individuals) of the respective regulatory authorities. The burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

To calculate the estimate of the hours per response, FDA will use the average data collection duration for the same facility types during the 2015–2016 data collection. FDA estimates that it will take the persons in charge of full-service restaurants and fast-food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2017–2018 data collection, the burden estimate was 106 minutes (1.76 hours) in full-service restaurants and 73 minutes (1.21 hours) in fast-food restaurants. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full-service restaurant, including both the program director's and the person in charge's responses, is 134 minutes (104 + 30) (2.23 hours). The total burden estimate for a data collection in a fast-food restaurant, including both the program director's and the person in charge's responses, is 112 minutes (82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2017–2018 data collection, we estimate a refusal rate of 2 percent for the data collections within restaurant facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.36	544
2021–2022 Data Collection (Full-Service Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.73	692
2021–2022 Data Collection—Completion of Section 2—All Facility Types.	800	1	800				0.5 (30 minutes)	400
2021–2022 Data Collection—Entry Refusals—All Facility Types.				16	1	16	0.08 (5 minutes)	1.28
Total Hours								1,637.28

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).'' Available at *https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf*
2. FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at *https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf*
3. FDA, ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at *https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm*
4. FDA National Retail Food Team, ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' (2010). Available at *https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm*
5. FDA, ''FDA Food Code.'' Available at *https://www.fda.gov/FoodCode.*

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05325 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1857]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food

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 requirements associated with current good manufacturing practice,

hazard analysis, and risk-based preventive controls for human and animal food.

DATES: Submit either electronic or written comments on the collection of information by May 17, 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 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 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–1857 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food.'' 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.

Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Human Food—21 CFR Part 117; Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Animal Food—21 CFR Part 507

OMB Control Number 0910–0751—Revision

This information collection supports FDA regulations setting forth criteria and definitions applicable to human food and to animal food, as established under the FDA Food Safety and Modernization Act (FSMA) (Pub. L.

111–353). Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system. The purpose of the regulations is to prevent the introduction of adulterated and/or misbranded products into the marketplace and ensure the safety of both human foods and animal foods in accordance with sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342 and 343). Generally, domestic and foreign food facilities that are required to register in accordance with section 415 of the FD&C Act (21 U.S.C. 350d) must comply with these requirements, unless an exemption applies. It is important to note, however, that applicability of the current good manufacturing practice requirements is not dependent upon whether a facility is required to register. Regulations governing human food are set forth in part 117 (21 CFR part 117), while regulations governing animal food are found in part 507 (21 CFR part 507). Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals.

The regulations include recordkeeping necessary to demonstrate compliance with the requirements; however, respondents that meet the definition of a ''qualified facility,'' under 21 CFR 117.3 and 507.3, are subject to reporting. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart D for human food and animal food, respectively, respondents must attest to their status. To assist respondents in this regard, we have developed Forms FDA 3942a (Quality Facility Attestation: Human Food) and 3942b (Quality Facility Attestation: Animal Food), available for downloading from our website at: *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation.*

Section 418(l)(2)(B)(ii) of the FD&C Act (21 U.S.C. 350g(l)(2)(B)(ii)) directs us to issue guidance on documentation required to determine status as a qualified facility. Accordingly, we issued a guidance for industry entitled ''Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals,'' also available for downloading from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility.* The guidance discusses the content, format, frequency, and timing of submissions. For efficiency of Agency operations, we are now accounting for burden we attribute to reporting associated with Forms FDA 3942a and 3942b, currently approved under OMB control number 0910–0854, with this information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
117.201(c); qualified facility as reported on Form FDA 3942a.	37,134	[2] 0.5	18,567	0.5 (30 minutes)	9,284
507.7(c); qualified facility as reported on Form FDA 3942b.	1,120	0.5	560	0.5 (30 minutes)	280
Total					9,564

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN: HUMAN FOODS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
117.126(c) and 117.170(d); food safety plan and reanalysis.	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records.	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)–(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual.	46,685	1	46,685	0.25 (15 minutes)	11,671
Total					6,237,142

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN: ANIMAL FOODS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Subpart A—General Provisions					
507.4(d); documentation of animal food safety and hygiene training.	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, verification, recall plan, validation, reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records That Must Be Established and Maintained					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Total			11,635,372		1,163,258

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN: HUMAN FOODS [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address.	37,134	1	37,134	0.25 (15 minutes)	9,284

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

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels.	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	974	1	974	1	974
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					27,841.76

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

Based on a review of the information collection since our last request for OMB approval, we have made slight adjustments to reflect a decrease in third-party disclosure burden associated with animal foods. In this submission we provide a cumulative estimate for related disclosure activities that we had previously accounted for separately.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05332 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5666]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 April 15, 2021.

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 title of this information collection is ''Empirical Study of Promotional Implications of Proprietary Prescription Drug Names.'' Also include the FDA docket number found in brackets in the heading of this document.

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

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: (1) Advertising features, including content and format; (2) target populations; and (3) research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas, advertising features and target populations.

Because we recognize that the strength of data and the confidence in the robust nature of the findings is improved by utilizing the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey on direct-to-consumer advertisements conducted in 1999.

During the prescription drug approval process, sponsors propose proprietary names for their products. These names undergo a proprietary name review that involves the Office of Drug Safety, the relevant medical office, and OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which, among other things, provides that labeling can misbrand a product if false or misleading representations are made (see 21 U.S.C. 321(n), 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading. OPDP focuses its review on identifying names that overstate the efficacy or safety of the drug, suggest drug indications that are not accurate, suggest superiority without substantiation, or are of a fanciful nature that misleadingly implies unique effectiveness or composition. This research will focus on the effect on consumers' and/or healthcare providers' perceptions of a drug product of names that overstate the efficacy of the drug product. An overstatement of efficacy can occur, for example, in terms of level of efficacy, in which the degree of relief is overstated, or in terms of the type of effect, in which case there is a mismatch with the indication of the drug. The drug products that are studied will be fictitious, and whether the names overstate the drug products' efficacy will be determined with regard to the products' fictitious degree of efficacy.

The proposed study is designed to provide systematic, empirical evidence to answer two research questions:

- *Primary research question:* How, if at all, do names that suggest the medical condition for which a drug is indicated affect consumers' and/or healthcare providers' perceptions of prescription drugs?
- *Secondary research question:* How, if at all, do names that suggest an overstatement of the degree of efficacy of the drug affect consumers' and/or healthcare providers' perceptions of prescription drugs?

The ideas generated in the Prescription Drug User Fee Amendments pilot project proprietary name review concept paper of 2008 [1] provided a starting point for the study.

[1] *https://www.regulations.gov/docket?D=FDA-2008-N-0281.*