

*Public Meeting Time and Date:* 9 a.m.–4 p.m., April 2, 2008.

*Place:* NIOSH Hamilton Laboratory, 5555 Ridge Ave, Cincinnati, OH, 45213, telephone (513) 841-4366, fax (513) 841-4483.

*Status:* Meeting is open to the public, limited only by the space available (the room accommodates approximately 80 people). Persons who are not U.S. citizens will need approval to enter the NIOSH building and should contact Douglas Trout, MD, MHS, by March 5, 2008, to arrange for this. Those who cannot attend in person are encouraged to email comments. Deadline for e-mailed comments is April 16, 2008.

*Background:* According to 2002 U.S. Census data, there were approximately 21,000 employees working in flavoring production and about 1.5 million workers in food manufacturing nationwide. Employees have complex exposures in terms of the physical form of the agents (solid, liquid, and gas) and the number of different chemicals used. Severe respiratory health effects have been identified among workers after exposure to flavoring chemicals such as diacetyl (a component of butter flavoring). NIOSH investigators have begun a research effort evaluating analytical methods, exposure assessment, and engineering controls in the flavoring and food production industries. This research is intended to provide information necessary to reduce occupational exposures and prevent health effects among workers in these industries.

The meeting will consist of two parts: (1) External peer review of the research protocol. Peer reviewers external to CDC will be present to provide technical (scientific) review comments for the project officers to maximize the relevance and quality of the proposed research; and (2) Stakeholder meeting. The latter part of the meeting will be structured to hear stakeholder comments on important occupational safety and health issues related to this research.

Participants wishing to provide stakeholder comments may do so via E-mail or may request an opportunity to make a five minute presentation. Participants making a presentation at the meeting must submit their comments in writing at the time of the meeting. All participants (whether making a presentation or not) are requested to register for the free meeting by sending an E-mail to [DTrout@cdc.gov](mailto:DTrout@cdc.gov) with their name, affiliation, whether they are requesting time to speak briefly, and, if so, the general topic(s) on which they wish to speak. Participants wishing to speak are encouraged to register early.

The public meeting is open to everyone, including all workers, representatives of professional societies, organized labor, employers, researchers, health professionals, government officials and elected officials. Broad participation is desired.

*Contact Person For Technical Information:* Dr. Douglas Trout, MD, MHS, Associate Director for Science, Division of Surveillance, Hazard Evaluations, and Field Studies, NIOSH, telephone (513) 841-4428. Comments and meeting registrations may also be E-mailed to [DTrout@cdc.gov](mailto:DTrout@cdc.gov), or sent via mail to: Dr. Douglas Trout, NIOSH, 4676 Columbia Parkway, R-12, Cincinnati, OH 45226.

Dated: February 27, 2008.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

[FR Doc. E8-4333 Filed 3-5-08; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers of Disease Control and Prevention

#### Notice of Public Meeting

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting and request for public comment on the NIOSH Research Project entitled "Effectiveness of Extension Ladder Safety Innovations". The meeting will include a presentation/overview of the project that will be followed by comments on the technical and scientific aspects of the planned research. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments also will be considered. Written comments should be sent to Dr. Peter Simeonov, NIOSH, Division of Safety Research, Mailstop G800, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888 or via E-mail at [psimeonov@cdc.gov](mailto:psimeonov@cdc.gov), and should be received on or before March 31, 2008.

*Public Meeting Time and Date:* 9 a.m.–12 p.m., April 9, 2008.

*Place:* NIOSH, 1095 Willowdale Road, Conference Room L-1BCD,

Morgantown, West Virginia 26505-2888.

*Purpose of Meeting:* To provide individual comments on the technical and scientific aspects of the research proposal directed to the prevention of fall injuries associated with the use of extension ladders among construction workers. The proposed research seeks to establish engineering solutions, with human factors considerations beyond the traditional regulation and training approaches, to minimize the possibility of workers making unsafe choices or actions, and thus reduce fall-from-ladder incidents.

*Status:* The meeting is open to the public, limited only by the space available (the room accommodates approximately 50 people). Due to limited space, notification of intent to attend the meeting must be made to Peter Simeonov, Ph.D., no later than March 31. Dr. Simeonov can be reached at (304) 285-6268 or by E-mail at [psimeonov@cdc.gov](mailto:psimeonov@cdc.gov). Requests to attend the meeting will be accommodated on a first-come basis.

*Contact Persons for Technical Information:* Hongwei Hsiao and Dr. Simeonov, Project Officers, Division of Safety Research, NIOSH, CDC, Mailstop G800, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, (304) 285-5910 and (304) 285-6268, E-mail [hhsiao@cdc.gov](mailto:hhsiao@cdc.gov) & [psimeonov@cdc.gov](mailto:psimeonov@cdc.gov). Copies of the research proposal may be obtained by contacting Dr. Simeonov.

Dated: February 27, 2008.

**James D. Seligman,**

*Chief Information Office, Centers for Disease Control and Prevention.*

[FR Doc. E8-4334 Filed 3-5-08; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0119]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Yardarm Knot Fisheries, LLC, to market test canned Pacific salmon that deviates from the U.S. standard of identity for canned Pacific salmon. The purpose of the temporary permit is to

allow the applicant to measure consumer acceptance of the product and assess commercial feasibility.

**DATES:** This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than June 6, 2008.

**FOR FURTHER INFORMATION CONTACT:** Ritu Nalubola, 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 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods 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), FDA is giving notice that a temporary permit has been issued to Yardarm Knot Fisheries, LLC, 3600 15th Ave. West, suite 300, Seattle, WA 98119.

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 (21 CFR 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. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of not more than 1.35 million pounds (or 612 thousand kilograms) of the test product. The test product will be manufactured by Yardarm Knot Fisheries, LLC, at Mile 1.5 Alaska Peninsula Highway, Naknek, Alaska 99633. The test product will be distributed by Yardarm Knot Fisheries, LLC, throughout the United States. The information panel of the label will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food will be declared on the label as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the

introduction of the product into interstate commerce, but not later than (see **DATES**).

Dated: February 28, 2008.

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

[FR Doc. E8-4316 Filed 3-5-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0128] (formerly  
Docket No. 2007D-0396)

#### Draft Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation; Reopening of Comment Period; Public Conference

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

**ACTION:** Notice of reopening of comment period; notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until June 30, 2008, the comment period for the draft guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation," published in the *Federal Register* of October 25, 2007 (72 FR 60681). FDA is also announcing a public conference entitled "Detecting and Investigating Drug-Induced Liver Injury During Clinical Trials." FDA is cosponsoring the conference with the American Association for the Study of Liver Diseases (AASLD) and the Pharmaceutical and Research Manufacturers of America. The purpose of the conference is to discuss the draft guidance and to solicit additional input on the issues and questions presented in this document.

**DATES:** The public conference will be held on March 26, 2008, from 8 a.m. to 6 p.m. and March 27, 2008, from 8 a.m. to 3 p.m. Please register by March 14, 2008, to make an oral presentation during the open public session on March 27, 2008. Submit written or electronic comments on the draft guidance, the conference program and presentations, and the issues and questions presented in this document by June 30, 2008.

**ADDRESSES:** The public conference will be held at the National Labor College (NLC), 10000 New Hampshire Ave., Silver Spring, MD 20903.

Submit written comments to the Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, e-mail: [lane.pauls@fda.hhs.gov](mailto:lane.pauls@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Reopening of Comment Period for the Draft Guidance

In the *Federal Register* of October 25, 2007, FDA issued the draft guidance "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" and invited comments by December 24, 2007. This draft guidance describes methods for detecting drug-induced liver injury (DILI) that may occur during the course of conducting controlled clinical trials. To provide interested persons additional time to review the draft guidance and submit comments, the agency is reopening the comment period until June 30, 2008.

##### II. The Public Conference

###### A. Why Are We Holding This Public Conference?

The purpose of the conference is to discuss the draft guidance and issues that it may raise and to solicit additional input on the issues and questions presented in this document.

###### B. What Are the Topics We Intend to Address at the Conference?

We hope to discuss a large number of issues at the conference, including, but not limited to:

- The approach to detecting the potential for severe DILI described in the draft guidance;
- What stopping rules should govern the administration of an investigational agent during a clinical trial;
- When should rechallenge of a suspected injurious agent be considered;
- Should patients or study participants with stable chronic liver disease be included in clinical trials; and
- Other issues and questions raised by the conference attendees or others.

###### C. Is There a Fee and How Do I Register for the Conference?

There is a modest fee to attend the conference, to defray the costs of meals provided, rental of the NLC meeting facility, travel expenses for invited