Disease associated with Flavobacterium	associated with Flavobacterium branchiophilum and
branchiophilum in freshwater salmonids	for the control of Gyrodactylus spp. in
	freshwater-reared salmonids

SYNDEL Ferndale, Wa — "Our goal with these label extensions is to fill an unmet need by providing government, commercial hatcheries and other fish production facilities with legal options for protecting fish from common health concerns. Freshwater salmonid facilities run the risk of the parasite Gyrodactylus, which causes mortality and reduced growth. The lack of options for treating fungus on fish has historically resulted in aquaculture facilities resorting to using treatments that are less than ideal, and our product provides hatcheries with an approved option for treating fish. Ultimately, our aim is to support hatchery efforts to meet the world's growing food demand with safe and healthy options. We would also like to thank our Federal partners at UMESC and FDA CVM's Office of Research for their efforts to generate the supporting data" Syndel CEO Chris McReynolds said.

FDA PRESS RELEASE — "This approval will help provide a critical treatment for improving fish health. The agency also anticipates that resource management agencies will use this approved treatment for aiding in the restoration of certain freshwater fish populations." The new product indications address disease concerns identified by aquaculture facilities in the US FWS Aquatic Animal Drug Approval Partnership's Unmet Fish Drug Needs Survey.

For the FDA Freedom of Information Summary on the Supplemental Approval for 35% PEROX-AID®, visit: https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/7407

ABOUT SYNDEL— Syndel is a privately held company that has developed and marketed high quality aquaculture pharmaceutical health and nutritional products worldwide for more than 40 years. Syndel has headquarters located in Ferndale, Washington, USA (including our quality control laboratories, and FDA inspected manufacturing plant) and a Canadian office located in Nanaimo, BC, Canada. www.syndel.com