

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS element	Inclusion criteria	Exclusion criteria
Outcomes	<i>All KQs:</i> Primary efficacy outcomes (<i>i.e.</i> , pain, function, disability, pain interference); harms and adverse effects (<i>e.g.</i> , dizziness, nausea, sedation, development of cannabis use disorder); secondary outcomes (<i>i.e.</i> , psychological distress including depression and anxiety, quality of life, opioid use, sleep quality, sleep disturbance, health care utilization).	<i>All KQs:</i> Other outcomes.
Time of follow-up	<i>All KQs:</i> short term (1 to <6 months), intermediate term (6 to <12 months), long term (≥1 year).	<i>All KQs:</i> studies with <1-month of treatment or followup after treatment.
Setting	<i>All KQs:</i> Any nonhospital setting or setting of self-directed care.	<i>All KQs:</i> Hospital care, hospice care, emergency department care.
Study design	<i>All KQs:</i> RCTs; observational studies with a concurrent control group for harms, and to fill gaps in the evidence for benefits.	<i>All KQs:</i> Other study designs.

Abbreviations: RCT = randomized controlled trial.

Dated: November 27, 2020.

Marquita Cullom,
Associate Director.

[FR Doc. 2020-26570 Filed 12-1-20; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)-RFA-PS-21-003, PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices; and RFA-PS-21-004, Implementing and Evaluating a Data-to-Care Rx Strategy.

Date: February 23-24, 2021.

Time: 10:00 a.m.-5:00 p.m., EST.

Place: Teleconference, Centers for Disease Control and Prevention, Room

1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329-4027.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop US8-1, Atlanta, Georgia 30329-4027, (404) 718-8833, GAnderson@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2020-0121]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the

following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on December 1, 2020 from 2:00 p.m. to 5:00 p.m., EST (times subject to change).

Written comments must be received on or before December 3, 2020.

ADDRESSES: For more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

You may submit comments, identified by Docket No. CDC-2020-0121 by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** Docket No. CDC-2020-0121, c/o Attn: November 23, 2020 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-8, Atlanta, GA 30329-4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the <https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS-H24-8, Atlanta, GA 30329-4027; Telephone: 404-639-8367; Email: ACIP@cdc.gov.

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102-3.150(b), less than 15 calendar days' notice is

being given for this meeting due to the exceptional circumstances of the COVID-19 pandemic and rapidly evolving COVID-19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID-19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: <http://www.cdc.gov/vaccines/acip/index.html>. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID-19 vaccine allocation. A recommendation vote is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and

may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Written Public Comment: Written comments must be received on or before December 3, 2020.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the December 1, 2020 ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m., EST, November 30, 2020 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EST, December 1, 2020. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

*Director, Strategic Business Initiatives Unit,
Office of the Chief Operating Officer, Centers
for Disease Control and Prevention.*

[FR Doc. 2020-26587 Filed 11-30-20; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1987-P-0074]

Canned Pacific Salmon Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending Bumble Bee Seafoods Inc.'s temporary permit to market test canned skinless and boneless chunk salmon packed in water that contains sodium tripolyphosphate to inhibit protein curd formation during retorting. The temporary permit is amended to add an additional manufacturing location. This amendment will allow the applicant to continue to test market the test product and collect data on consumer acceptance of the test product.

FOR FURTHER INFORMATION CONTACT:

Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 13, 1987 (52 FR 26186), we issued a notice announcing that we had issued a temporary permit to Bumble Bee Seafoods, Inc., San Diego, CA 92123, to market test products identified as canned skinless and boneless chunk salmon packed in water and containing added sodium tripolyphosphate to inhibit protein curd formation during retorting. The permit allowed for the test product to be manufactured at a plant located in Petersburg, AK. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned Pacific salmon in 21 CFR 161.170, which were issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of April 8, 1988 (53 FR 11710), we issued a notice announcing that we had amended the temporary permit to permit the test product be manufactured at one additional plant, Chugach Alaska Fisheries, Inc., Ocean Dock Rd., Cordova, AK 99574.

In the **Federal Register** of September 6, 1988 (53 FR 34354), we issued another notice announcing that we were extending the expiration date of the permit to either the effective date of a