''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: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 240–402–6511, email: *cderdatastandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's CDER is issuing this **Federal Register** notice to announce the date that support will begin for version 1.1 of the CDISC SENDIG–DART and version 1.6 of the CDISC SDTM and the dates when such new standard and version update will be required in certain submissions. The FDA guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (October 2020) (eStudy Data guidance), posted on FDA's Study Data Standards Resources web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm,* implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in NDAs, ANDAs, certain BLAs, and certain INDs submitted to CDER or the Center for Biologics Evaluation and Research by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standards and version updates to FDA-supported study data standards that will be added to the Catalog, when the support for such standards and version updates begins or ends, and when the requirement to use such standards and version updates in submissions begins or ends.

Support for version 1.1 of the CDISC SENDIG–DART and version 1.6 of the CDISC SDTM will begin on March 15, 2021, the transition date. The requirement for electronic submissions to be submitted using version 1.1 of the CDISC SENDIG–DART will begin March 15, 2023, for NDAs, ANDAs and certain BLAs, and March 15, 2024, for certain INDs. The requirement for electronic submissions to be submitted using version 1.6 of the CDISC SDTM will begin on March 15, 2022.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04609 Filed 3–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

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 generic clearance for the collection of quantitative data on tobacco products and communications.

DATES: Submit either electronic or written comments on the collection of information by May 4, 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 May 4, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 4, 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–2018–N–0180 for ''Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.'' 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: 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: 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.

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

OMB Control Number 0910–0810—Extension

To conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will conduct research and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the health risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these educational and public information programs have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and develop health messages relating to the control and prevention of disease. In conducting such research, FDA will use quantitative methods (*i.e.,* surveys, experimental studies) for studies about tobacco products. These studies may be used to collect information related to the formative pretesting of tobacco communication messages and other materials directed at consumers. This type of research involves: (1) Assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs; (2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and (3) adding to the regulatory science knowledge base. Quantitative studies play an important role in exploring areas of research and gathering information because they can be used to summarize a population of interest on key variables or reveal systematic relationships between variables.

Formative pretesting is a staple of best practices in communications research. Obtaining voluntary feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about the perceived effectiveness of messages, advertisements, and materials in reaching and successfully communicating with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials, including questionnaires or images, directed at consumers while the materials are still in the developmental stage.

In addition, quantitative information is needed by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on behavior, knowledge, and attitudes about tobacco products, including postmarketing surveillance of tobacco products.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	485,580	1	485,580	0.083 (5 minutes)	40,465
Self-Administered Surveys	133,728	1	133,728	0.33 (20 minutes)	44,576
Total					85,041

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

Number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of activities that may be administered and estimated burden levels during the 3-year period. Time to read, review, or complete the activity is built into the ''Average Burden per Response'' figures. Our estimated burden for the information collection reflects an overall increase of 60,000 hours and a corresponding increase of 461,808 responses. We attribute the adjustment to an increase in the number of new quantitative studies that are anticipated underneath this information collection during the next 3 years (proposed extension).

Dated: March 1, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04606 Filed 3–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1189]

Canned Tuna Deviating From the Standard of Identity; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is amending StarKist Seafood Company's temporary permit to market test canned tuna. The temporary permit is amended to add three additional manufacturing locations and to increase the amount of test product. 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 June 20, 2014 (79 FR 35362), we issued a notice announcing that we had issued a temporary permit to StarKist Seafood Company, 225 North Shore Dr., Pittsburgh, PA 15212, to market test products identified as canned tuna products. The permit allowed for the test product to be manufactured at Galapesca S.A., Km. 12.5 Via A Duale, Guayaquil, Ecuador, and StarKist Samoa Co., 368 Atu'u Rd., Pago Pago, American Samoa 96799. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned tuna in 21 CFR 161.190, which was issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of March 7, 2016 (81 FR 11813), we issued a notice announcing that we were extending the temporary market permit issued to StarKist Seafood Company. The extension allows the applicants to continue to measure consumer acceptance of the products and assess the commercial feasibility of the products, in support of a petition to amend the standard of identity for canned tuna. The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for canned tuna that may result from the petition or 30 days after denial of the petition.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to StarKist Seafood Company, to allow the test product to be manufactured at three additional plants: Tropical Canning (Thailand) Public Co., LTD., 1/1 M.2 T.Thungyai, Hatyai, Songkhla 90110, Thailand; ISA Value Co., Ltd., 44/4 Moo1, Petchkasem Road, Yaicha, Sampran, Nakornpathom 73110, Thailand; and Tri-Marine (Solomon Islands), Soltuna Ltd., 1 Tuna Dr., Noro, Western Province, Solomon Islands. We are also amending the temporary permit to increase the amount of test product to be market tested to 213,500,000 pounds (96,841,971 kilograms) in retail cans of various sizes. All other conditions and terms of this permit remain the same.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04607 Filed 3–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the COVID–19 Health Equity Task Force

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

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the COVID–19 Health Equity Task Force (Task Force) will hold a virtual meeting on March 26, 2021. The purpose of this meeting is to discuss equitable vaccine access and acceptance. This meeting is open to the public and will be live-streamed at *www.hhs.gov/live.* Information about the meeting will be posted on the HHS Office of Minority Health website: *www.minorityhealth.hhs.gov/healthequitytaskforce/* prior to the meeting.

DATES: The Task Force meeting will be held on Friday, March 26, 2021, from approximately 12 p.m. to 3 p.m. ET (times are tentative and subject to change). The confirmed time and agenda will be posted on the COVID–19 Health Equity Task Force website: *www.minorityhealth.hhs.gov/*