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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

0811 '02 JUL 12 AS 52

**Oxytetracycline Hydrochloride for Marking Fish; Availability of Data**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, human food safety, and environmental data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of a solution of oxytetracycline hydrochloride for skeletal marking of finfish by immersion. The data, contained in Public Master File (PMF) 5667, were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses.

**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 C. Gotthardt, Center for Veterinary Medicine (HFV-131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: jgotthar@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Oxytetracycline hydrochloride soluble powder, used in solution for skeletal marking of juvenile finfish by immersion as an aid in identification is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, oxytetracycline hydrochloride is subject to section 512 of the act (21 U.S.C. 360b), requiring 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)).

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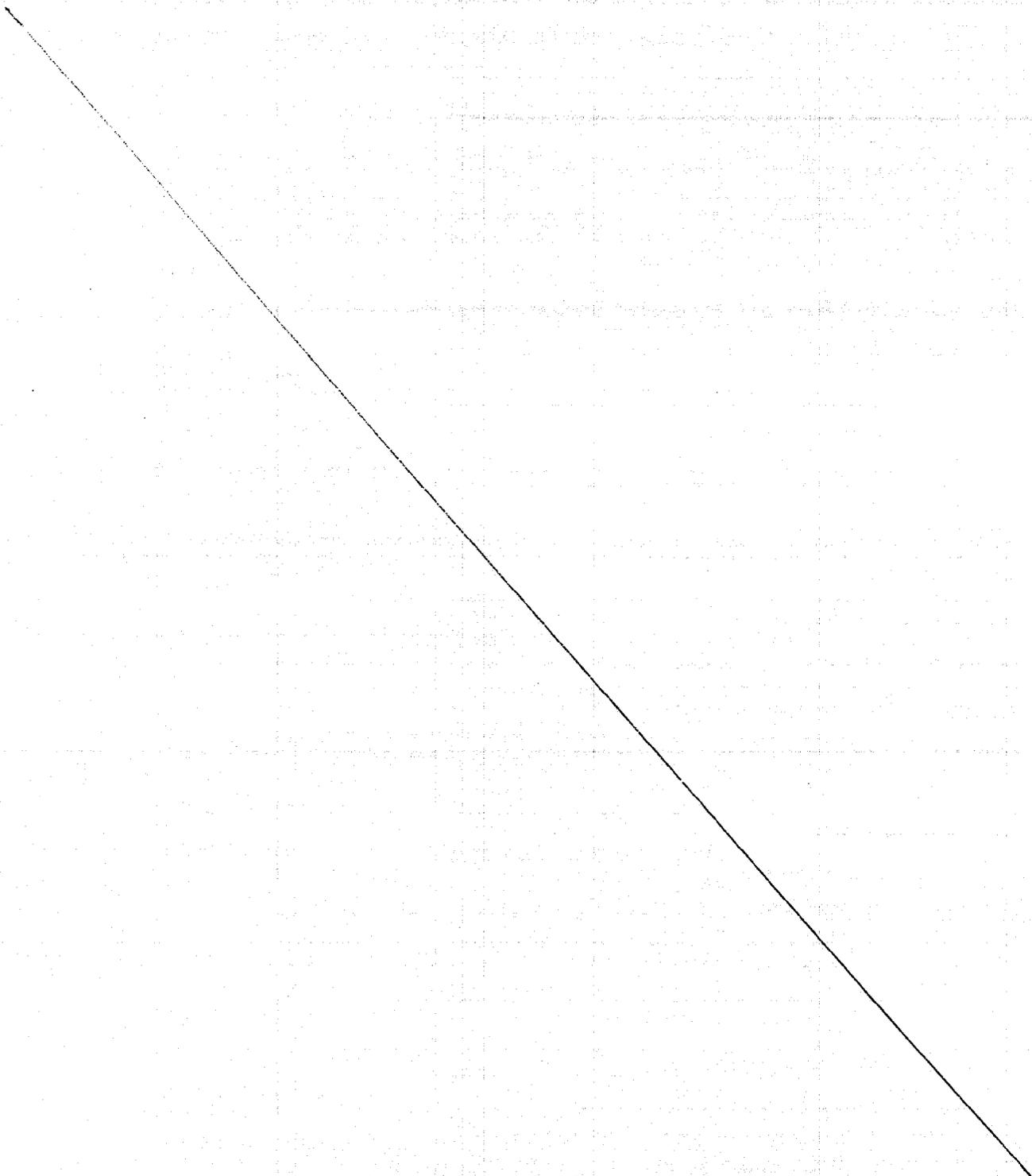
NAD-1

The NRSP-7 Project, North Eastern Region, New York State College of Veterinary Medicine, Cornell University, Ithaca, NY 14850, has provided target animal safety, effectiveness, human food safety, and environmental data for use of oxytetracycline hydrochloride soluble powder for skeletal marking of fish by immersion. These data are contained in PMF 5667.

Under §§ 25.15(d) and 25.33(d)(4) (21 CFR 25.15(d) and 25.33(d)(4)), sponsors of NADAs and supplemental NADAs for drugs in minor species, including wildlife and endangered species, are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement when the drug has been approved for use in another or the same species where similar animal management practices are used. The categorical exclusion applies unless, as defined in § 25.21 (21 CFR 25.21), extraordinary circumstances exist which indicate that the proposed action may significantly affect the quality of the human environment. Therefore, based upon information available, FDA agrees that when the application is submitted, the applicant may claim a categorical exclusion under § 25.33(d)(4) provided that the applicant can state that to the best of the applicant's knowledge, as in § 25.21, no extraordinary circumstances exist. It is assumed that the applicant has made a reasonable effort to determine that no extraordinary circumstances exist.

Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5667 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 supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; data concerning manufacturing methods, facilities, and controls; and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning PMF 5667 or requirements for approval of an NADA or supplement may contact Joan C. Gotthardt (see **FOR FURTHER INFORMATION CONTACT**).

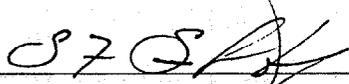
In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information provided in PMF



5667 to support approval of an application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/27/02

June 27, 2002.



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

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