compliance with the Paperwork Reduction Act (PRA; Pub. L. 96–511): Title VI Native American Caregiver Support Program Reports.

Title of Information Collection: Title VI Native American Caregiver Support Program Report.

Type of Request: New.

Use: Collection of information, from Title VI grantees, to use in reporting information on programs funded by Title VI as required under section 202(a)(19), section 614(a)(2), and section 614(a)(3) of the Older Americans Act, as amended.

Frequency: Semi-Annually.

Respondents: Tribal Organizations.

Estimated Number of Responses: 110.

Estimated Burden Hours: 110.

Additional Information or Comments: A copy of the above mentioned Title VI Native American Caregiver Support Program Report can be obtained by calling M. Yvonne Jackson, Ph.D., Director, Office for American Indian, Alaskan Native and Native Hawaiian Programs, Administration on Aging, 330 Independence Avenue, SW., Washington, DC 20201; telephone (202) 619–2713. Written comments and recommendations regarding the Native American Caregiver Support Program Report should be sent within 60 days of the publication of this notice to the following address: Administration on Aging, Wilbur J. Cohen Federal Building, 330 Independence Avenue, SW., Room 4743, Washington, DC 20201. Attn: M. Yvonne Jackson, Ph.D.

Dated: November 9, 2001.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 01–28729 Filed 11–15–01; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oxytetracycline 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 human food safety data that sponsors may use in support of a new animal drug application (NADA) or supplemental NADA for the treatment of walleye and northern pike with oxytetracycline in medicated feed for bacterial infections. The U.S. Geological Survey, Upper Midwest Environmental Sciences Center (UMESC), La Crosse, WI, compiled the data that is contained in Public Master File (PMF) 5646.

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: Julia A. Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6976, e-mail: joriani@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

Oxytetracycline, used for the treatment of bacterial infections in walleye and northern pike, 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 is subject to section 512 of the act (21 U.S.C. 360b), which requires that its use in walleye and northern pike for bacterial infections be the subject of an approved NADA or supplemental NADA. Walleye and northern pike are minor species under 21 CFR 514.1(d)(1)(ii).

Researchers from UMESC have provided human food safety data for the use of oxytetracycline in walleye and northern pike. The researchers conducted oxytetracycline tissue residue depletion studies in northern pike and walleye. These studies were conducted in accordance with good laboratory practices.

Juvenile northern pike were fed medicated feed containing oxytetracycline at either 70.9 milligrams per kilogram (mg/kg) body weight/day for 10 days or 94.2 mg/kg body weight/day for 10 days at a water temperature of 13.8 °C. Juvenile walleye were fed medicated feed containing oxytetracycline at 89.0 mg/kg body weight/day for 10 days at a water temperature of 17.5 °C. The treated fish were sampled at various timepoints.

The tissues were analyzed for oxytetracycline residues using a validated high performance liquid chromatography (HPLC) method entitled ''Determination of Oxytetracycline in the Edible Tissue of Fish Fillets'' (UMESC, SOP No. CAP 413.1, 3/30/98). This HPLC method has been bridged to the regulatory microbiological assay for oxytetracycline in tissue entitled ''Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocol'' (U.S. HHS/PHS/FDA, Washington, DC, revised October, 1968). The tissue residues were below the tolerance of 2 parts per million at all timepoints (21 CFR 556.500) as shown in table 1 and 2 of this document.

TABLE 1.—MEAN OXYTETRACYCLINE (OTC) CONCENTRATIONS (PARTS PER MILLION (PPM)) IN SKIN-ON FILLET FROM WALLEYE FED 89.0 MILLIGRAMS PER KILOGRAM PER DAY OTC FOR 10 DAYS AT WATER TEMPERATURE OF 17.5 °C (N=20 FOR ALL TIMEPOINTS EXCEPT ON DAY 2, N=18)

Withdrawal Time (Days)	Mean OTC Residues (ppm)
1	0.721±0.244
2	0.549±0.148
3	0.667±0.217
4	0.689±0.233
7	0.449±0.170
9	0.444±0.184
11	0.361±0.110
14	0.301±0.093

TABLE 2.—MEAN OXYTETRACYLINE LEVELS (PARTS PER MILLION) IN SKINLESS NORTHERN PIKE MUSCLE FOLLOWING DOSING FOR 10 DAYS WITH MEDICATED FEED AT 13.8 °C (N=40 FOR ALL SAMPLING TIMEPOINTS EXCEPT FOR DAY 10 SAMPLES, N=39)

Withdrawal Time (Days)	Fish Fed Biodiet Grower (Trout Feed) at 70.9 Milligrams Per Kilogram Per Day (mg/kg/day)	Fish Fed Walleye Grower (Walleye Feed) at 94.2 mg/kg/day
1	0.203±0.042	0.314±0.091
2	0.198±0.056	0.319±0.098
4	0.162±0.034	0.267±0.068
6	0.122±0.039	0.211±0.053
8	0.098±0.026	0.147±0.049
10	0.068±0.017	0.125±0.034

Data and information on safety are contained in PMF 5646. When you submit NADAs or supplemental NADAs, you may, without further authorization, reference the PMF to support approval of an application filed under 21 CFR 514.1(d). You must include a reference to the PMF and other information needed for approval when you submit an NADA or supplemental NADA. The information needed for approval in addition to the reference to the PMF includes effectiveness data; target animal safety data; data concerning manufacturing methods, facilities, and controls; animal drug labeling; and information addressing potential environmental impacts. If you need more information concerning the PMF or requirements for approval of an NADA or supplemental NADA, contact Julia A. Oriani (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety data and information provided in this PMF to support approval of an application may, upon approval of such application, be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 6, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–28680 Filed 11–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0475]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' This draft guidance provides information for applicants on how to submit abbreviated new drug applications (ANDAs) in electronic format.

DATES: Submit written or electronic comments on the draft guidance by January 15, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ruth Warzala, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845, e-mail: ESUB_OGD@CDER.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' In the Prescription Drug User Fee Act as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999, the agency announced the availability of two guidances for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDAs'' (64 FR 4432) and ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (64 FR 4433). These guidances were the first two of a series of guidances for industry on making regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types and structured formats, including ANDAs, investigational new drug applications, and product licensing applications. When finalized, this draft guidance should be used in conjunction with the two previously issued guidances (64 FR 4432 and 4433, respectively).

CDER has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these electronic submissions could not previously be archived and could only be made in addition to a complete paper submission. The electronic data submission program is now being expanded to include all parts of ANDA so that the electronic submission can replace the paper submission as the archival copy of ANDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).