

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier L. CLAWSON

DDM

Hydrogen Peroxide Solution for Control of Various Fungal and Bacterial Diseases in Fish; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, and environmental data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of a 35 percent solution of hydrogen peroxide by immersion for control of mortality in several life stages of certain freshwater-reared finfish species due to various fungal and bacterial diseases. The data, contained in Public Master File (PMF) 5639, were compiled by the United States Geological Survey, Biological Resources Section, Upper Midwest Environmental Sciences Center.

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: Joan Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Hydrogen peroxide solution used by immersion for control of mortality in several life stages of certain freshwater-reared finfish species due to various fungal and bacterial diseases is a new animal drug under

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NAD 1

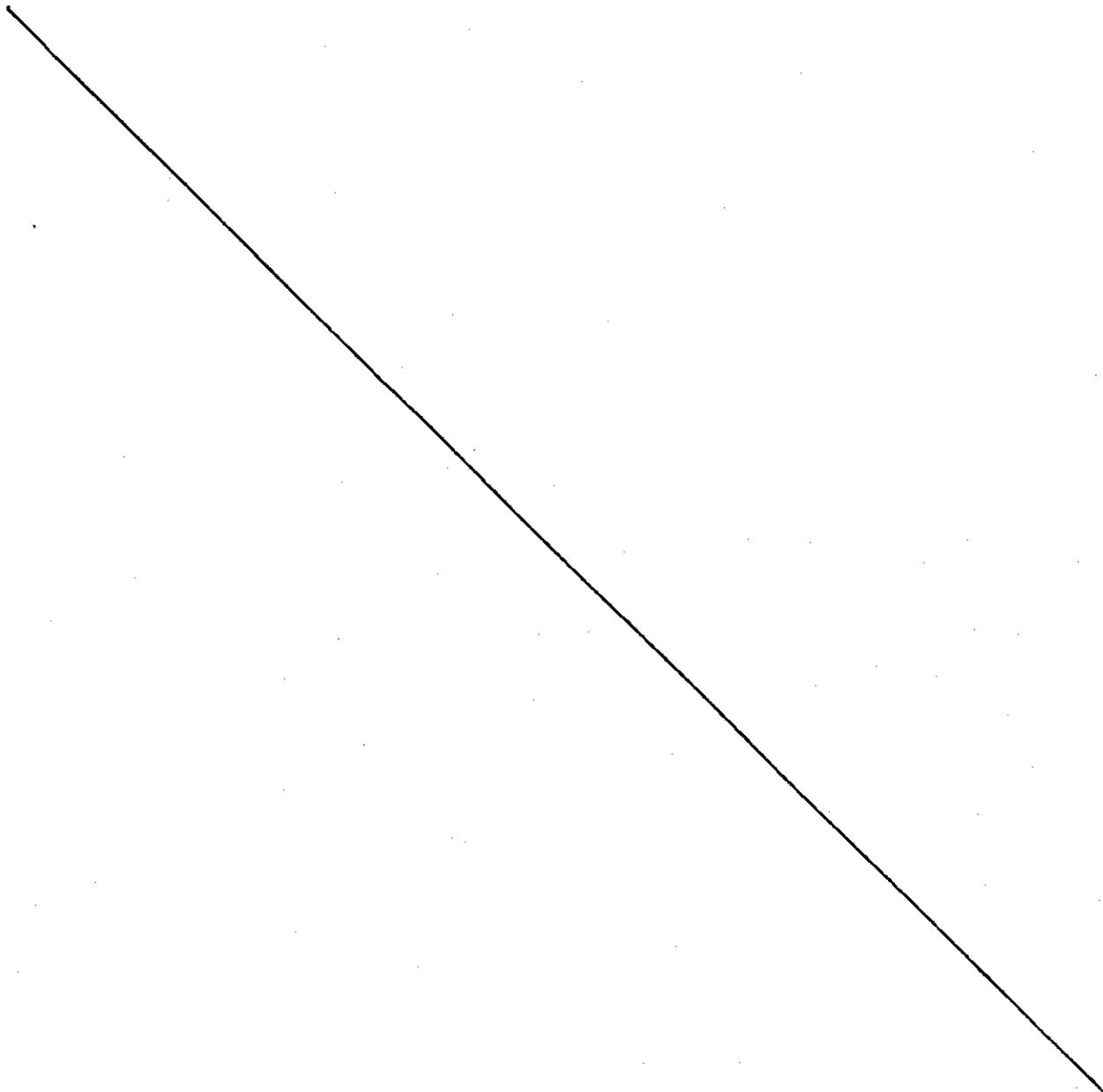
section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, hydrogen peroxide is subject to section 512 of the act (21 U.S.C. 360b) which requires that its uses be the subject of an approved NADA or supplemental NADA. Fish are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The United States Geological Survey, Biological Resources Section, Upper Midwest Environmental Sciences Center, 2630 Fanta Reed Rd., La Crosse, WI 54603, has provided effectiveness and target animal safety data; and an environmental assessment (EA) for use of a 35 percent solution of hydrogen peroxide by immersion for control of mortality in certain freshwater-reared finfish species in several life stages due to various fungal and bacterial diseases. These data and the EA are contained in PMF 5639.

FDA has reviewed the EA, carefully considered the environmental impacts of the use of a 35 percent solution of hydrogen peroxide on freshwater finfish, and has concluded that the use will not have a significant impact on the human environment. A finding of no significant impact (FONSI) has been prepared and is also contained in PMF 5639.

Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5639 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 5639 or requirements for approval of an NADA or supplemental NADA may contact Joan C. Gotthardt (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 5639 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. The EA and FONSI contained in PMF 5639 have also been placed in the docket.



Dated: 1/11/07
January 11, 2007.

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Stephen F. Sundlof,
Director,

Center for Veterinary Medicine.
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