

activities and the surveillance systems maintained have expanded.

CDC and the Council of State and Territorial Epidemiologists (CSTE) collect data on disease and preventable conditions in accordance with jointly approved plans. Changes in the surveillance program and in reporting methods are effected in the same manner. At the onset of this surveillance program in 1968, the CSTE and CDC decided on which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health. Surveillance forms are distributed to the State and local health departments who voluntarily submit these reports to CDC

at variable frequencies, either weekly or monthly. CDC then calculates and publishes weekly statistics via the Morbidity and Mortality Weekly Report (MMWR), providing the states with timely aggregates of their submissions.

The following diseases/conditions are included in this program: Diarrheal disease surveillance (includes campylobacter, salmonella, and shigella), foodborne outbreaks, arboviral surveillance (ArboNet), Influenza virus, including the annual survey and influenza-like illness, Respiratory and Enterovirus surveillance, rabies, waterborne diseases, cholera and other vibrio illnesses, Listeria, Calcinet, Harmful Algal Bloom-related Infectious

Surveillance System (HABISS) data entry form, and the HABISS monthly reporting form. These data are essential on the local, state, and Federal levels for measuring trends in diseases, evaluating the effectiveness of current prevention strategies, and determining the need for modifying current prevention measures.

This request is for revision of the currently approved data collection for three years. The revisions include minor changes to reporting forms already approved under this OMB Control Number. Because of the distinct nature of each of the diseases, the number of cases reported annually is different for each. There is no cost to respondents other than their time.

#### ESTIMATE OF ANNUALIZED BURDEN HOURS

| Form   | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|--|-----------------------|------------------------------------|--|-------------------------|
| Diarrheal Disease Surveillance: <i>Campylobacter</i> (electronic) .....                | 53                    | 52                                 | 3/60                                   | 138                     |
| Diarrheal Disease Surveillance: <i>Salmonella</i> (electronic) .....                   | 53                    | 52                                 | 3/60                                   | 138                     |
| Diarrheal Disease Surveillance: <i>Shigella</i> (electronic) .....                     | 53                    | 52                                 | 3/60                                   | 138                     |
| Foodborne Outbreak Form .....  | 54                    | 25                                 | 15/60                                  | 338                     |
| Arboviral Surveillance (ArboNet) .....   | 57                    | 1,421                              | 4/60                                   | 5,400                   |
| —Influenza virus (fax, Oct–May) .....  | 8                     | 33                                 | 10/60                                  | 44                      |
| —Influenza virus (fax, year round) .....   | 15                    | 52                                 | 10/60                                  | 130                     |
| *** Influenza virus (Internet; Oct–May) .....  | 13                    | 33                                 | 10/60                                  | 72                      |
| *** Influenza virus (Internet; year round) .....                                       | 24                    | 52                                 | 10/60                                  | 208                     |
| —Influenza virus (electronic, Oct–May) .....   | 9                     | 33                                 | 5/60                                   | 25                      |
| —Influenza virus (electronic, year round) .....  | 14                    | 52                                 | 5/60                                   | 61                      |
| Influenza Annual Survey .....  | 83                    | 1                                  | 15/60                                  | 21                      |
| Influenza-like Illness (Oct–May) .....   | 824                   | 33                                 | 15/60                                  | 6,798                   |
| Influenza-like Illness (year round) .....  | 496                   | 52                                 | 15/60                                  | 6,448                   |
| Monthly Respiratory & Enterovirus Surveillance Report: Excel format (electronic) ..... | 25                    | 12                                 | 15/60                                  | 75                      |
| National Respiratory & Enteric Virus Surveillance System (NREVSS) .....                | 92                    | 52                                 | 10/60                                  | 797                     |
| Rabies (electronic) .....  | 40                    | 12                                 | 8/60                                   | 64                      |
| Rabies (paper) .....   | 15                    | 12                                 | 20/60                                  | 60                      |
| Waterborne Diseases Outbreak Form .....  | 26                    | 2                                  | 20/60                                  | 17                      |
| Cholera and other <i>Vibrio</i> illnesses .....  | 450                   | 1                                  | 20/60                                  | 150                     |
| CaliciNet .....  | 30                    | 10                                 | 10/60                                  | 50                      |
| Listeria .....   | 53                    | 1                                  | 30/60                                  | 27                      |
| HABISS data entry form .....   | 10                    | 12                                 | 8                                      | 960                     |
| HABISS monthly reporting form .....  | 10                    | 12                                 | 30/60                                  | 60                      |
| Total .....  | .....                 | .....                              | .....                                  | 22,219                  |

Dated: December 29, 2009.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2008–N–0119]

##### Canned Pacific Salmon Deviating From Identity Standard; Extension of Temporary Permit for Market Testing

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued

to Yardarm Knot Fisheries, LLC, to market test products designated as “skinless and boneless sockeye salmon” that deviate from the U.S. standard of identity for canned Pacific salmon. The extension will allow the permit holder to continue to collect data on consumer acceptance of the product while the agency takes action on a petition to amend the standard of identity for canned Pacific salmon that was submitted by Yardarm Knot Fisheries, LLC.

**DATES:** The new expiration date of the permit will be either 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, whichever the case may be.

**FOR FURTHER INFORMATION CONTACT:** Catalina Ferré-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

**SUPPLEMENTARY INFORMATION:** In accordance with § 130.17 (21 CFR 130.17), FDA issued a temporary permit to Yardarm Knot Fisheries, LLC, 3600 15th Avenue West, Suite 300, Seattle, Washington 98119, to market test canned Pacific salmon that deviates from the U.S. standard of identity for canned Pacific salmon (§ 161.170 (21 CFR 161.170)) (73 FR 12180, March 6, 2008). The agency issued the permit to facilitate market testing of a food deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

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.

Dated: December 16, 2009.

**Barbara Schneeman,**

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

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## 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 § 803.52(f)(11)(i) 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