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.

In the **Federal Register** of April 24, 2020 (85 FR 23047), we issued a notice announcing that we amended the temporary permit 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.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to Bumble Bee Seafoods, Inc., to allow the test product to be manufactured at an additional plant, RS Cannery Company Limited, located at 255/1 Industrial Soi 3, Bangpoo Industrial Estate, Samutprakarn 10280, Thailand. All other conditions and terms of this permit remain the same.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26533 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1119; FDA–2010–N–0622; FDA–2011–N–0016; FDA–2009–N–0501; and FDA–2019–N–6098]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified and Thermally Processed Low-Acid Foods	0910–0037	10/31/2023
Color Additive Certification Requests and Recordkeeping	0910–0216	10/31/2023
Recordkeeping and Records Access Requirements for Food Facilities	0910–0560	10/31/2023
Reporting and Recordkeeping Requirements for Reportable Food	0910–0643	10/31/2023
Focus Groups as Used by the Food and Drug Administration	0910–0497	11/30/2023

Dated: November 25, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26571 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. The notice also invites comment on electronic Form FDA 3978 that allows manufacturers of infant formula to submit reports and notifications in a standardized format.

DATES: Submit either electronic or written comments on the collection of information by February 1, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 1, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0190 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Requirements—21 CFR Parts 106 and 107

OMB Control Number 0910–0256—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of subsections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, we have issued the agency guidance document entitled, ''Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.'' The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.*

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a format of their own choosing will still have the option to do so. Form FDA 3978 prompts a respondent to include reports and notifications in a standard electronic format and helps the respondent organize their submission to include only the information needed for our review. Screenshots of Form FDA 3978 and instructions are available at *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.*

Description of Respondents: Respondents to this information collection are manufacturers of infant formula.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act or 21 CFR	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for exempt infant formula; § 107.50(b)(3) and (4).	3	2	6	4	24
Notifications for exempt infant formula; § 107.50(e)(2)	1	1	1	4	4
Requirements for quality factors— growth monitoring study exemption; § 106.96(c).	4	9	36	20	720
Requirements for quality factors—PER exemption; § 106.96(g).	1	34	34	12	408
New infant formula registration; § 106.110	4	9	36	0.50 (30 mins.)	18
New infant formula submission; § 106.120	4	9	36	10	360
Total					2,188

[1] There are no capital or operating and maintenance costs associated with the information collection.

Based on a review of the information collection, we have adjusted our burden estimate to correct a nominal calculation error. This reflects a decrease of 62 annual responses and a corresponding decrease of 308 annual hours.

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

The total estimated annual reporting burden is 2,188 hours, as shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

FD&C act or 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Burden per record	Total hours
Part 106—SUBPART B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106—SUBPARTS C–G: Quality control; audits; quality factors; records and reports	5	726.8	3,634	6	21,818
Part 107—SUBPART C; Exempt infant formulas	3	10	30	300	9,000
Exempt infant formula production; GMP; audits, recordkeeping, & reports	3	634	1,902	45	85,590
Total					125,822

[1] There are no capital costs or operating and maintenance costs associated with the information.
[2] Numbers have been rounded.

The total estimated annual recordkeeping burden is 125,822 hours, as shown in table 2.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Nutrient labeling; §§ 107.10(a) and 107.20	5	13	65	8	520

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

We estimate compliance with our infant formula labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26537 Filed 12–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: HIV National Strategic Plan 2021–2025 Available for Public Comment

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft HIV National Strategic Plan: A Roadmap to End the HIV Epidemic (2021–2025) (HIV Plan) available for public comment. The draft HIV Plan may be reviewed at *www.hiv.gov.*

DATES: All comments must be received by 5:00 p.m. ET on December 14, 2020 to be considered.

ADDRESSES: All comments must be submitted electronically to *HIVPlanComments@hhs.gov* to be considered.

FOR FURTHER INFORMATION CONTACT: Harold J. Phillips, OIDP, *Harold.Phillips@hhs.gov,* 202–725–8872.

SUPPLEMENTARY INFORMATION: The National HIV/AIDS Strategy, first released in 2010 and updated in 2015, changed the way that Americans talk about HIV and the ways that stakeholders prioritize and coordinate resources and deliver prevention and care services that support people with HIV or at risk for HIV. As a result, the nation's new HIV infections have declined from their peak in the mid-1980s—although remaining stable over the past decade—and people with HIV in care and treatment are living longer, healthier lives. In 2018 the estimated number of new HIV infections was 36,400. A robust prevention toolbox that includes pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and syringe services programs (SSPs) has lowered a person's risk of acquiring HIV. Research in recent years has proven that people with HIV who take antiretroviral therapy achieve and maintain an undetectable viral load, not protect their health but also have effectively no risk of transmitting HIV through sex.

This stability in the annual number of new infections, though, has further illuminated opportunities for focused efforts. According to the most recent available data, less than one-half (38.9%) of the U.S. population have ever been tested for HIV [1] and an estimated 161,800 (14%) people with HIV are unaware of their status.[2] Only 63% of people diagnosed with HIV are virally suppressed.[3] Approximately 80% of new HIV infections are due to people who do not know they have HIV or are not receiving regular care,[4] and only 18% of the approximately 1.2 million people indicated for PrEP are receiving it.[5] [6]

To respond and address the HIV public health epidemic, OASH through OIDP, in collaboration with a steering committee composed of a wide array of federal partners, has led and coordinated development of the HIV Plan. Opportunities for public input were provided, and public comments received were reviewed and analyzed, to help inform development of the components of the HIV Plan. The HIV Plan covers the entire country, provides a roadmap across the federal government, non-federal partners and stakeholders in all sectors of society, and encourages integration of several key components that are vital to our collective work.

The HIV Plan is the nation's third consecutive national HIV strategy. It sets forth bold targets for ending the HIV epidemic in the United States by 2030, including a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. The HIV Plan articulates goals, objectives, and strategies to prevent new infections, treat people with HIV to improve health outcomes, reduce HIV-related disparities, and better integrate and coordinate the efforts of all partners to end the HIV epidemic in the United States. The HIV Plan also establishes indicators to measure progress, with quantitative targets for each indicator, and designates populations disproportionately impacted by and at risk for HIV as well as key areas of focus.

The order of goals, objectives, and strategies does not indicate any prioritization, and many are intertwined. The following are the HIV Plan's vision and four goals:

Vision: The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment and lives free from stigma and discrimination. This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race,

[1] National HIV Testing Day—June 27, 2019. MMWR. 2019;68:561. doi: *http://dx.doi.org/10.15585/mmwr.mm6825a1.*

[2] Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2014–2018. *HIV Surveillance Supplemental Report* 2020;25(1). Accessed September 28, 2020. *http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.*

[3] Harris NS, Johnson AS, Huang YLA, et al. *Vital Signs:* status of human immunodeficiency virus testing, viral suppression, and HIV preexposure prophylaxis—United States, 2013–2018. *MMWR.* 2019;68:1117–1123. doi: *http://dx.doi.org/10.15585/mmwr.mm6848e1.*

[4] Li Z, Purcell DW, Sansom SL, et al. *Vital Signs:* HIV transmission along the continuum of care—United States, 2016. *MMWR.* 2019;68:267–272. Figure 1. doi: *http://dx.doi.org/10.15585/mmwr.mm6811e1.*

[5] Harris NS, Johnson AS, Huang YLA, et al. *Vital Signs:* status of human immunodeficiency virus testing, viral suppression, and HIV preexposure prophylaxis—United States, 2013–2018. *MMWR.* 2019;68:1117–1123. doi: *http://dx.doi.org/10.15585/mmwr.mm6848e1.*

[6] Centers for Disease Control and Prevention. HIV Surveillance Data Tables (early release): Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): HIV diagnoses and linkage to HIV medical care, 2019 (reported through December 2019); and preexposure prophylaxis (PrEP)—2018, updated. *HIV Surveillance Data Tables* 2020;1(2). Accessed October 16, 2020. *https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/index.html.*