

Dated: August 14, 2008.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E8-19220 Filed 8-20-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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 (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: August 8, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-19299 Filed 8-20-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation (S10) Review.

Date: September 8, 2008.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency O'Hare, 9300 Bryn Mawr Avenue, Rosemont, IL 60018.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, (301) 435-4511, whitmarshb@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Cell Biology Integrated Review Group Interdisciplinary Interactions Study Section.

Date: September 22-23, 2008.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: George Washington University Inn, 824 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301-435-1022, balasundaramd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Applications Related to Dementia, Substance Abuse, or Behavioral Development.

Date: September 24, 2008.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ellen K. Schwartz, EDD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3168, MSC 7770, Bethesda, MD 20892, 301-435-0681, schwarte@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: September 25, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ross D. Shonat, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7849, Bethesda, MD 20892, 301-435-2786, shonatr@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Nanotechnology Study Section.

Date: September 30-October 1, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Joseph D. Mosca, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 435-2344, moscajos@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group Vaccines Against Microbial Diseases Study Section.

Date: October 2-3, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Chicago Marriott Downtown, 540 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Jian Wang, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 435-2778, wangjia@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

Date: October 2-3, 2008.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Richard A. Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435-1219, currieri@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—A Study Section.

Date: October 2, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Fisherman's Wharf Hotel, 2500 Mason Street, San Francisco, CA 94133.

Contact Person: Joanna M. Pyper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435-1151, pyperj@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: October 2-3, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Fisherman's Wharf Hotel, 2500 Mason Street, San Francisco, CA 94133.

Contact Person: Robert Freund, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: October 2, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301-435-1740, fanp@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: GMPB and HBPP.

Date: October 3, 2008.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2174, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

Name of Committee: Health of the Population Integrated Review Group; Nursing Science: Adults and Older Adults Study Section.

Date: October 5-6, 2008.

Time: 5 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Melinda Tinkle, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, MSC 7770, Bethesda, MD 20892, (301) 594-6594, tinklem@csr.nih.gov.

Name of Committee: Digestive Sciences Integrated Review Group; Clinical and Integrative Gastrointestinal Pathobiology Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mushtaq A. Khan, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301-435-1778, khanm@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Glia Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street, San Francisco, CA 94102.

Contact Person: Toby Behar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435-4433, behart@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street, NW, Washington, DC 20007.

Contact Person: Denise Beusen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7806, Bethesda, MD 20892, (301) 435-1267, beusend@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Arnold Revzin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7824, Bethesda, MD 20892, (301) 435-1153, revzina@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Michael Micklin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435-1258, micklinm@csr.nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Francois Boiler, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7848, Bethesda, MD 20892, 301-435-1019, bollefr@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Biological Rhythms and Sleep Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Frances Drake, 450 Powell Street, San Francisco, CA 94102.

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1208,

MSC 7844, Bethesda, MD 20892, 301-435-1119, mselmanoff@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group, Modeling and Analysis of Biological Systems Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Malgorzata Klosek, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435-2211, klosekm@mail.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Central Visual Processing Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Frances Drake, 450 Powell Street, San Francisco, CA 94102.

Contact Person: Judith A. Finkelstein, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892, 301-435-1249, finkelsj@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Anterior Eye Disease Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Jerry L. Taylor, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301-435-1175, taylorje@csr.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Lee Rosen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171, rosenk@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Carol Hamelink, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5040H, MSC 7850, Bethesda, MD 20892, (301) 451-1328, hamelinc@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Legacy Hotel, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, knechtm@csr.nih.gov.

Name of Committee: Health of the Population Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Heidi B. Friedman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301-435-1721, hfriedman@csr.nih.gov.

Name of Committee: Cardiovascular Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Rajiv Kumar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7802, Bethesda, MD 20892, 301-435-1212, kumarra@csr.nih.gov.

Name of Committee: Digestive Sciences Integrated Review Group; Gastrointestinal Mucosal Pathobiology Study Section.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Express Hotel & Suites, 550 North Point Street, San Francisco, CA 94133.

Contact Person: Peter J. Perrin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, (301) 435-0682, perrinp@csr.nih.gov.

Name of Committee: Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: George M. Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301-435-0696, barnasg@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: October 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Weijia Ni, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435-1507, niw@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: October 6-7, 2008.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Jane A. Doussard-Roosevelt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435-4445, doussarj@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

Date: October 6-7, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Reston, 1800 Presidents Street, Reston, VA 20190.

Contact Person: Lee S. Mann, JO, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301-435-0677, mannl@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 13, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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