Dated: August 14, 2008.

Robert Sargis,

Reports Clearance Officer.

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

BILLING CODE 4184–01–M

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]

BILLING CODE 4160–01–S

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 Intercellular 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