++ Assess ACHC's ability to report deficiencies to the surveyed home infusion therapy and respond to the home infusion therapy's plan of correction in a timely manner.

++ Establish ACHC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of ACHC's staff and other resources.

++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.

++ Review ACHC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

The November 25, 2019 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC's HIT accreditation requirements and survey process with the Medicare CfCs of part 486, subpart I and the survey and certification process requirements of part 488, subpart L. Our review and evaluation of ACHC's HIT application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, ACHC has completed revising its standards and certification processes in order to meet the condition at:

- § 486.520(c), to address the requirement of the plan of care must be periodically reviewed by the physician.
- § 486.525(a)(3), to address the requirement of remote monitoring for the provision of home infusion therapy.
- § 488.1010(a)(6)(iv), to revise ACHC's survey procedures for surveys.
- § 488.1010(a)(6)(v), to revise ACHC's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.
- § 488.1010(a)(6)(vi), to revise ACHC's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that ACHC's requirements for HITs meet or exceed our requirements. Therefore, we approve ACHC as a national accreditation organization for HITs that request participation in the Medicare program, effective April 23, 2020 through April 23, 2024.

IV. Collection of Information Requirements

This document does not impose information collection and requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 14, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–08718 Filed 4–23–20; 8:45 am]

BILLING CODE 4120–01–P

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 allow for the canned skinless and boneless chunk salmon packed in water with or without sodium tripolyphosphate and to update the 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: Loretta A. Carey, 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 final rule for any proposal to amend the standard of identity for canned Pacific salmon that may result from the National Food Processors Association's petition, submitted on behalf of Bumble Bee Seafoods, Inc., and other salmon packers holding temporary permits, or 30 days after termination of such proposal.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to Bumble Bee Seafoods, Inc., to allow for the canned skinless and boneless chunk salmon packed in water with or without sodium tripolyphosphate and to allow the test product to be manufactured only at one

plant, Pataya Food Industries Ltd., located at 90/6 Moo 7, Settakit Road, Tambol Tarsai, Amphur Maung, Samutsakorn 74000 Thailand. All other conditions and terms of this permit remain the same.

Dated: April 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08762 Filed 4–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1423]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Imports and Electronic Import Entries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by May 26, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Imports and Electronic Import Entries

OMB Control Number 0910–0046—Revision

This information collection supports Agency regulations found in 21 CFR part 1, subparts D (§§ 1.70 through 1.81 (21 CFR 1.70 through 1.81)) and E (§§ 1.83 through 1.101 (21 CFR 1.83 through 1.101)), governing FDA import activities and related Agency guidance. Specifically, the regulations prescribe the required data elements that respondents must submit when importing, or offering for import, an FDA-regulated article into the United States. Review of the data elements allows FDA to continue to meet its responsibilities pertaining to current submission requirements established by the U.S. Customs and Border Protection (CBP) related to the submission of entry information in using its Automated Commercial Environment (ACE) system, or any CBP-authorized electronic data interchange (EDI) system. Respondents (ACE filers) submit important and useful information about FDA-regulated products being imported or offered for import into the United States so that we may effectively and efficiently review products and determine their admissibility. In addition, and as set forth in the regulations, certain product types are subject to additional data elements (for example, 21 CFR 1.77 prescribes additional data elements for radiation-emitting products), as well as those data elements applicable to all products.

We are revising the information collection to provide for a weekly entry filing program (WEF). More detailed information on Foreign Trade Zones (FTZ)/WEF, is available at *https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing.* The WEF program, which is available for some FDA-regulated products, allows entry filers to file a single entry estimating the amount of merchandise anticipated to be removed from an FTZ and offered for U.S. consumption during a 7-day period. To participate, we recommend respondents who wish to file a weekly entry of FDA-regulated products with CBP to first request a preliminary assessment from FDA. As part of this assessment, we recommend submission of the following information:

- FDA Import Division(s) [1] with geographic oversight over the FTZ location;
- Identification of whether products are manufactured or stored in the FTZ;
- FTZ site/subzone number and address;
- Importer of Record (IOR) Facility Establishment Identifier (FEI), if known;
- Manufacturer FEI, if known; and
- Port of entry.

The division information is necessary so that we can appropriately route the submission within the Agency. Information on whether the product is stored or manufactured in the zone is necessary for FDA to determine the applicable admissibility requirements. The FTZ and port information is necessary to ensure that basic requirements in 19 CFR part 146 are met. The IOR and manufacturer FEI information is requested by FDA to expedite the admissibility review. Requests to participate in the WEF process are submitted to the FDA Import Division Office covering the intended port of entry.

We are also revising the information collection to include our Import Trade Auxiliary Communication System (ITACS), currently approved under OMB control number 0910–0842. The ITACS is used by the import trade community and was implemented to improve communication with FDA. By utilizing ITACS, respondents to the information collection have the ability to establish an account and electronically check the status of FDA-regulated entries and lines, submit entry documentation, submit the location of goods availability for those lines targeted for examination by FDA, and check the estimated laboratory analysis completion dates for lines that have been sampled. For further information regarding ITACS, please visit our website at *https://www.fda.gov/industry/import-systems/itacs.*

In the **Federal Register** of January 3, 2020 (85 FR 318), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Upon review of our active information collection inventory, however, and on our own initiative, we have decided to make additional revisions to the information collection to improve the efficiency of Agency operations. Specifically, we are including Form FDA 766 ''Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts'' (currently approved under OMB control number 0910–0025) as the collection instrument for 21 CFR 1.95. Form FDA 766 facilitates collection of information associated with certain general enforcement provisions for importing FDA-regulated articles into the United States. The form

[1] Some FTZs are covered by multiple Import Divisions.