

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0039]

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Certifier A. Corbin

Chloramine-T for Control of Bacterial Gill Disease in Freshwater-Reared Salmonids; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness and target animal safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of chloramine-T by immersion for the control of mortality in freshwater-reared salmonids due to bacterial gill disease. The data, contained in Public Master File (PMF) 5893, were compiled by the U.S. Department of the Interior, U.S. Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership Program.

ADDRESSES: Submit NADAs or supplemental NADAs to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Chloramine-T used by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act

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(the act) (21 U.S.C. 321(v)). As a new animal drug, chloramine-T is subject to section 512 of the act (21 U.S.C. 360b) which requires that its uses be the subject of an approved NADA or supplemental NADA. Fish are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The U.S. Department of the Interior, U.S. Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership Program, 4050 Bridger Canyon Rd., Bozeman, MT 59715, has provided effectiveness and target animal safety data for use of chloramine-T by immersion for control of mortality in freshwater-reared salmonids due to bacterial gill disease. These data are contained in PMF 5893.

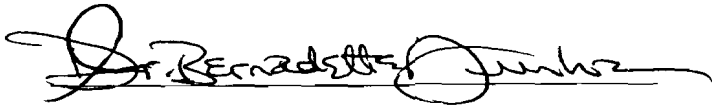
Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5893 to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: data concerning human food safety; and manufacturing methods, facilities, and controls. Persons desiring more information concerning PMF 5893 or requirements for approval of an NADA or supplemental NADA may contact the Center for Veterinary Medicine (see **FOR FURTHER INFORMATION CONTACT**).

In accordance with the freedom of information provisions of 21 CFR part 20, a summary of safety and effectiveness data provided in PMF 5893 to support approval of an application may be seen in the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane,
rm. 1061, Rockville, MD 20852, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: 08/08/2008

August 8, 2008.



Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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