patterns, traffic flows, and outlet characteristics. Consumers typically choose between nearby retail fuel outlets with similar characteristics along their planned routes. The geographic markets for the retail sale of diesel are likely similar to the corresponding geographic markets for retail gasoline as many diesel consumers exhibit the same preferences and behaviors as gasoline consumers.

The Acquisition would eliminate competition in these local markets, resulting in a merger to monopoly in each market for the retail sale of gasoline and the retail sale of diesel fuel. Retail fuel outlets compete on price, store format, product offerings, and location, and pay close attention to competitors in close proximity, on similar traffic flows, and with similar store characteristics. The combined entity would be able to raise prices unilaterally in the two local markets. Absent the Acquisition, Tri Star and Hollingsworth would continue to compete head to head in these local markets.

Entry into each relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Significant entry barriers include the availability of attractive real estate, the time and cost associated with constructing a new retail fuel outlet, and the time associated with obtaining necessary permits and approvals.

V. The Proposed Consent Agreement

The proposed Consent Agreement would remedy the Acquisition's likely anticompetitive effects by requiring Tri Star to divest certain Tri Star and Hollingsworth retail fuel assets to Cox in each local market.

The proposed Consent Agreement requires that the divestiture be completed no later than 10 days after Tri Star consummates the Acquisition. The proposed Consent Agreement further requires Tri Star and Hollingsworth to maintain the economic viability, marketability, and competitiveness of each divestiture asset until the divestiture to Cox is complete. For up to twelve months following the divestiture, Tri Star and Hollingsworth must make available transitional services, as needed, to assist Cox with the divestiture assets.

In addition to requiring outlet divestitures, the proposed Consent Agreement also requires Respondents to provide the Commission notice before re-acquiring the divested outlets for ten years. The prior notice provision is necessary because an acquisition of either or both divested assets would likely raise the same competitive concerns and may fall below the HSR Act premerger notification thresholds.

The proposed Consent Agreement contains additional provisions designed to ensure the effectiveness of the proposed relief. For example, Respondents have agreed to an Order to Maintain Assets that will issue at the time the proposed Consent Agreement is accepted for public comment. The Order to Maintain Assets requires Respondents to operate and maintain each divestiture outlet in the normal course of business, through the date the Respondents complete the divestiture. The Commission may appoint an independent third party as a Monitor to oversee the Respondents' compliance with the requirements of the proposed Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission, Commissioner Slaughter not participating.

April J. Tabor,

Secretary.

[FR Doc. 2020–14508 Filed 7–6–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1411]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of Food and Drug Administration Regulated Products

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a new collection of information to collect entitled ''Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of FDA Regulated Products.''

DATES: Submit either electronic or written comments on the collection of information by September 8, 2020.

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 September 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 8, 2020. 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–2020–N–1411 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment and the Safety, Efficacy, and Usage of FDA Regulated Products.'' 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 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 Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment and the Safety, Efficacy, and Usage of FDA Regulated Products

OMB Control Number 0910–NEW

FDA is seeking to conduct qualitative and quantitative research studies to better understand consumers', patients', caregivers', academic/scientific experts', and public health professionals' perceptions and behaviors regarding various issues and outcomes associated with disease prevention, treatment, and the safety and efficacy off all FDA-regulated products. These studies may consist of small groups, focus groups, individual indepth interviews, and surveys relating to the evaluation of disease prevention and treatment and the safety, efficacy, and usage of FDA-regulated products and communication messages and strategies, and other materials directed to consumers, patients, caregivers, and public health professionals (*e.g.,* evaluate the effectiveness of communication messages, educational materials, and interventions directed toward promoting and protecting human and animal health).

Among the general provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is charged with promoting the public health through regulatory oversight as well as clinical research. Specifically, section 1003 of the FD&C Act (21 U.S.C. 393(d)(2)(C) and (D)) provides that the Commissioner of Food and Drugs shall be responsible for research. Accordingly, FDA is seeking to conduct qualitative and quantitative research studies. These studies may consist of small groups, focus groups, individual in-depth interviews, and surveys relating to the evaluation of disease prevention and treatment and the safety, efficacy, and usage of FDA-regulated products and communication messages and strategies, and other materials directed to consumers, patients, caregivers, and public health professionals (*e.g.,* evaluate the effectiveness of communication messages, educational materials, and interventions directed toward promoting and protecting human and animal health).

The information collection is intended to support research conducted by, or on behalf of, FDA. Understanding consumers, patients, caregivers, academic/scientific experts, and public health professionals' perceptions and behaviors plays an important role in improving FDA's decision-making processes and communications impacting various stakeholders. To better understand consumers, patient, caregivers, academic/scientific experts, and public health professionals' perceptions and behaviors regarding various issues and outcomes associated the disease prevention, treatment, and the safety, efficacy, and usage of products overseen by the Agency, FDA is requesting approval of this generic information collection request.

The qualitative and quantitative research anticipated by FDA aligns with Agency objectives. For example, among

eight scientific priorities is the goal to support social and behavioral sciences. Such research helps the Agency meet this goal by:

- Identifying gaps in the target audience's knowledge regarding FDA-regulated products, and outcomes associated the disease prevention, treatment;
- reaching diverse audiences;
- assessing target audiences' knowledge, perceptions, and behaviors about FDA-regulated products;
- evaluating the effectiveness of FDA's communications;
- exploring ways to incorporate patient input into decision-making;
- leveraging real-world data;
- evaluating outcomes; and
- integrating the knowledge gained from the research into Agency communications, activities, interventions, and programs.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions: information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups or telephone interviews, and consent forms as appropriate. Respondents also will be advised of the following: (1) The nature of the activity; (2) the intended purpose and use of the data collected; (3) FDA sponsorship (when appropriate); and (4) the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any individual questions.

Only Agency or Agency-sponsored personnel will have access to individual-level surveys, interviews, or focus group data. All project staff from a contractor or cooperative agreement grantee conducting the information collection must take required measures to ensure respondent privacy and confidentiality of data. Personally identifiable information (PII) shall be limited to data that may be required in the process of respondent enrollment. PII will be accessible to only those contractors or cooperative agreement grantee who need it and will not be linked to interview data. Neither FDA employees nor any Federal employee of any other agency will have access to PII. All PII will be destroyed by contractors as soon as feasible following data collected during interviews.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all data will be reported to FDA in aggregate form, with no links to individuals preserved. Reports generated by this information collection will be used only for research purposes and for the development of communication messages.

Social and behavioral testing efforts described in this proposal are typically considered exempt from the ''Regulations for the Protection of Human Subjects'' in accordance with 45 CFR 46.101(b)(3). Before data are collected, FDA researchers must obtain either an exemption or an expedited or full approval for all research from FDA's institutional review board (IRB).

When FDA's IRB determines that minors are capable of giving assent, the IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor potentially participating in the research in a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should: (1) Contain an explanation of the study; (2) a description of what is required of the subject (*e.g.,* what he or she will experience (whether the minor will be in the hospital, whether the minor's parents will be with him or her, etc.)); (3) an explanation of any risks and pain associated with the study; (4) an explanation of any anticipated change in the minor's appearance; and (5) an explanation of the benefits to the minor or others.

FDA plans to use the data collected under this generic clearance to inform its FDA-regulated products educational, interventions, outcomes, and regulatory science programs, materials and resources and disease prevention and treatment. FDA expects the data to guide the formulation of the Agency's educational and public health objectives on FDA-regulated products and support development of subsequent research efforts. The data will not be used to make policy or regulatory decisions. Rather, these data will: (1) Inform FDA's public education campaigns and other educational/interventional materials directed to informing consumers, patients, caregivers, and public health professionals about human and animal health issues and (2) provide information on the safety, efficacy, and usage of FDA-regulated products.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

FDA will submit individual qualitative and quantitative collections under this generic clearance to the OMB. Individual collections will also undergo review by FDA's IRB, senior leadership in the for the primary investigator's respective offices, and PRA specialists.

Description of Respondents: The respondents to this collection of information are all FDA stakeholders including, general population individuals, as well as consumers of certain products, patients and their caregivers, academic/scientific experts, individuals from specific target labor groups such as physicians, medical specialists, pharmacists, dentists, nurses, veterinarians, dietitians, and other public health professionals.

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
Interviews/Surveys/Focus Groups	2,520	14.6	36,792	0.25 (15 minutes)	9,198

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

This is a new collection of information whose total estimated annual reporting burden is 9,198 hours. The number of participants to be included in each individual generic submission under this collection of information will vary, depending on the nature of the compliance efforts and the target audience.

Dated: June 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14517 Filed 7–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1206]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the dates that support and requirement will begin for version 1.7 of the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model (SDTM) Implementation Guide (IG) 3.3, as well as for version 2.1 of the Define-Extensible Markup Language (Define-XML). CBER and CDER are also announcing the date that support and requirement will end for version 1.3 of the CDISC SDTM IG 3.1.3. The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

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–2020–N–1206 for ''Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3.'' Received comments 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: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *cderdatastandards@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: On December 17, 2014, FDA published a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data guidance), posted on FDA's Study Data Standards Resources web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data guidance 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 new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and certain investigational new drug applications (INDs) submitted to