identity for canned Pacific salmon that may result from the petition or 30 days after denial of the petition, whichever the case may be.


The permit covers limited interstate marketing tests of a product identified as Yardarm Knot “Skinless and Boneless Sockeye Salmon.” This canned salmon product may deviate from the U.S. standard of identity for canned Pacific salmon (§ 161.170) in that the product is prepared by removing the skin and bones of the salmon used. Therefore, in addition to the optional forms of pack provided in § 161.170(a)(3), this temporary marketing permit provides for an alternative “skinless and boneless” form of pack. The test product meets all the requirements of the standard with the exception of the “skinless and boneless” form of pack.

On April 9, 2009, Yardarm Knot Fisheries, LLC, requested that its temporary marketing permit be extended to allow for additional time for the market testing of its test product and indicated that it had moved its corporate office to the address stated below. The petitioner has also submitted a petition requesting that FDA amend the standard of identity for canned Pacific salmon.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of the product identified in the original permit (73 FR 12180, March 6, 2008). FDA is inviting interested persons to participate in the market test under the conditions that apply to Yardarm Knot Fisheries, LLC, except that the designated area of distribution shall not apply. Any person who wishes to participate in the extended market test must notify, in writing, the Supervisor, Product Evaluation and Labeling Team, Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must include a description of the test product to be distributed, a justification statement for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by applicable sections of 21 CFR part 101.

Therefore, under the provisions of § 130.17(i), FDA is extending the temporary permit granted to Yardarm Knot Fisheries, LLC, 2440 West Commodore Way, Suite 200, Seattle, Washington 98199 to provide for continued marketing tests of not more than 1.35 million pounds (or 612 thousand kilograms in weight) annually of the canned Pacific salmon identified in this notice. FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule to amend the standard of identity for canned Pacific salmon that may result from the petition or 30 days after denial of the petition.

All other conditions and terms of this permit remain the same.


Barbara Schneeman,
Director, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. E9–31196 Filed 1–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2009–N–0576]

Event Problem Codes Web Site; Center for Devices and Radiological Health; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Web site where the Center for Devices and Radiological Health (CDRH) is posting updates to the problem codes used in conjunction with the medical device adverse event reports (MDR) regulation.

DATES: Submit electronic or written comments at any time.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Terrie L. Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., rm. 3324, Silver Spring, MD 20993, 301–796–6130.

SUPPLEMENTARY INFORMATION:

I. Background

Under part 803 (21 CFR part 803), user facilities and importers are required to submit FDA Form 3500A for deaths and serious injuries that a medical device may have caused or to which it may have contributed. Block F10 of FDA Form 3500A asks user facilities and importers to provide event problem codes for both the patient and the device. Manufacturers are required by § 803.21(b)(1) to include “Any information missing on the user facility report or importer report, including any event codes that were not reported * * *.” The patient problem codes indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnoses. The device codes describe device failures or issues related to the device that are encountered during the event. The medical device reporting regulation also states that if CDRH makes modifications to these reporting codes, the information will be made available to all reporters (§ 803.21(b)).

FDA is announcing the availability of a Web site that will make modifications to the problem codes available to all reporters and will also fully describe the problem codes. The Web site is located at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm. This Web site reflects the current updates to the problem codes, provides a description for each problem code, and notes that April 2, 2010, is the target date to reject all inactivated and retired codes specified in this update. After April 2, 2010, no old codes or code numbers will be accepted. The Web site also describes a joint project between CDRH and the
Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of the Director’s home page: http://www.nih.gov/about/director/acd.htm, where an agenda and any additional information for the meeting will be posted when available.


Anna Snouffer,
Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–31233 Filed 1–4–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of Mental Health, Special Emphasis Panel K99.
Date: January 28, 2010.
Time: 10 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852–9609, 301–402–6807, libbeym@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel Center Review.
Date: February 26, 2010.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: The Mandarin Oriental, 1330 Maryland Avenue, SW., Washington, DC 20024.

Contact Person: Francois Boiler, MD, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892–9606, 301–443–1513, bollerf@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)


Jennifer Spaelth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–31143 Filed 1–4–10; 8:45 am]
BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

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

The meeting 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: National Institute on Drug Abuse Special Emphasis Panel; Substance Use and Abuse Among U.S. Military Personnel, Veterans, and their Families.

Date: March 9–10, 2010.
Time: 9 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Nadine Rogers, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–402–2105, rogersn2@nida.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)