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: *lana.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

academic (but not government or industry) speakers, and other expenses. The fee for the 2-day meeting for registrants from industry is $350, and the fee for academic or government registrants is $175. Fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, which has extensive experience in planning, executing, and organizing educational meetings. Register online at *http://www.aasld.org*. Although the NLC facility is spacious, registration will be on a first-come, first-served basis. If you would like to make an oral presentation during the open hour of the conference on March 27, 2008, you must register with Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) by close of business on March 14, 2008. To make a presentation, you will be asked to provide your name, title, business affiliation (if applicable), address, and type of organization you represent (e.g., industry, consumer organization). Persons registered to make an oral presentation should check in before the conference. If you need special accommodations because of a disability, please contact Lana Pauls at least 7 days before the conference.

D. Where Can I Find Out More About This Public Conference?

Background information on the conference, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cder/livertox* and *http://www.aasld.org*.

E. Conference Transcripts

We will prepare a transcript of the conference presentations and discussions and will post it online along with copies of slides shown. The transcript will be available for review on the Internet at *http://www.fda.gov/cder/livertox* approximately 30 days after the conference.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the issues and questions presented in this document or at the conference. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4361 Filed 3–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6460, Silver Spring, MD 20993–0002, 301–796–0700, e-mail: *grace.carmouze@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at *http://www.fda.gov/cder/pediatric/index.htm* summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.